FEDERAL REGISTER

Vol. 89 Monday,
No. 88 May 6, 2024

Pages 37059–37964

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 89 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–09512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:	
Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 89, No. 88

Monday, May 6, 2024

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR
Proclamations:
10744.....37059

5 CFR
890.....37061

6 CFR
Proposed Rules:
26.....37141

10 CFR
Ch. III.....37079
429.....37778
430.....37778

12 CFR
1610.....37091

14 CFR
39 (2 documents).....37109, 37111
Proposed Rules:
39 (2 documents).....37142, 37144

18 CFR
Proposed Rules:
2.....37147
38.....37147

21 CFR
112.....37448
809.....37286
Proposed Rules:
809.....37158

23 CFR
490.....37113
1300.....37113

26 CFR
1.....37706
26.....37116
301 (2 documents).....37116, 37706
602.....37116

32 CFR
310.....37127

33 CFR
100.....37130
147.....37130
165.....37134

36 CFR
219.....37135

40 CFR
52.....37137

42 CFR
438.....37522
440.....37522
457.....37522
460.....37522

45 CFR
80.....37522
84.....37522
92.....37522
147.....37522
155.....37522
156.....37522

48 CFR
727.....37948
742.....37948
752.....37948
1602.....37061
1609.....37061

50 CFR
635.....37139

Federal Register
Vol. 89, No. 88
Monday, May 6, 2024

Presidential Documents

Title 3—

The President

Proclamation 10744 of May 1, 2024

National Day of Prayer, 2024

By the President of the United States of America

A Proclamation

On this National Day of Prayer, we recognize the power of prayer to strengthen our spirits, draw us together, and create hope for a better tomorrow.

The right to practice our faiths freely and openly is enshrined in the Constitution and remains at the core of our American spirit. For centuries, Americans of every religion and background have come together to lift up one another and our Nation in prayer. Throughout America's history, faith and prayer have helped fuel some of the greatest moral missions of our time—from the abolition of slavery to the fight for voting rights and the Civil Rights Movement. Many of our Nation's greatest leaders have been motivated by faith to push all of us toward a more perfect Union and to bend the arc of the moral universe toward justice.

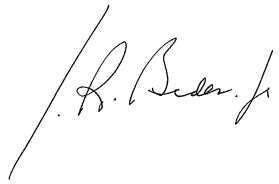
Prayer is also deeply personal: For the First Lady and me, and so many across this Nation, prayer has helped us find solace during tough times and stay grounded in good ones. Prayer has helped the bravest among us—including our Nation's service members and their caregivers, survivors, and families—summon the courage to make great sacrifices for our democracy. It has guided the hands of medical professionals, who heal our loved ones, and steeled the nerves of our first responders, who put everything on the line to keep the rest of us safe. We will never know the full impact of prayer on our Nation or the world, but we remain confident that it makes a profound difference each and every day.

Scripture tells us to rejoice in hope, be patient in tribulation, and be constant in prayer. This year, my prayer for our Nation is that we keep faith that our best days are ahead of us and continue to believe in honesty, decency, dignity, and respect. May we see each other not as enemies but as fellow human beings, each made in the image of God and each precious in His sight. May we leave no one behind, give everyone a fair shot, and give hate no safe harbor. May we remember that nothing is beyond our capacity if we act together.

The Congress, by Public Law 100–307, as amended, has called on the President to issue each year a proclamation designating the first Thursday in May as a ''National Day of Prayer.''

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 2, 2024, as a National Day of Prayer. I call upon the citizens of our Nation to give thanks, in accordance with their own faith and conscience, for our many freedoms and blessings, and I invite all people of faith to join me in asking for God's continued guidance, mercy, and protection.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of May, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–09919
Filed 5–3–24; 8:45 am]
Billing code 3395–F4–P

Rules and Regulations

Federal Register
Vol. 89, No. 88
Monday, May 6, 2024

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

48 CFR Parts 1602 and 1609

RIN 3206–AO43

Postal Service Reform Act; Establishment of the Postal Service Health Benefits Program

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This rule finalizes an interim final rule that established the Postal Service Health Benefits (PSHB) Program for Postal Service employees, Postal Service annuitants, and their eligible family members, pursuant to the Postal Service Reform Act of 2022. This Program will include health benefits plans available to United States Postal Service (Postal Service) employees, Postal Service annuitants, and their eligible family members starting January 1, 2025. For these individuals, eligibility for enrollment or coverage in FEHB plans based on Postal Service employment will end on December 31, 2024, and they will be able to enroll in or be covered only by PSHB plans after that time. Open Season for enrollee selection of PSHB plans will occur from November 11 through December 9, 2024. OPM will publish the negotiated PSHB plan rates and benefits for the 2025 plan year in September 2024. This rule adopts the provisions of the interim final rule with minor clarifications on the Office of Personnel Management's (OPM) implementation of the PSHB Program.

DATES: Effective July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Louise Dyer Yinug, Senior Policy Analyst, at (202) 972–0913.

SUPPLEMENTARY INFORMATION:

Executive Summary

On April 6, 2023, OPM issued an interim final rule (88 FR 20383) to establish the Postal Service Health Benefits (PSHB) Program within the Federal Employees Health Benefits (FEHB) Program as required by the Postal Service Reform Act of 2022 (PSRA), Public Law 117–108. The interim final rule amended subparts A, C, and E of 5 CFR part 890 related to the FEHB Program and 48 CFR chapter 16, the OPM Federal Employees Health Benefits Acquisition Regulation (FEHBAR). The interim final rule also added a new subpart P to 5 CFR part 890 regulating the new PSHB Program within the FEHB Program.

OPM is making several changes between the interim final rule and this final rule:

- In § 890.1604, OPM is clarifying the requirements to enroll in Medicare Part B by expressly providing that the exceptions referring to events occurring ''as of January 1, 2025'' includes events that occur on January 1, 2025.
- Section 890.1604(c) is reserved in anticipation of future rulemaking.
- In § 890.1604(e), OPM is clarifying that a Postal Service annuitant or their family member who is required to be enrolled in Medicare Part B must promptly notify OPM or the Postal Service, in writing, if they choose not to enroll in or to disenroll from Medicare Part B.
- In § 890.1604, OPM is removing reference to the Postal Service as the entity to receive documentation of overseas residency to qualify for an exception to the Part B enrollment requirement.
- In § 890.1606(e), OPM is correcting a typographical error by removing the word ''the'' before ''January 1 of the next year.''

These changes do not affect OPM's estimation of the regulatory impact of the PSHB Program.

To the greatest extent possible, OPM aligned the rules pertaining to PSHB plans with the regulations governing FEHB plans. Where there was no existing rule applicable to FEHB plans, OPM implemented rules to provide the greatest flexibility for Postal Service employees, Postal Service annuitants, and their family members. An example of this is the rules pertaining to disenrollment from PSHB for Medicare eligible annuitants who are not enrolled in Medicare Part B despite the requirement to be so enrolled. OPM is defining such a circumstance as a termination of coverage, with rights to a temporary extension of coverage and conversion rights, rather than a cancellation of coverage.

The PSHB Program includes health benefits plans available to Postal Service employees, Postal Service annuitants, and their eligible family members starting January 1, 2025. For these individuals, eligibility for enrollment or coverage in FEHB plans based on Postal Service employment will end after December 31, 2024, and they will be able to enroll in or be covered only by PSHB plans starting January 1, 2025. Subject to limited exceptions, Postal Service annuitants who retire and become entitled to Medicare Part A after January 1, 2025, and their family members who are entitled to Medicare Part A will be required to enroll in Medicare Part B as a condition of eligibility to enroll in the PSHB Program.

The exceptions to the Medicare Part B enrollment requirement for PSHB enrollment described at § 890.1604 are:

- Individuals who are Postal Service annuitants on or before January 1, 2025, and who are not both entitled to Medicare Part A and enrolled in Medicare Part B on January 1, 2025;
- Individuals who, on January 1, 2025, are Postal Service employees and are aged 64 and over;
- Postal Service annuitants and family members residing outside the United States and its territories who demonstrate their residency;
- Postal Service annuitants and their family members enrolled in certain Department of Veterans Affairs (VA) health care benefits. This exemption is derived from 5 U.S.C. 8903c(e)(3)(A)(iv)(II), which refers to individuals ''enrolled in health care benefits provided by the VA under subchapter II of chapter 17 of title 38, United States Code.'' Subchapter II of chapter 17 of title 38, U.S.C. governs who is eligible for various VA health care benefits, including eligibility for VA hospital care and medical services. There is a limited class of veterans who are not required to enroll in the system of patient enrollment referred to in 38 U.S.C. 1705(a) in order to receive VA benefits described in subchapter II of chapter 17 of title 38, United States

Code. As such, this regulation is drafted to include all veterans described in 38 U.S.C. 1710, including those who are not required to enroll in the VA's system of patient enrollment referred to in 38 U.S.C. 1705(a);

- Postal Service annuitants and family members eligible for health services provided by the Indian Health Service; and
- A family member of a Postal Service annuitant who is not required to enroll in Medicare Part B, based on a statutory exception, in order to be eligible for PSHB coverage.

OPM will contract with carriers to offer two categories of health benefits plans through the broad umbrella of the FEHB Program, established under 5 U.S.C. 8901 *et seq*. OPM's authority to contract for FEHB plans and OPM's authority to contract for PSHB plans are in separate parts of the FEHB statute. First, pursuant to 5 U.S.C. 8902, OPM may contract with carriers to offer FEHB plans. Second, pursuant to 5 U.S.C. 8903c, OPM may now contract with carriers to offer PSHB plans through the PSHB Program within the FEHB Program. The broad umbrella of the FEHB Program comprises both FEHB plans and PSHB plans. OPM started the process of approving carrier participation in the PSHB Program when the interim final rule became effective on June 5, 2023.

This rule finalizes the interim final rule at 88 FR 20383 with minimal changes, as discussed further in the preamble, due to comments received during the 60-day comment period and a minor technical correction.

Background

Section 101 of the PSRA adds new section 8903c to 5 U.S.C. chapter 89 and directs OPM to establish the PSHB Program within the FEHB Program for Postal Service employees, Postal Service annuitants, and their eligible family members. OPM will administer the PSHB Program in accordance with 5 U.S.C. chapter 89, and implementing regulations (5 CFR parts 890 and 892 and 48 CFR chapter 16), including these amended regulations. In general, the provisions of the FEHB Program apply to the PSHB program; however, there are a number of provisions that are unique to the PSHB program. See 5 U.S.C. 8903c(c)(3).

The PSHB Program was authorized under the Title I Postal Service Financial Reforms provisions in the PSRA in furtherance of Congress's objective to ''improve the financial position of the Postal Service while increasing transparency and accountability of the Postal Service's operations, finances, and performance.'' [1] OPM issued an interim final rule to set forth standards to implement section 101 of the PSRA to establish the PSHB Program. The first Open Season for the PSHB Program will begin on November 11, 2024, and run through December 9, 2024, and the first contract year will begin January 2025.

Section 102 of the PSRA (''The USPS Fairness Act'') amends 5 U.S.C. 8909a, which was established in the Postal Accountability and Enhancement Act of 2006 (Pub. L. 109–435), and required the Postal Service to pre-fund health benefits costs for its retirees. Section 102 of the PSRA repeals the requirement to pay actuarially determined normal cost and amortization payments into the Postal Service Retiree Health Benefits Fund (PSRHBF) established at 5 U.S.C. 8909a, and cancels any unpaid amounts previously required to be paid under section 8909a.[2] Section 102(b) requires OPM to calculate an amount that the Postal Service will pay annually into the PSRHBF using a formula set forth at 8909a(d)(1). This amount will be calculated by June 30 of each year beginning in 2026.

A. Legislative Requirements for Establishing the PSHB Program

Section 101 of Title I of the PSRA directs OPM to ''establish the Postal Service Health Benefits Program within the Federal Employees Health Benefits Program'' under 5 U.S.C. chapter 89. The PSRA specifies that ''[e]xcept as otherwise provided . . . any [PSHB] contract . . . shall be consistent with the requirements of this chapter for contracts under section 8902 with carriers to offer health benefits plans.'' Therefore, generally, the requirements of the FEHB Program will apply to the PSHB Program, unless otherwise set forth in the PSRA or in 5 CFR part 890.

The PSHB Program is required by statute to begin in January 2025 and will be the health benefits program available to Postal Service employees, Postal Service annuitants, and their eligible family members. Further, Medicare-eligible Postal Service annuitants and their Medicare-eligible family members will be required to enroll in Medicare Part B as a condition of enrollment in PSHB. There are several statutory exceptions to the Medicare Part B enrollment requirement, including current Postal Service annuitants and their family members who are not enrolled in Part B, Postal Service employees who have reached the age of 64 and their family members, Postal Service annuitants and their family members residing abroad, and Postal Service annuitants and their family members eligible for VA health care or Indian Health Service services.

The PSRA requires OPM to direct PSHB Carriers to coordinate PSHB coverage with Medicare for enrollees and their family members covered by Medicare. This coordination must include Part D prescription drug coverage for Medicare Part D-eligible individuals. In the initial contract year, the PSRA requires OPM to contract with health insurance carriers to provide coverage with benefits and cost-sharing equivalent to FEHB plans offered by the same carrier, except to the extent needed to integrate Medicare Part D prescription drug benefits.

The PSRA requires OPM to share information with other agencies to implement the statutory requirements, including the Medicare Part B enrollment requirement and the Medicare Part B special enrollment period administered by the Social Security Administration (SSA).

B. PSHB Program Background Information

The PSRA establishes the PSHB Program within the FEHB Program. The FEHB Program was established in 1960 and provides a choice of health plans, including fee-for-service plans and health maintenance organizations, to approximately 8.2 million covered individuals including employees of the Federal Government, Federal retirees (referred to as annuitants due to their eligibility for an annuity), members of their families, former spouses, and other groups statutorily eligible as enumerated in 5 U.S.C. 8901 or set forth in other authorizing legislation. Currently, Postal Service employees, Postal Service annuitants, and their family members are also eligible for FEHB pursuant to 39 U.S.C. 1005.

Health benefits plans offered under the FEHB Program cover a wide range of health services including routine physical exams, primary and specialist provider visits, inpatient hospital care, outpatient care, surgery, laboratory and diagnostic tests, prescription drugs, and mental health services. Required benefits are listed in broad categories at

[1] H. Rept. 117–89- Postal Service Reform Act of 2021, H.Rept.117–89, 117th Cong. (2023), *https://www.congress.gov/congressional-report/117th-congress/house-report/89/1*.

[2] The requirement for pre-funding payments into the PSRHBF was established by the 2006 Postal Accountability and Enhancement Act (Pub. L. 109–435) and required the Postal Service to pre-fund future health benefits costs for its retirees through fixed payments from 2007 and 2016. Pursuant to the Postal Accountability and Enhancement Act, these fixed payments ended in 2016 and were replaced with annual normal costs payments and amortization payments for the estimated unfunded liability.

5 U.S.C. 8904 and include ''hospital benefits'', ''surgical benefits'', ''medical care and treatment'', and ''obstetrical benefits'', among others. Eligible individuals, including Postal Service employees, Postal Service annuitants, and their eligible family members, can have additional dental and vision coverage through the Federal Employees Dental and Vision Insurance Program.

OPM negotiates the benefits, coverage, and premium details of each plan in the FEHB Program with health benefits carriers each year. Each year, OPM issues guidance for health benefits carriers preparing health benefits plan proposals. The guidance for the 2025 plan year is available here: *https://www.opm.gov/healthcare-insurance/carriers/fehb/2024/2024-04.pdf.* This guidance references OPM's commitment to ensuring that the Federal Government offers competitive, comprehensive health insurance benefits and includes OPM's policy goals and initiatives for the year. The guidance outlines technical requirements for each proposal, including benefit package details such as actuarial value, benefit changes from the previous year, and the drug formulary.

Carriers offering PSHB plans, as part of the FEHB Program, will be subject to the same or similar guidance as is issued to FEHB plans. The PSRA requires that carriers offering PSHB plans will, to the greatest extent practicable, offer benefits and cost-sharing (*e.g.,* deductibles, copayments, and coinsurance) equivalent to the benefits and cost-sharing for FEHB plans for that carrier in the initial contract year.

Generally, an enrollment in a health benefits plan under the FEHB Program may be continued into retirement if the enrollee has been enrolled in a health benefits plan under the FEHB Program for five years before retiring or, if less than five years, for all periods in which they were eligible to enroll. Enrollees in an FEHB plan can also enroll in Medicare when they become eligible for Medicare regardless of whether they are retired or still actively employed. Medicare is the primary payer for annuitants who are enrolled in an FEHB plan and covered by Medicare. The rules for continuing a PSHB enrollment into retirement parallel those applicable for FEHB but the Medicare enrollment requirements differ for PSHB as discussed in the next section.

C. PSHB Program Eligibility

Under the PSRA, Postal Service employees whose Government contribution under chapter 89 is paid by the Postal Service, Postal Service annuitants whose Government contribution under chapter 89 is required to be paid under 5 U.S.C. 8906(g)(2), and family members of those Postal Service employees and Postal Service annuitants are eligible for coverage under the PSHB Program. Starting January 2025, these Postal Service employees and Postal Service annuitants may not enroll in an FEHB plan. The major difference in eligibility between PSHB plans and FEHB plans is that, generally, as a condition of eligibility in the PSHB Program, the PSRA requires that Postal Service annuitants and their eligible family members who are entitled to Medicare Part A (also referred to as ''covered Medicare individuals''), must enroll in Medicare Part B, unless an exception applies. Those exceptions are described in the Executive Summary and at § 890.1604 and are discussed more fully in the section ''Regulatory Changes in This Final Rule.''

A ''covered Medicare individual'' under section 8903c(a)(1) means an individual who is entitled to Medicare Part A, excluding an individual who is eligible to enroll under section 1818 or 1818A of the Social Security Act (42 U.S.C. 1395i–2, 1395i–2a). Individuals entitled to Medicare Part A under 1818 are individuals age 65 or older who are not otherwise entitled to premium-free Medicare Part A, typically due to not having the required work history for premium-free Part A. Individuals entitled to enroll under 1818A are disabled individuals who lose Medicare coverage solely because they have exceeded the amounts allowed for substantial gainful work.[3] These individuals are exempt from the Medicare Part B enrollment requirement that applies to most other Postal Service annuitants and their family members.

For purposes of the FEHB Program, 5 U.S.C. 8901(5) defines a ''member of family'' of employees and annuitants to include spouses and children under 22 years of age, subject to exception, including natural children, adopted children, stepchildren, and foster children. The enactment of the Affordable Care Act in 2010 required health insurers to cover dependents until age 26. At that time, OPM issued updates to its regulations codified at 5 CFR 890.302(b) and (c) to reflect that change, which defines FEHB covered family members to include such children until they reach the age of 26, subject to exception. The PSHB Program will align with 5 CFR part 890 regarding the definition of family members for all purposes, including the Medicare SEP opportunity.

The PSRA adds new definitions to chapter 89. Section 8903c(a)(9) defines a Postal Service employee as ''an employee of the Postal Service enrolled in a health benefits plan under this chapter whose Government contribution is paid by the Postal Service.'' Under section 8903c(a)(8), a Postal Service annuitant ''means an annuitant enrolled in a health benefits plan under this chapter whose Government contribution is required to be paid under section 8906(g)(2).'' Therefore, individuals not meeting the statutory definition of a Postal Service annuitant or Postal Service employee are not eligible to enroll in a PSHB plan. If such individuals are eligible for enrollment in an FEHB plan, they may enroll or continue enrollment in such plan.

The PSRA does not establish a distinct category for Postal Service compensationers, those employees who sustain workplace-related illness or injury, receive workers' compensation payments through the Department of Labor's Office of Workers' Compensation Programs (OWCP) because of that illness or injury, and who are determined by the Secretary of Labor to be unable to return to duty. Section 8901 of title 5, U.S.C. includes ''an employee who receives monthly compensation under subchapter I of chapter 81 of this title and who is determined by the Secretary of Labor to be unable to return to duty'' in the definition of annuitant.[4] However, the PSRA definition of Postal Service annuitant is limited to those who are enrolled in a health benefits plan under 5 U.S.C. chapter 89, whose Government contribution is required to be paid under section 8906(g)(2).

Section 8906(g)(2) authorizes Government contributions for health benefits for individuals who become Postal Service annuitants ''by reason of retirement'' and their survivors. These contributions are paid first by the Postal Service Retiree Health Benefits Fund with any remaining amount paid by the Postal Service. The description in 8906(g)(2) does not include Postal Service compensationers, as they have not become annuitants by reason of retirement. Postal Service compensationers are more closely aligned with the 8903c(a) definition of Postal Service employee, whose Government contribution is paid by the Postal Service.

The definition of Postal Service employee, rather than Postal Service

[3] For more information, see SSA's amounts for Substantial Gainful Activity at *https://www.ssa.gov/oact/cola/sga.html.*

[4] 5 U.S.C. 8901(3)(C).

annuitant, will include Postal Service compensationers. Postal Service compensationers will not be subject to the Medicare Part B enrollment requirement, regardless of Medicare Part A entitlement.

D. Centralized Enrollment

The FEHB Program's enrollment functions are decentralized processes that utilize independent systems at different Federal agencies. For purposes of the PSHB Program, OPM will shift certain responsibilities from the employing office to a centralized enrollment system which will be administered by OPM. The centralized enrollment system will be an electronic enrollment solution for all PSHB stakeholder groups including enrollees, the Postal Service and other employing offices, and PSHB Carriers. The centralized enrollment system will include an online portal to enter and process enrollment transactions (*e.g.,* uploading verification of eligibility), robust decision support tools, and a customer support center to assist enrollees via phone, email, or online chat. Persons who are unable to access the online portal will be able to enroll through other means such as phone, fax, or mail. The interim final rule included regulatory provisions in §§ 890.1605, 890.1606, 890.1608, and 890.1614 specifying that OPM will assume responsibility for the following health benefits actions for the PSHB Program: enrollment, changes of enrollment, correction of errors, election not to enroll, and disenrollment of enrollees and removal of family members.

Comments Received on the Interim Final Rule and OPM's Responses

OPM received a total of 71 comments on the interim final rule. Most of these were from individual Postal Service employees, Postal Service annuitants, and their family members. There were also several detailed comment letters from stakeholders including health insurers and employee organizations. In addition to comments supporting the policies in the interim final rule, OPM received comments raising questions or expressing concerns with aspects of the interim final rule, mostly from individual Postal Service employees, Postal Service annuitants, and their family members.

Many public comments expressed support for the alignment between the FEHB and PSHB Programs. Commenters expressed support for issues in the rule including the January 1—December 31 plan year for PSHB plans, OPM's approach to automatic enrollment of Postal Service employees and Postal Service annuitants who do not elect a PSHB plan during the transitional Open Season, OPM's integration of Medicare Part D prescription drug benefits for Medicare enrollees, OPM's member-centric approach allowing for an additional enrollment opportunity for Postal Service annuitants or family members who are inadvertently not enrolled in Medicare Part B, despite the requirement as a condition to maintain PSHB enrollment, and OPM's establishment of centralized enrollment through a new electronic enrollment system for PSHB.

In reviewing comments received in response to the interim final rule and feedback received, OPM determined a need to provide additional specification on several topics that were beyond the scope of the interim final rule. Accordingly, OPM will soon issue a proposed rule that further explains and expands on the implementation of the PSHB Program to provide clarity for PSHB Carriers, other agencies, and Postal Service employees, annuitants, and their family members before the Program begins enrollment for 2025. Topics OPM plans to address in more detail in the proposed rule include: reconsideration of initial decisions concerning PSHB eligibility; application of the Medicare Part B requirement and associated exceptions in specific scenarios; allocation of Reserves credits; calendar year alignment of government contribution requirements; financial reporting and actuarial calculations; premium payment prioritization from the Postal Service Retiree Health Benefits Fund; and Medicare Part D integration. A summary of the comments received during the 60-day comment period and OPM's responses follows; however, OPM notes that additional details on the topics listed above will be provided through the new rulemaking.

A. Transition From FEHB Plans to PSHB Plans

The interim final rule detailed the process by which Postal Service employees, Postal Service annuitants, and their family members will transition from FEHB plan coverage to PSHB plan coverage for plan year 2025. Medicare covered Postal Service annuitants who retire after January 1, 2025, and the Medicare covered members of family are required to enroll in Medicare Part B to remain enrolled in a PSHB plan, with limited exceptions.

Comments: OPM received several comments with concerns about the effect of the new program on Postal Service annuitants and their family members. Specifically, the commenters are concerned about two new requirements: the requirement to transition from an FEHB plan to a PSHB plan and the requirement for most Postal Service annuitants and their Medicare-covered family members to enroll in Medicare Part B to maintain enrollment in the PSHB Program. A theme of the concerns is that many Postal annuitants plan their retirement based on the benefits packages available at the time of their employment and the PSHB Program changes those plans involuntarily.

Response: Pursuant to 5 U.S.C. chapter 89, the PSHB Program must include Postal Service employees, Postal Service annuitants, and their eligible family members. The law also requires that Medicare covered Postal Service annuitants, with limited exceptions as described in the Executive Summary, enroll in Medicare Part B to maintain enrollment in the PSHB. OPM is required to implement these statutory provisions and is not able to modify these mandates by regulation. As such, OPM will not make a regulatory change in response to these comments.

Comment: A commenter asked that OPM consider creating a hardship exception allowing individuals to continue in their chosen FEHB plan after the PSHB Program begins, should that plan not be offered in PSHB. The commenter stated that some small regional plans may not be available, creating a potential loss of access to coverage under those plans due to the creation of PSHB.

Response: OPM does not have the statutory authority to allow a hardship exception as requested by the commenter. Where a small regional plan is no longer available in the PSHB Program, coverage will nonetheless always be available under one of the nationwide PSHB plans.

Comments: Several commenters requested that Postal annuitants who retired under the Civil Service Retirement System, rather than the Federal Employees Retirement System, be allowed to maintain coverage under an FEHB plan.

Response: OPM does not have the statutory authority to allow an exception based on a Postal Service annuitant's retirement system.

Comments: Several commenters asked why employees of the United States Postal Inspection Service would be required to transition to PSHB.

Response: The United States Postal Inspection Service is part of the United States Postal Service as defined by statute. While certain individuals may receive other Federal benefits, those benefits are not relevant to the

definition of Postal Service employee under 5 U.S.C. 8903c(a)(9).

Comments: Several commenters asked if PSHB Program enrollment will count towards the five-year FEHB Program enrollment requirement to retire with FEHB coverage from another agency.

Response: Yes, the five-year requirement under the FEHB Program will continue to be in effect for the PSHB Program. An individual is eligible to continue enrollment in a PSHB plan into retirement if they meet the five-year requirement and were enrolled in a PSHB plan immediately before retirement. The five-year requirement does not change and is not changed by the Medicare Part B enrollment requirement for certain Postal Service annuitants enrolled in PSHB.

A Postal Service annuitant, whose Government contribution is required to be paid under 5 U.S.C. 8906(g)(2), is not eligible to continue enrollment in an FEHB plan. *See* section 8903c(d). As stated in the preamble of the interim final rule, in order to continue coverage into retirement, enrollees in the PSHB Program will be subject to the FEHB Program requirement of being covered by a plan for the 5 years of service immediately before retirement, or if less than 5 years, for all service since their first opportunity to enroll. See § 890.306.

A Postal Service annuitant who (at the time the individual becomes an annuitant) was enrolled in a health benefits plan under chapter 89, including under section 8903c, can meet that 5-year requirement if they were so enrolled as a Postal Service employee, as an employee defined at 5 U.S.C. 8901(1), or a mix of both in order to maintain health benefits after retirement. Similarly, an annuitant who is not a Postal Service annuitant, whose Government contribution is not required to be paid under 8906(g)(2), may meet the 5-year requirements for continuing FEHB coverage into retirement, if they were enrolled in a plan under chapter 89 as both an employee defined at 5 U.S.C. 8901(1) and as a Postal Service employee.

Comment: One commenter asked if a Postal Service annuitant is eligible to enroll under their spouse's FEHB eligibility rather than moving to the PSHB.

Response: Yes, the PSHB Program does not affect the eligibility of any Postal Service employee or Postal Service annuitant to be covered as a family member under an FEHB plan. In this circumstance, the spouse of the Postal Service annuitant would need to cover the Postal Service annuitant under their FEHB plan during Open Season 2024. The Postal Service annuitant would also need to elect not to enroll in a PSHB plan during the transitional Open Season to avoid automatic enrollment in a PSHB plan.

B. Medicare Part B Enrollment Requirement for Postal Service Annuitants

Many commenters asked about the details of the Medicare Part B enrollment requirement for Postal Service annuitants enrolled in a PSHB plan. OPM is taking the opportunity to clarify in this preamble and regulatory text some details about how the Medicare Part B requirement will be enforced after the launch of the PSHB Program.

The PSRA authorized a Medicare Part B Special Enrollment Period (SEP) for certain Postal Service annuitants and their family members. Codified at section 1837(o) of the Social Security Act (42 U.S.C. 1395p), the six-month special enrollment period will run from April 1 through September 30, 2024. Postal Service annuitants and their family members who are entitled to Medicare Part A but not enrolled in Medicare Part B as of January 1, 2024 are eligible to enroll in Medicare Part B during the SEP. The PSRA allows the Postal Service to pay any applicable Medicare Part B late enrollment penalties for individuals who enroll during this SEP.

As explained below in the section of the preamble discussing the changes included in this final rule, OPM is amending § 890.1604 to clarify the timing aspects of several exceptions that are statutorily required to apply ''as of January 1, 2025''.

Comment: A commenter said that many Postal Service annuitants may be unaware of the requirement to enroll in Medicare Part B to maintain PSHB coverage. The commenter requested that such annuitants be automatically enrolled in Medicare Part B.

Response: OPM and the Postal Service are working together on educational materials to explain the transition to PSHB and the Medicare Part B enrollment requirements. They include plain language written materials such as fact sheets and tri-fold mailers, multi-media activities such as a five-part video series available at *https://www.keepingposted.org/postal-service-health-benefits.htm,* and regular ''lunch and learn'' virtual seminars. The Postal Service and OPM have been engaged in ongoing communication with Postal Service employees, annuitants, and their family members since late 2022 when OPM published FAQs on its website at *https://www.opm.gov/healthcare-insurance/pshb/.*

OPM does not have the authority to enroll Postal Service annuitants in Medicare Part B automatically and will not make a regulatory change in response to this comment. Postal Service annuitants or their family members who enroll in Medicare Part B during the Special Enrollment Period may be subject to a Medicare Part B late enrollment penalty.[5] The PSRA allows the Postal Service to pay such late enrollment penalty on behalf of the annuitant or family member.

Comment: Some commenters asked when family members of disabled Postal Service annuitants are required to enroll in Medicare Part B.

Response: A family member of a disabled Postal Service annuitant is required to enroll in Medicare Part B if the family member themselves are a Medicare covered individual. As described in the interim final rule, the Medicare Part B enrollment requirement applies regardless of how the Postal Service annuitant becomes entitled to Medicare Part A, such as age, end stage renal disease or receiving Social Security disability payments for 24 months. A family member of a PSHB enrollee who is a disabled Postal Service annuitant is required to enroll in Medicare Part B if both the Postal Service annuitants and the family member are Medicare covered individuals (meaning that both are entitled to Medicare Part A), unless the family member qualifies for an individual exception as listed in the Executive Summary and at § 890.1604 and discussed more fully in the section ''Regulatory Changes in This Final Rule.''

Comment: A commenter asked whether a family member must maintain Part B coverage if the family member is enrolled in Medicare Part B prior to January 1, 2025, but the Postal Service annuitant, under whose PSHB enrollment the family member is covered, is not required to enroll in Part B.

Response: No, a Medicare covered family member is required to be enrolled in Medicare Part B only if the Postal Service annuitant under whose PSHB enrollment the family member is covered, is required to be enrolled in Medicare Part B. OPM is amending § 890.1604 to clarify the requirements and exceptions for enrolling in Medicare Part B, as described in the Executive Summary and in the section

[5] Explanation of Medicare late enrollment penalties available here: *https://www.medicare.gov/basics/costs/medicare-costs/avoid-penalties.*

''Regulatory Changes in this Final Rule.''

C. Exceptions to the Medicare Part B Enrollment Requirement

OPM received several comments regarding the details of the requirement for Postal Service annuitants to enroll in Medicare Part B. The interim final rule addressed the requirement in § 890.1604, including several statutory exceptions to that requirement described in the Executive Summary and in the section ''Regulatory Changes in This Final Rule.''

Comment: A commenter expressed support for OPM's rule to allow self-attestations as proof of eligibility for health services from the Indian Health Service (IHS). The same commenter asked OPM to confirm that PSHB Carriers will not be responsible for determining whether PSHB enrollees qualify for the exception based on eligibility for IHS health services.

Response: OPM is not authorizing PSHB Carriers to determine whether an individual is excepted from the Medicare Part B enrollment requirement under the IHS exception or any other exceptions under § 890.1604. Under part 890, a carrier may only verify an individual's relationship to the enrollee to confirm whether they are an eligible family member.

Comment: Several commenters requested clarification regarding how the PSHB Program will affect enrollees residing outside the United States especially as it relates to Medicare coverage.

Response: The interim final rule included a list of exceptions to the Medicare Part B enrollment requirement at 5 CFR 890.1604(c). These exceptions included an exception for Medicare covered Postal Service annuitants and Medicare covered members of family residing outside the United States. The PSRA and this final rule requires that individuals residing outside the United States will demonstrate such residency. OPM and the Postal Service are working together to operationalize the details of how individuals will demonstrate residency outside the United States. OPM is amending § 890.1604 to clarify the requirements and exceptions for enrolling in Medicare Part B.

D. Changes To Coverage and Premium Costs Due to the Medicare Part B Enrollment Requirement

Comment: OPM received several comments from Postal Service employees and Postal Service annuitants currently enrolled in FEHB plans seeking more information about anticipated changes to their medical, physician, and pharmaceutical coverage and health insurance premiums when they are required to enroll in Medicare Part B to maintain coverage under the PSHB Program.

Response: OPM negotiates health benefits and premiums each year with carriers. As delineated in the interim final rule, a carrier's PSHB plan must provide equivalent benefits and cost-sharing to the carrier's FEHB plan in the 2025 contract year. Approved PSHB Carriers will submit benefit and rate proposals for PSHB plans by the end of May 2024. OPM expects that full benefits and premium information for 2025 PSHB plans will be available in September 2024.

OPM is asking carriers to focus on Medicare coordination in both FEHB plans and PSHB plans for 2025. The call letter for the 2025 FEHB and PSHB plan year [6] states ''All Carriers must implement a multi-pronged educational outreach effort to eligible enrollees focused on Medicare coordination. . . . FEHB and PSHB Program members for whom Medicare is primary must receive medical and drug coverage equal to or greater than the medical and drug coverage they would have received without Medicare Advantage Prescription Drug Plan (MA–PD) EGWP or Prescription Drug Plan (PDP) EGWP.''

The call letter further ensures robust coordinated coverage by directing carriers that ''The PSRA requires PSHB Carriers, in the initial contract year, to provide benefits and cost-sharing that are equivalent to the benefits and cost-sharing of that Carrier's 2025 FEHB plan option, except to the extent needed to integrate Medicare Part D prescription drug benefits. PDP EGWP formularies must, at a minimum, include the same covered drugs under the plan's formulary. Furthermore, every drug covered under a plan option's formulary must be covered at the same or lower cost-share by the plan's PDP EGWP formulary. In circumstances where equivalent drug benefits and cost-sharing (not actuarial equivalence) cannot be met due to limitations in integrating Medicare Part D prescription drug benefits, PSHB Carriers must provide justification explaining why they cannot meet this standard.''

E. Continuity of Costs and Coverage Between FEHB Plans and PSHB Plans

Comment: OPM received many comments regarding changes in premium costs and benefits between FEHB plans and PSHB plans. There were questions about specific covered services and requesting information about whether such services will be covered in a similar way after the launch of the PSHB Program. Several commenters raised concerns about possible cost increases after the launch of the new program.

Response: The PSRA requires that, in the initial contract year, a carrier offering PSHB plans must offer coverage with equivalent benefits and cost-sharing to FEHB plans offered by that carrier, except to the extent needed to integrate Medicare Part D prescription drug benefits. This requirement was codified in the interim final rule at § 890.1610 ''Minimum standards for PSHB Program plans and Carriers.''

OPM is approving carriers for participation in the PSHB Program. Approved carriers will submit plan benefit and rate proposals by the end of May 2024, the plan premiums will be made public in September 2024, and more detailed plan brochures will be available prior to Open Season 2024 at *https://www.opm.gov/healthcare-insurance/open-season.*

In order to ensure that the drug coverage under a PSHB plan's Medicare Part D EGWP is equal to the drug coverage under the PSHB plan, OPM has required that PSHB plans' ''PDP EGWP formularies must, at a minimum, include the same covered drugs under the plan's formulary. Furthermore, every drug covered under a plan option's formulary must be covered at the same or lower cost-share by the plan's PDP EGWP formulary.'' *See supra* note 6.

F. Information Sharing

The interim final rule outlined a process for agencies to share relevant information for OPM's administration of the PSHB Program. This included implementing a statutory requirement for OPM and the SSA to share information necessary to identify individuals who may be eligible to enroll in Medicare Part B during the 6-month Medicare special enrollment period (SEP) from April 1, 2024, to September 30, 2024.

Comment: A commenter suggested that coordination of benefits with Medicare at 5 U.S.C. 8910(d) requires OPM to expand PSHB information sharing regulations at 5 CFR 890.1612 to the entire FEHB Program and allow carriers to access that information for coordination and reporting purposes.

Response: OPM agrees that information sharing between agencies is critical to administer the PSHB Program effectively. OPM is not expanding our information sharing effort to the entire FEHB Program since the PSRA's

[6] *https://www.opm.gov/healthcare-insurance/carriers/fehb/2024/2024-04.pdf.*

information sharing provisions are intended to implement the PSHB Program and its Medicare enrollment requirement for certain Postal Service annuitants and their family members. Similarly, OPM does not intend to provide the information that is the subject of interagency information sharing agreements to carriers, except in limited circumstances required to operate the PSHB Program as permitted under the Privacy Act.

G. Centralized Enrollment System

The interim final rule explained that OPM will develop and implement a centralized enrollment system for the PSHB Program. The centralized enrollment system will be an electronic enrollment solution for PSHB enrollees, the Postal Service and other employing offices (including OPM's Retirement Services office for Postal Service annuitants), and PSHB Carriers. The centralized enrollment system will include an online portal to be used to process enrollment transactions and will include decision support tools and customer support to assist enrollees and their family members.

Comment: Several commenters made specific recommendations about the mechanics and operations of OPM's PSHB central enrollment system. Commenters requested elements such as specific data fields, a total cost calculator, and filtering capabilities.

Response: OPM appreciates the comments and will consider the recommendations in the system design. In July 2023, OPM awarded a contract for the development of the PSHB System. The scope of the project includes enrollment functions and a customer support center that will service PSHB employees, annuitants, and family members. The center will provide services such as eligibility determinations, enrollment support, and enrollment and premium reconciliation and a decision support tool.

That request for proposal (RFP) is available at *https://sam.gov/opp/94b39c9c3e504c02ae593ab3fab7a342/view.*

The RFP includes nearly 300 distinct requirements, including determining eligibility based on listing all necessary data fields to manage eligibility and enrollment, the ability for users to calculate total costs, and sort and filter plan information. OPM is on track with development of the system and is determining how and when these functionalities will be rolled out.[7]

Comment: One commenter requested that OPM continue to provide periodic updates to carriers as the centralized enrollment system is developed, so that carriers can make appropriate adjustments to their systems and processes.

Response: OPM intends to continue regular communications with carriers as OPM's plans for the central enrollment system development. Carriers may contact their OPM contract representatives with specific questions.

H. PSHB Contracting

The interim final rule included several provisions related to contracting, including requirements for PSHB Carriers and PSHB plans.

Comment: Several commenters had specific recommendations about contracts, including details about the contract effective date and several comments related to accounting principles.

Response: OPM appreciates the comments and notes that PSHB contracting details are outside the scope of the regulation.

I. Automatic Enrollment

The interim final rule implemented the requirement that Postal Service employees and Postal Service annuitants who do not make an PSHB plan election during the transitional Open Season in 2024 will be automatically enrolled in a PSHB plan with coverage effective January 1, 2025.

Comment: A commenter requested clarification on 5 CFR 890.1605(c), regarding how automatic enrollment will work for a carrier that has three FEHB plan options but intends to offer only two PSHB plan options.

Response: In the interim final rule at § 890.1605(c)(2), when a carrier offers more than one PSHB plan or option in 2025, the individual will be automatically enrolled in the PSHB plan and option offered by the carrier that provides equivalent benefits and cost sharing to the individual's 2024 FEHB plan and option, as determined by OPM. In a case where the carrier is not offering a PSHB plan, the individuals enrolled in the carrier's FEHB plan in 2024 will be automatically enrolled in the lowest-cost nationwide PSHB plan option that is not a high deductible health plan and does not charge an association or membership fee. *See* § 890.1605(c)(3). OPM will apply the FEHB regulation at 5 CFR 890.301(n) to determine the lowest-cost nationwide plan. Per that regulation, OPM can designate an alternate plan for automatic enrollments if circumstances dictate this. All automatic enrollments will be into a PSHB plan of the same enrollment type (self only, self and family, or self plus one) as the 2024 FEHB plan. OPM plans to provide additional details regarding specific automatic enrollment circumstances in future rulemaking.

Comment: One commenter asked for clarity regarding the definition of a carrier for purposes of automatic enrollment and recommended that OPM allow automatic enrollment into the same carrier as under FEHB, regardless of whether the plans available in the PSHB Program are offered under a different contract than the enrollee's current FEHB plan.

Response: In the interim final rule, OPM defined ''PSHB Carrier'' at 48 CFR 1602.170–20, as follows: ''PSHB Carrier means a carrier that enters into a contract with OPM under 5 U.S.C. 8902 to offer a health benefits plan in the PSHB Program.'' The interim final rule provided that the enrollee is automatically enrolled into a PSHB plan offered by the same carrier. This is true even though the PSHB plan is under a different contract with OPM than the enrollee's 2024 FEHB plan. OPM will automatically enroll the enrollee into a PSHB plan offered by a different carrier (the lowest-cost nationwide PSHB plan option that is not a high deductible health plan and does not charge an association or membership fee) if the carrier of the enrollee's 2024 FEHB plan does not offer a PSHB plan in 2025.

J. Health Benefits Education Program

Comment: One commenter requested that OPM provide outreach and education to Postal Service annuitants and their families regarding the changes to their coverage options under the PSHB Program.

Response: The Postal Service is coordinating with OPM and other agency partners to inform Postal Service employees, Postal Service annuitants, and their family members about the transition to the PSHB Program and

[7] From the PSHB System Performance Work Statement (*https://sam.gov/api/prod/opps/v3/opportunities/resources/files/81805a8de14f4084b5650da08d347e42/download?&status=archived&token=*) ''Starting in the fall of 2024, the system will process all enrollments and changes in enrollments for PSHB, including open season transactions, qualifying life events, and enrollments for newly eligible. The fully functional system will provide an account-based, one-stop-shop where enrollees can: (1) compare and learn about PSHB plan options, including benefits, provider networks, formulary, cost-sharing, and total out-of-pocket expenses, (2) select a plan that fits the unique needs of their family, and (3) complete the enrollment process. The system will also serve as the authoritative source for PHSBP enrollment data, ensure enrollee eligibility by exchanging data with relevant Federal agencies, and provide real-time enrollment and premium transaction information to all employing agencies and participating PSHBP health insurance issuers (herein referred to as Carriers).''

their coverage options. This education has been ongoing since late 2022 when OPM published FAQs on its website at *https://www.opm.gov/healthcare-insurance/pshb/.* Under 5 U.S.C. 8903c(l), the Postal Service is responsible for establishing a Health Benefits Education Program. The Postal Service's Health Benefits Education Program notifies eligible individuals about the PSHB Program, coverage options, and the Medicare Part B enrollment requirement.

In October 2023, USPS published a bulletin announcing an update to its Employee and Labor Relations Manual (ELM) to incorporate the Health Benefits Education Program at *https://about.usps.com/postal-bulletin/2023/pb22634/html/welcome.htm.* This Program included notifications of PSHB options, Medicare enrollment requirements, links to submit inquiries from employees and annuitants, and navigator activities for program education. The updates included in the October 2023 Postal Bulletin were effective immediately and were incorporated in the ELM as of March 31, 2024.

OPM and the Postal Service have been collaborating on education materials since 2022. Those informational materials include plain language written materials such as fact sheets and tri-fold mailers. There are also multi-media activities such as a five-part video series available at *https://www.keepingposted.org/postal-service-health-benefits.htm* and regular ''lunch and learn'' virtual seminars.

The Postal Service's Health Benefits Education Program notifies eligible individuals about the PSHB Program and provides information about coverage options, and the Medicare Part B enrollment requirement.

Additionally, PSHB plan premiums will be made public in September 2024, and more detailed plan brochures will be available prior to Open Season 2024 at *https://www.opm.gov/healthcare-insurance/open-season.*

K. Prescription Drug Benefits and Integration of Medicare Part D

As noted in the preamble to the interim final rule, PSHB plans must provide prescription drug benefits through Medicare Part D to Part D-eligible Postal Service annuitants and their Part D-eligible family members. Under 5 U.S.C. 8903c(h), PSHB plans are required to provide prescription drug benefits to these individuals through ''employment-based retiree health coverage'' either through a ''prescription drug plan (PDP)'' or a contract with a ''PDP sponsor'' of a prescription drug plan, as these terms are defined in sections 1860D–22(c)(1), 1860D–41(a)(14), and 1860D–41(a)(13) of the Social Security Act, respectively. A carrier providing prescription drug benefits may, subject to OPM's approval, provide a Medicare Advantage plan with prescription drug benefits (MA–PD) so long as the carrier also provides a PDP.

Comment: Several commenters asked about how the timing of Medicare Part D coverage will align with the January 1–December 31 plan year of the PSHB Program. One commenter requested that OPM review the Centers for Medicare & Medicaid Services (CMS) rules to determine if Medicare Part D coverage needs to begin on the first day of the following month in a PSHB retroactive enrollment to avoid violation of CMS requirements.

Response: OPM appreciates the comment and is actively engaged with key stakeholders to ensure that enrollees and covered family members experience a seamless enrollment process. OPM notes that the proposed rule will provide more information regarding PSHB Program implementation of Medicare Part D coverage.

Comment: One commenter requested that OPM address perceived conflicts between the Internal Revenue Service (IRS) requirements for high deductible health plans with health savings accounts and CMS guidance around Part D prescription drug plans.

Response: OPM, through its guidance, rate and benefits negotiations, contract administration and negotiations process, will ensure that carriers' plan proposals are in compliance with all applicable requirements.

Comment: One commenter raised a concern about OPM's method for automatically enrolling members who do not choose a PSHB plan during the transitional Open Season in 2024. This commenter was concerned about whether members may be automatically enrolled into a plan with a standalone PDP, and whether an MA–PD plan may be more advantageous for such members.

Response: As directed by the PSRA, PSHB Carriers must integrate Medicare Part D into their PSHB plan design through a PDP or a contract with a PDP sponsor. OPM will also consider approving a carrier's MA–PD plan so long as the carrier provides a PDP. Whether a carrier provides Medicare Part D through a PDP or through a PDP and MA–PD does not affect automatic enrollment into a PSHB plan during the transitional Open Season. If an individual wants to be covered by a PDP or MA–PD, if available, under a PSHB plan enrollment then the enrollee may choose a PSHB plan with the desired prescription drug benefits during the transitional Open Season. OPM notes that the proposed rule will provide more information regarding program implementation, including group enrollment and Medicare Part D plans including MA–PD plans.

Comment: One commenter asked that OPM encourage or require PSHB plans to offer health reimbursement arrangements (HRAs) with sufficient funds to offset the cost of any Medicare Part D income-related monthly adjusted amount (IRMAA), or alternatively, to reduce the costs of Part B premiums or other out-of-pocket expenses if not subject to IRMAA.

Response: PSHB Carriers may propose to offer HDHPs with an HRA, and individuals may enroll in such a plan and use the HRA to help pay for qualified medical expenses, Medicare premiums including any applicable IRMAA, and other qualified medical expenses. As demonstrated in the Federal Employees Health Benefits and Postal Service Health Benefits Programs Call Letter for 2025, OPM is working with carriers to inform enrollees about the possible impact of the IRMAA.

L. Medicare Part B Special Enrollment Period (SEP)

The PSRA authorized a 6-month Medicare Part B SEP that will run from April 1 through September 30, 2024. This SEP is codified in the Social Security Act and will allow enrollment in Medicare Part B for Postal Service annuitants who are entitled to Medicare Part A and their family members who are entitled to Medicare Part A and not already enrolled in Medicare Part B. In the interim final rule, OPM included a process to share information with SSA to identify individuals who may be eligible to enroll in Medicare Part B during the SEP.

Medicare-eligible individuals may have several opportunities to sign up for Medicare. More information is available at the CMS website here: *https://www.medicare.gov/basics/get-started-with-medicare/sign-up/when-can-i-sign-up-for-medicare.* If an individual does not enroll in Medicare Part B at their earliest opportunity, they may be subject to a permanent Medicare Part B late enrollment penalty.[8] The PSRA allows the Postal Service to pay any applicable Medicare Part B late enrollment penalty on behalf of individuals who enroll during the SEP in 2024. If a Medicare-eligible Postal

[8] *https://www.medicare.gov/basics/costs/medicare-costs/avoid-penalties.*

Service annuitant or covered family member not enrolled in Medicare Part B declines to enroll during the PSRA-authorized SEP in 2024, they may be subject to the Medicare late enrollment penalty if they choose to enroll in Medicare Part B at a later date. Such individual may also be eligible other SEPs due to extenuating circumstances. For example, Medicare Part B has an SEP for individuals impacted by an emergency or natural disaster.[9]

Comment: A commenter asked if OPM and SSA will include any additional criteria to determine who is eligible for the SEP.

Response: OPM does not have the authority to establish eligibility criteria for the Medicare Part B SEP. Under the PSRA, the SEP is available to a Postal Service annuitant who is entitled to Medicare Part A and who is an annuitant as of January 1, 2024 and their family members who are entitled to Medicare Part A, excluding those eligible to enroll in Medicare under section 1818 or 1818A of the Social Security Act.

Comment: A commenter requested further clarification regarding the SEP for PSHB, asking specifically if OPM intends to create an appeals process for those who believe that they are eligible for SEP but were misinformed or were never informed.

Response: OPM is coordinating with SSA and the Postal Service to prepare for the 6-month Medicare Part B SEP. The PSRA requires that OPM establish a process to provide information to SSA about Postal Service annuitants and covered family members who may be eligible for Medicare Part B during the PSRA SEP. Any appeals related to an individual's eligibility to enroll in Medicare Part B would be handled by SSA according to that agency's procedures. OPM does not have the authority to enroll individuals in Medicare Part B or to handle appeals of SSA's enrollment decisions.

Comment: A commenter requested clarification as to whether any PSHB plan information will be available at the beginning or during the SEP to allow individuals eligible to enroll in Medicare Part B during the SEP to consider the PSHB plans in deciding whether to enroll in Part B.

Response: The PSRA authorized a 6-month Medicare Part B SEP that will run from April 1 through September 30, 2024. OPM expects to make PSHB premium rate information available in September 2024. PSHB plan benefit information, including detailed plan brochures, will be ready according to OPM's standard schedule for releasing such information before Open Season begins. Due to the plan application and contract negotiation schedule, there is no opportunity to make this information available sooner.

Comment: A commenter asked if OPM would consider extending the SEP to ensure Medicare Part B decisions and PSHB decisions can be made at the same time.

Response: The Medicare Part B SEP is established by statute under the PSRA and is administered by SSA. The authorizing language for the SEP, codified in the Social Security Act at section 1837(o)(1)(B) (42 U.S.C 1395p(o)(1)(B)) states that eligible individuals ''may elect to be enrolled under this part during a special enrollment period during the 6-month period beginning on April 1, 2024.'' OPM does not have the legal authority to extend the Medicare Part B SEP.

Comment: A commenter asked when individuals would be notified about SEP eligibility.

Response: OPM is coordinating with SSA and the Postal Service to identify individuals who may be eligible to enroll in Medicare Part B during the 2024 SEP. In January 2024, the Postal Service mailed informational postcards that included information about the PSRA Medicare Part B SEP to Postal Service annuitants and family members who were not enrolled in Medicare Part B. The Postal Service mailed notifications to eligible individuals in March 2024.

M. OPM Administration of PSHB

Comment: A commenter made a recommendation about the timing of the maximum Government contribution calculation and recommends that OPM release the maximum Government contribution earlier to create fair competition between all carriers.

Response: In the interim final rule, OPM addressed the Postal Service contribution at § 890.1613(b). OPM must determine the Government contribution consistent with the timing requirements at 5 U.S.C. 8906 and 5 CFR 890.501. OPM will endeavor to release PSHB and FEHB rates as soon as possible, no later than September 2024, and in a manner that does not impede fair competition.

N. Allocation of Carrier Reserves

Comment: One commenter recommended that OPM promote fair allocation of carrier reserves.

Response: OPM issued Carrier Letter 2023–13 (CL 2023–13) in July 2023 available at *https://www.opm.gov/healthcare-insurance/carriers/fehb/2024/2024-04.pdf* outlining a methodology to allocate FEHB plan reserves from FEHB plans to PSHB plans. In short, reserves will be allocated based on 2024 premium income attributable to the Postal Service and non-Postal Service populations for each plan option. OPM considered incorporating a risk component in the allocation of reserves; however, OPM determined the method outlined in CL 2023–13 is most consistent with current FEHB practice. As explained in CL 2023–13, OPM intends to use a similar approach for allocating medical loss ratio (MLR) credits between FEHB plans and PSHB plans offered by the same carrier.

Comment: One commenter inquired about the effect of PSHB on Postal Service annuitants who are eligible to continue their health insurance plan and pay the employee share of premium out of pocket directly to the National Finance Center and not as a deduction from their annuity.

Response: All payment options that are available for FEHB plans, including direct pay, will be available for enrollees in PSHB plans. Note that, if an annuitant pays both the employee share and the Government's share of premium, then the annuitant is not within the statutory definition of a Postal Service annuitant and is not subject to transition to a PSHB plan and will remain eligible for enrollment in an FEHB plan.

Regulatory Changes in This Final Rule

OPM is amending § 890.1604 in response to comments requesting clarification around the requirements for certain Postal Service annuitants and their family members to enroll in Medicare Part B, as discussed in the previous section. Specifically, OPM is clarifying how we are implementing the statutory language at 5 U.S.C. 8903c(e).

OPM is making this change to provide more clarity as to the applicability of exceptions to the Medicare Part B enrollment requirement under 5 CFR 890.1604. The statutory language in 5 U.S.C. 8903c(e), ''as of'' January 1, 2025, can be interpreted to either include or exclude events occurring on January 1, 2025. To avoid potential confusion and to ensure that Postal Service employees and annuitants can make informed decisions about their health coverage during important life events, OPM is revising the regulatory text to provide additional clarity on eligibility for the Medicare Part B exceptions.

Therefore, OPM is clarifying timing aspects of several exceptions to the requirement to enroll in Medicare Part

[9] *https://www.medicare.gov/basics/get-started-with-medicare/sign-up/when-does-medicare-coverage-start#SEP.*

B. Specifically, OPM is clarifying that the statutory exception at 5 U.S.C. 8903c(e)(3)(A)(i), which applies to individuals ''as of'' January 1, 2025, includes individuals who are annuitants ''on or before'' January 1, 2025, and who were not both entitled to Medicare Part A and enrolled in Medicare Part B ''on'' January 1, 2025. OPM is making this change to ensure that the regulations are clear and specific when the exceptions are applicable so that all individuals can make informed decisions. For example, a Postal Service employee's last day of service is December 31, 2024. Because this individual will be an annuitant on January 1, 2025, the individual is eligible for an exception to the requirement to enroll in Medicare Part B under 5 CFR 890.1604(d)(1)(i). This clarification also applies to employees age 64 on or before January 1, 2025. For example, a Postal Service employee turning age 64 on January 1, 2025, is eligible for an exception to the Medicare Part B requirement under 5 CFR 890.1604(d)(1)(ii) because they will be age 64 on January 1, 2025. This clarification is included in § 890.1604(d)(1)(i) and (ii).

OPM is revising the regulatory text of § 890.1604 related to demonstrating residency outside the United States to provide more operational flexibility to the Postal Service and OPM by removing the specific entity that will receive information about overseas residency. These changes are in § 890.1604(d)(1)(iii) for annuitants and § 890.1604(d)(2)(ii) for family members.

We are reserving § 890.1604(c) in anticipation of future rulemaking.

OPM is revising § 890.1604(e) (now codified at § 890.1604(f) due to insertion of the new, reserved paragraph (c)) to clarify that a Postal Service annuitant or their family member who is required to be enrolled in Medicare Part B must promptly notify OPM or the Postal Service, in writing, if they choose not to enroll in or to disenroll from Medicare Part B as described in § 890.1608(e). This implements the PSRA requirement codified at 5 U.S.C. 8903c(g)(3)(D) that OPM issue regulations allowing individuals to cancel coverage in writing to the Postal Service, while allowing flexibility for OPM to also take these cancellations in writing.

Under part 890, OPM has imposed similar responsibilities on individuals to inform OPM of any changes that may affect their or their family member's eligibility or coverage, for instance, if an individual is covered under another insurance plan. (*See* 5 CFR 890.302(a)(2)(ii), ''To ensure that no person receives benefits under more than one enrollment, each enrollee must promptly notify the insurance carrier as to which person(s) will be covered under his or her enrollment; *see* also 5 CFR 890.1605(d)(2) ''The enrollee must affirmatively notify the PSHB Carrier, employing office, or OPM of any changes to members of family;'' and § 890.808(b)(4), ''The former spouse will be required to certify that he or she meets the requirements . . . and that he or she will notify the employing office within 31 days of an event that results in failure to meet one or more of the requirements.'').

OPM is correcting a typo in § 890.1606(e) by removing the word ''the'' before ''January 1 of the next year.'' This correction does not affect the PSHB Program or policy.

The changes outlined in this section do not affect OPM's estimation of the regulatory impact of the PSHB Program.

Regulatory Impact Analysis

A. Need for Regulatory Action

This final rule follows an interim final rule implementing sections 101 and 102 of the PSRA, which direct OPM to establish the PSHB Program for Postal Service employees, annuitants, and their eligible family members. These sections of the PSRA amend 5 U.S.C. chapter 89, which identifies: the individuals who, starting in January 2025, will be eligible to enroll in a PSHB plan and may not remain in an FEHB plan under their Postal Service employment or retirement; those who must enroll in Medicare Part B to maintain enrollment in PSHB; the health benefits plans that should be offered to the greatest extent practicable; PSHB plan requirements; the need for automatic enrollment in certain circumstances; contributions by the Postal Service; how reserves for PSHB plans are to be structured; requirements for information sharing; and other requirements necessary for PSHB Program implementation.

The PSHB Program is contained within chapter 89, which governs the FEHB Program generally. The PSRA confirms that PSHB plans are subject to the same provisions as FEHB plans unless they are inconsistent with the PSRA. OPM is given the discretion to make such determinations.

Section 101 of the PSRA, codified at 5 U.S.C. 8903c, directs OPM to issue regulations establishing the PSHB Program and gives OPM the discretion to include ''any provisions necessary to implement this section.'' Section 8903c(g) addresses the topics for which Congress specifically instructed OPM to promulgate rules, clarifies how existing rules for the FEHB Program will apply to the PSHB Program, and provides new requirements regarding eligibility and enrollment, information sharing with other agencies, PSHB Carrier requirements, and other rules that will govern the PSHB Program. This rule finalizes the provisions of the interim final rule and provides transparency into how OPM is implementing the PSRA, memorializes processes and procedures that will apply, and give individuals who will be impacted as much information about the PSHB Program as early as possible.

B. Summary of Impacts

Overall, the PSRA and the PSHB Program, through this final rule, promote the financial stability and long-term viability of the Postal Service, which provides a crucial role for society with respect to communication, commerce, and political participation. The Postal Service was established as a basic and fundamental service for the public to provide prompt, reliable, and efficient nationwide postal services, including mail and package delivery. With the Postal Service's wide reach in providing essential services to nearly everyone in the U.S. in some form, its long-term stability is crucial. The PSRA helps improve the Postal Service's financial position. Ultimately, a financially sustainable Postal Service ensures that it can continue to fulfill its universal service mission and make the investments needed to support service excellence and network efficiency and to introduce enhanced products and services for its customers.

This societal benefit will result primarily from the removal of the prefunding obligation related to future retiree health benefits and the shifting of insurance coverage costs away from the Postal Service to Medicare, and ultimately to taxpayers, who together with beneficiaries, fund Medicare. The Postal Service is generally self-funded, and the Postal Service, along with its employees, pay taxes to fund Medicare each year, but many of its employees do not enroll in Medicare after they retire. Therefore, unlike other employers who offer retiree health benefits and pay Medicare taxes, the Postal Service has not been able to ensure that its retiree health care program fully utilizes Medicare. Enabling the Postal Service to generally require its annuitants who are entitled to Medicare Part A to enroll in Medicare Part B when eligible ensures that the Postal Service can utilize Medicare in a similar manner as other employers, which strengthens its financial position and therefore its ability to continue its critical public service mission.

From a societal perspective, the primary costs associated with the implementation of the PSHB Program will be administrative and operational costs necessary to initiate and maintain the program, including development of information technology (IT) systems, education and outreach, and additional administrative staffing for the design, maintenance, and oversight of the increased quantity of health plans. These costs will be largest in the initial start-up phase and will be borne by Federal agencies, as well as carriers offering both FEHB plans and PSHB plans. The PSRA appropriated $94 million in implementation funding for OPM and other Federal agencies for these administrative and operational costs. Pursuant to section 101(d)(4) of the PSRA, the Postal Service deposited the appropriated funds into the Treasury as a miscellaneous receipt from the Postal Service Fund in fiscal year 2022.

Most of the impact from the PSRA and this regulation will occur via distributional effects. The principal transfer will be the shifting of premium costs from the Postal Service and PSHB members to Medicare as a result of the Medicare Part B enrollment requirements and the integration of Medicare Part D coverage into PSHB plans. This Part D integration could also result in a portion of costs being transferred to the pharmaceutical industry via the statutory manufacturer discounts provided to Part D, in conjunction with discounts negotiated with individual FEHB plans. Further, integrating Part D coverage into PSHB plans may result in a transfer of costs to carriers, particularly those with little Medicare experience, who may need to contract with third-party vendors to assist with integration, increasing administrative costs. The segmentation of the current FEHB risk pool will result in premiums reflective of each separate risk pool's health care utilization and costs, which are estimated to be higher for Postal Service enrollees compared with non-postal.[10] This may result in a slight reduction in FEHB premiums following implementation.

Ultimately, the total costs and benefits associated with the PSRA and this final rule are highly uncertain because enrollee and carrier reactions to the effects on Medicare, the FEHB Program, and the new PSHB Program are unknown. In accordance with Office of Management and Budget (OMB) Circular A–4, the following sections outline the benefits, costs, and transfers associated with section 101 of the PSRA and this final rule in more detail. Where specific costs were quantifiable, they are included in table 1. As described below, the rule is expected to result in estimated average annualized costs of $50.6 million at a 3% discount rate and $50.2 million at a 7% discount rate over the eleven-year period of 2022–2032. In addition, the rule is expected to result in estimated average annualized net transfers from the Postal Service to Medicare of $347 million at a 3% discount rate and $343.3 million at a 7% discount rate over the eight-year period of 2025–2032.

C. Regulatory Baseline

The regulatory baseline for the final rule is the FEHB Program as it is currently administered, as the eligible population under both programs will largely remain the same. Postal Service employees, Postal Service annuitants, and their eligible family members are currently eligible for FEHB coverage. This population totals approximately 915,000 enrollees and 1.9 million total covered lives. There are nearly 700,000 Postal Service annuitants, including about 123,000 survivor annuitants. Of the Postal Service annuitants, about 500,000 are currently enrolled in the FEHB Program. A majority of these are Self-Only enrollments while 200,000 are Self Plus One or Self and Family enrollments.

Beginning in the 2025 plan year, the PSHB Program will be the only health benefits program available through the Postal Service to Postal Service employees, Postal Service annuitants, and their eligible family members. Unless they meet a specified exception, as previously outlined, Postal Service Medicare covered annuitants and their Medicare covered members of family will be required to enroll in Part B or will risk losing their eligibility to continue enrollment in the PSHB Program. Once an annuitant loses eligibility for enrollment in PSHB, it cannot be reinstated. As with the regulatory baseline, those covered by a PSHB plan will also be responsible for Medicare premiums.

Currently, Postal Service annuitants and their family members who are participating in FEHB are not required to enroll in Medicare Part B, regardless of Medicare eligibility status. Based on 2021 data, OPM estimates that 75% of Postal Service annuitants aged 65 and over have enrolled in Medicare Part B. There will be approximately 121,000 Postal Service annuitants and their eligible family members eligible to enroll in Part B during the six-month SEP beginning April 1, 2024.

Prior to the PSRA, the Postal Service paid the Government contribution for all Postal Service employees and annuitants enrolled in FEHB. The Government contribution was paid directly by the Postal Service for employees and from the PSRHBF for annuitants. In addition, the Postal Service was required under the Postal Accountability and Enhancement Act of 2006 to fully prefund retiree health benefits. Section 102 of the PSRA (''The USPS Fairness Act'') amended 5 U.S.C. 8909a to remove this prefunding requirement and replace it with a new calculation for annual payments into the PSRHBF beginning in 2026. The law maintains the requirement that the Postal Service continue to pay the Government contribution—directly for employees or through the PSRHBF for annuitants. The Postal Service is also required to pay the Medicare Part B late enrollment penalty for any Medicare covered annuitants and members of family who enroll in Part B during the 2024 SEP. As with the regulatory baseline, there is no Government contribution towards Part B premiums.

Carriers that participate in the PSHB Program will generally be subject to the same minimum requirements for plan design that exist for FEHB plans under the FEHB Program, but PSHB plans will be required to integrate Part D prescription drug benefits for Postal Service Medicare covered annuitants and Medicare covered members of family. In addition, carriers that are offering both PSHB plans and FEHB plans will need to offer equivalent benefits and cost sharing in the initial year, other than as needed to integrate Part D coverage.

D. Benefits of Regulatory Action and Implementation

The interim final rule implemented the requirements of the PSRA. That rule built on the statute by offering clarity and efficient implementation. The timely promulgation of the interim final rule allowed other Federal agencies, PSHB Carriers, and enrollees to begin necessary education and deliberation. This final rule corrects a typographic error in the interim final rule and clarifies some exceptions to the Medicare Part B enrollment requirement.

The Postal Service will benefit from fewer costs because of the removal of the past-due pre-funding payments and future pre-funding obligations related to the retiree health benefits costs and from having a retiree health benefits program in which more annuitants are

[10] *H.R. 3076, Postal Service Reform Act of 2021—Cost Estimate,* Congressional Budget Office (CBO) (2021). *https://www.cbo.gov/system/files/2021-07/hr3076.pdf.*

enrolled in Medicare. With fewer costs for retiree health benefits, the Postal Service will be better positioned to improve its financial stability. A more financially stable Postal Service would benefit the country overall. The Postal Service plays a critical role in the nation's communications, commerce, and voting infrastructure. In rural and remote communities especially, many of which lack adequate broadband access and rely heavily on mail service, the Postal Service's universal service mandate ensures crucial access to essentials including medicine and food.[11]

Within these communities, the Postal Service is often the only delivery service carrier with a door-to-door network and is heavily relied on by other delivery service carriers to provide ''last mile'' deliveries. According to the Postal Service Office of Inspector General, the Postal Service provided vital services during the COVID–19 pandemic, including the delivery of critical items such as medications, stimulus payments, election ballots, and record levels of home package deliveries.[12] A Government Accountability Office Report found that the Postal Service experienced a 9 percent decline in total mail volume in 2020 when compared to 2019, but package volume rose by 32 percent over the same period.[13] This underscores the importance of a stable Postal Service to the Nation.

With greater financial stability for the Postal Service, current Postal Service employees, Postal Service annuitants, and their family members will also see greater stability in their future health insurance coverage and other benefits.

Medicare covered annuitants may be eligible, depending on whether they meet statutory income and resource thresholds, for the low-income cost-sharing subsidies and premium subsidies that are part of the Medicare part D program, under section 1860D–14 of the Social Security Act.

E. Costs of Regulatory Action and Implementation

Implementation of the PSRA and this final rule necessitates the administration and oversight of new health benefits plans, including substantial member education and outreach efforts, additional interagency coordination and the creation of new IT processes to satisfy new statutory eligibility and enrollment requirements, creating startup and ongoing costs to agencies, enrollees, and carriers. Table 1 summarizes the assessment of the administrative costs associated with this regulatory action.

This table illustrates OPM's best estimate of costs, including startup and ongoing maintenance costs given the information available from OPM and other agencies at this time. The costs are still subject to modification as the program implementation continues. For the purposes of this regulatory impact assessment (RIA), *Startup Costs* were defined as upfront, non-recurring costs associated with the PSRA implementation, including regulatory review costs, and are represented as aggregate total expenditures for the years leading up to and immediately following the PSHB implementation. *Ongoing Costs* were defined as recurring costs (*e.g.,* salary costs) beginning in the years preceding or immediately following the PSRA implementation and expected to persist through at least FY2032. All ongoing costs are presented as fully loaded, annual totals. Given that onboarding and development will occur during the run-up period, ongoing costs are expected to gradually ramp up between FY2022–FY2025 and become fully loaded by the beginning of FY2026. These estimates for ongoing costs are preliminary, and funding for ongoing costs would be subject to the annual budget process.

TABLE 1—ESTIMATED ADMINISTRATIVE AND IMPLEMENTATION COSTS ASSOCIATED WITH THIS FINAL RULE

Agency/category	Startup costs	Ongoing costs [1]
OPM [2]	$81,680,944	$49,315,703
Personnel	.....	24,434,476
IT and IT Contracts	68,307,195	20,961,759
Non-IT Contracts	3,600,000	1,735,695
General (Supplies, Equipment, Communications, Training)	9,773,749	2,183,773
Postal Service	11,500,000	1,425,000
Implementation costs (updating systems, developing training materials, etc.)	11,500,000	.....
Personnel (4 Program and 2 IT full-time employees (FTEs))	.....	$925,000
Communications	.....	500,000
Department of Labor	72,500	2,000
Training and Communication	72,500	.....
Additional support and communication for separate Open Season	.....	2,000
Department of Veterans Affairs	395,000	.....
IT Contracts	395,000	.....
Social Security Administration	7,327,764	407,881
Staffing and Overhead	5,161,138	407,881
System Updates	2,166,626	.....
Ongoing Data Exchange	.....	TBD
Indian Health Service	.....	.....
Carriers	Unknown	Unknown
Total Known Administrative and Implementation Costs	100,976,208	51,150,584

[1] Ongoing costs represented as fully loaded annual costs beginning in FY2026 and remaining consistent through at least FY2032. Given that development and onboarding will occur during run-up period to PSHB implementation, ongoing costs will likely cross multiple fiscal periods and gradually ramp up between FY2022 and FY2025, although all costs are expected to become fully realized beginning in FY2026. All costs are represented based on 2022 dollars and pay scales and are subject to change based on PSHB enrollment and carrier participation following implementation.

[11] *The USPS and Rural America,* Institute for Policy Studies (2020), *https://inequality.org/wp-content/uploads/2020/04/IPS-policy-brief-USPS-Rural-America2.pdf.*

[12] *Audit Report Mail Service During the Early Stages of the COVID–19 Pandemic,* USPS Office of Inspector General (Jan. 2021), *https://www.uspsoig.gov/document/mail-service-during-early-stages-covid-19-pandemic.*

[13] *U.S. Postal Service: Volume, Performance, and Financial Changes since the Onset of the COVID–19 Pandemic,* Government Accountability Office Publication 21–261 (2021), *https://www.gao.gov/products/gao-21-261.*

[2] Table 1 does not utilize estimates from OPM's FY 2025 Congressional Budget Justification (CBJ). The FY 2025 CBJ estimates would reflect $80.1 million startup and $51.7 million ongoing costs.

Table 2 depicts the projected allocation of total startup and ongoing costs by year for fiscal years (FY) 2022 through 2032. Given that operations and maintenance activities are occurring in the run-up period, albeit at a different intensity, and a portion of start-up costs were allocated for go-live and post go-live support (*e.g.,* call centers), the expected costs for FY2022–FY2025 are composed of both startup and ongoing costs. Beginning in FY2026, expected costs are all attributable to recurring operational and maintenance activities.

TABLE 2—PROJECTED TOTAL ADMINISTRATIVE AND IMPLEMENTATION COSTS BY YEAR—ALL AGENCIES, FY2022–2032
[$ Millions]

Type of Cost [1]	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031	FY2032
Startup Costs	$3.68	$48.49	$46.74	$2.06	.....	.....	.....	.....	.....	.....	.....
Recurring Costs	3.69	17.98	28.39	50.47	51.15	51.15	51.15	51.15	51.15	51.15	51.15
Total Costs	7.38	66.47	75.14	52.53	51.15	51.15	51.15	51.15	51.15	51.15	51.15

[1] Annual cost projections are in terms of 2022 dollars and pay scales and *do not* reflect any adjustments for inflation, discounting, staffing promotions, etc. This table is intended only to summarize the expected timing of the costs outlined in table 1 and is not meant to reflect budgetary expectations.

Detailed Startup and Ongoing Cost Related to the PSRA

The following sections contain underlying details for the cost estimates presented in table 1, including, where appropriate, the assumptions and methodology used by individual agencies in preparing them. For the purposes of this regulatory impact assessment (RIA), *Startup Costs* were defined as upfront, non-recurring costs associated with the PSRA implementation, including regulatory review costs, and are represented as aggregate total expenditures for the years leading up to and immediately following the PSHB implementation. *Ongoing Costs* were defined as recurring costs (*e.g.,* salary costs) beginning in the years preceding or immediately following the PSRA implementation and expected to persist through at least FY2032. All ongoing costs are presented as fully loaded, annual totals. These estimates for ongoing costs are preliminary, and funding for ongoing costs would be subject to the annual budget process.

OPM

Startup Costs: OPM estimates a total of $81.6 million in start-up costs for the development and administration of the PSHB Program. This estimate includes $68.3 million of IT and IT contract costs for system development and updates, including the creation of the centralized enrollment system. The centralized enrollment system will consolidate data from multiple agencies, including the Postal Service, SSA, CMS, IHS, and VA, to create a centralized platform for verifying eligibility and processing enrollments. While a centralized enrollment system was not mandated by the PSRA, it will create efficiencies through the elimination of decentralized duplicative and manual processes and improve interagency communication. It is expected to yield long term cost-savings that will help offset significant upfront costs of development. Additional IT and IT contract costs are anticipated for updating existing systems, including Benefits Plus and the audit resolution tracking system, and developing new resources to improve customer experience, including the creation of an enrollment Decision Support Tool.

The remaining $13.4 million in estimated startup costs include $3.6 million for non-IT contractor support and regulatory review throughout implementation and $9.8 million for additional supplies, equipment, training, and communication related to the PSRA. All costs were estimated based on 2022 dollars and contract rates.

Ongoing Costs: As this is a new program, additional staffing and resources will be essential to establish and administer the PSHB. OPM estimates a total of $49.3 million in annual, ongoing costs related to the PSRA. This estimate consists of $24.4 million in annual salary costs for additional full-time employees (FTEs) necessary for contract oversight, program operations, systems maintenance, customer service, policy support, and general support. Additionally, OPM anticipates $21 million in annual IT and IT contract costs for ongoing system development and maintenance support, and an additional $1.7 million in annual, non-IT contract costs related to oversight and management of the increased number of health benefits plans within the PSHB and FEHB populations. Finally, OPM estimates an additional $2.2 million in annual costs for training, communications and overhead related to the PSHB program and the annual Open Season period.

The above costs are represented as fully loaded annual projections based on 2022 dollars. Salaries and overhead (benefits, equipment, etc.) were based on 2022 pay tables and Washington, DC metro area locality adjustment, an overhead percentage of 34%, and award and transit subsidies. This adjustment factor was used in lieu of a standard wage rate to more accurately reflect the historical trends in benefit costs for OPM employees, based on the anticipated locations and experience-levels of the aforementioned positions. Additionally, the wage rate is meant to capture overhead costs which were already represented in separate categories. All recurring costs are projected to be fully loaded beginning in FY2025 and to persist through at least FY2032. Given that development and onboarding will occur in the run-up to the PSHB implementation, OPM anticipates that annual costs related to the PSRA will increase steadily between FY2022 and FY2024.

Postal Service

Startup Costs: The Postal Service estimates $11.5 million in start-up costs for updating systems, development of training materials, and the development and maintenance of the Health Benefits Education Program. These estimates were calculated based on anticipated system configuration and assumed effort level and are subject to change based on additional requirements that may be required of the Postal Service.

Ongoing Costs: In preparation for and following implementation of the PSHB, the Postal Service estimates an additional $1.4 million in annual costs for increased staffing and communication needs. Specifically, the Postal Service estimates $0.9 million in

salary costs for 6 additional FTEs, including 4 Program and 2 IT FTEs, and an additional $0.5 million towards increased outreach, education, and communication. Given the general retirement eligibility ages in comparison to the Medicare eligibility age, there will be a 3- to-5-year gap between the time of retirement until Medicare enrollment. It will be critical during the initial implementation of the Program and for the subsequent 5–10 years to send constant communications regarding plan options and healthcare costs, along with information about Medicare Part B eligibility periods and how and when to enroll. Additional resources will also be needed to monitor enrollee compliance for the Medicare Part B enrollment exceptions requirements on an ongoing basis. Although recruitment, onboarding, and development costs will gradually ramp up preceding implementation, the ongoing costs are expected to become fully realized beginning in FY25 and will likely persist for a period of 5–10 years following implementation, at which point the Postal Service will reevaluate resourcing needs. All costs were estimated in terms of 2022 dollars and pay scales.

Department of Labor—Office of Workers' Compensation Programs (OWCP)

Startup Costs: OWCP estimates a total of $72,500 in startup costs related to the PSRA. These include an estimated $50,000 in staff time for training on the PSRA changes and implementation, and $22,500 for pre- and post-implementation mailings to approximately 12,500 claimants and beneficiaries regarding changes to health benefit coverage. All costs were estimated based on 2022 dollars and pay scales.

Ongoing Costs: Beginning in 2025, OWCP estimates an additional $2,000 of annual, recurring costs for the creation and distribution of mailing announcements and customer service response letters related to the PSHB Open Season.

Department of Veterans Affairs (VA)

Startup Costs: The VA anticipates startup costs for system updates and development to meet the information sharing requirements outlined in § 890.1612 of the regulation. In total, the VA estimates $395,000 worth of IT contractor development work will be needed to integrate the existing Veteran Verification process with the centralized Enrollment and Eligibility System. The estimated costs are based on the anticipated number of scrum teams and sprints required to build this functionality and the projected firm-fixed-price contract rates. All costs were estimated in 2022 dollars.

Social Security Administration (SSA)

Startup Costs: SSA estimates $7.3 million in startup costs for staffing support and system updates related to the PSHB implementation. These include an estimated $5.16 million in staffing costs for project management, policy and business process development, and additional technician support for the initial SEP. Additionally, SSA anticipates $2.17 million in up-front costs for system enhancements that will be necessary to support data exchanges and the initial SEP.

Ongoing Costs: SSA anticipates approximately 3 FTEs will be needed to support the PSHB following implementation, with estimated salary and overhead costs totaling $408,000 annually. These costs are based on the anticipated workload for processing annual enrollments and exceptions related to the Medicare coverage requirements for postal annuitants and family members. Additionally, SSA anticipates a small cost for the ongoing data exchange with OPM, although this cost cannot be determined until the data exchange is completed and will ultimately be reimbursed by OPM.

Indian Health Service

Indian Health Service (IHS) estimates de minimis costs for PSHB implementation. This is based upon the assumption that self-attestation will be utilized for Postal Service annuitants and family members to provide proof of eligibility for IHS health services for purposes of an exception to the Medicare Part B requirement.

Carriers (Not Quantified)

Carriers will also have startup costs to participate in the PSHB Program, although the magnitude of these costs is unknown and will likely vary by carrier. Based on the 2021 FEHB headcount, OPM estimates that 41 FEHB Carriers provide coverage to Postal Service enrollees, and they will therefore be impacted by implementation of the PSHB Program. OPM has received applications for participation in the PSHB Program from 36 carriers, all of which currently participate in the FEHB Program. These carriers are expected to incur additional costs associated with the creation and administration of separate PSHB plans. These costs will likely be incurred for internal training, updating enrollment processes and information systems, updating financial systems, and development of proposals specific to the PSHB Program.

In developing plan options for the PSHB, carriers will not simply be able to duplicate FEHB plan designs as the requirement to integrate Part D coverage is substantively different. While large carriers may be able to leverage existing experience integrating Medicare Part D coverage in their other books of business, the need to apply and submit a different PSHB proposal will be a cost to carriers. PSHB Carriers will continue to incur annual costs to offer plans as there will need to be two sets of proposals, contract negotiations, and enrollment processing for carriers offering both PSHB and FEHB plans. This will likely create additional staffing costs on an ongoing basis.

Postal Service Annuitants (Not Quantified)

Existing and future Postal Service annuitants may incur additional costs in navigating both Medicare and PSHB enrollment decisions, particularly in the initial years following implementation. Prior to the PSHB Program Open Season, a six-month SEP will be offered to provide Postal Service annuitants and their family members who are entitled to Medicare Part A with the opportunity to enroll in Medicare Part B. This enrollment window will take place before PSHB benefits and premiums are set, meaning participants will not know the details of the PSHB premiums when making their Medicare election during the SEP. This could create additional burden and confusion for participants and may result in suboptimal enrollment decisions.

As with the training and communications costs for the first year, Postal Service employees may continue to need training as they approach retirement. They may generally experience new costs associated with interacting with a new set of options, especially if they have already planned to take certain actions upon retirement which are now infeasible under the PSRA. Additionally, as is true currently under FEHB, retirement will not be a PSHB qualifying life event. Postal Service annuitants will need to understand how their PSHB plan election will work with the Part B requirement upon retirement or wait for Open Season alignment in both Medicare and the PSHB to make a suitable choice for their health care insurance needs.

Transfers

The main impact of section 101 of the PSRA and these rules will be a transfer of costs from the Postal Service to

Medicare, which is funded by taxpayers, including the Postal Service and its beneficiaries. Additionally, a portion of prescription drug costs will likely be transferred to pharmaceutical manufacturers due to applicable point-of-sale discounts received by Medicare Part D enrollees. Table 3 summarizes the projected changes in annual premium expenditures for each of the primary stakeholders. These projections were obtained from separate, independent analyses performed by CMS, the Postal Service, and OPM, which were produced at different points in time and with different underlying methods and assumptions and are therefore intended to summarize the directional transfer of costs among the different stakeholders, not the overall budgetary impacts of the PSRA. Additionally, all estimates were based on FEHB and Medicare coverage as of 2023, and do not incorporate any changes expected from the Inflation Reduction Act or Carrier Letter 2023–02.[14] Details on the methods and assumptions utilized by each agency are provided in the table 3 footnotes.

TABLE 3—NET TRANSFER EFFECTS

Agency/Outlay	Projected Change in Annual Coverage Costs Due to PSRA ($ Billions)												
	FY22	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	FY23–27	FY23–32
CMS[1]	0.00	0.00	0.00	0.50	0.76	0.92	1.11	1.16	1.35	1.53	1.73	2.18	9.06
Part B, net of premium[a]	0.00	0.00	0.00	0.09	0.18	0.24	0.31	0.39	0.47	0.57	0.68	0.51	2.93
Part D, net of premium and clawback[b]	0.00	0.00	0.00	0.41	0.58	0.68	0.80	0.77	0.88	0.96	1.05	1.67	6.13
USPS[2]	0.00	0.00	0.00	−0.30	−0.30	−0.30	−0.30	−0.40	−0.40	−0.40	−0.40	−0.90	−2.80
USPS share of employee premiums	0.00	0.00	0.00	−0.30	−0.30	−0.30	−0.30	−0.40	−0.40	−0.40	−0.40	−0.90	−2.80
PSRHBF Annuitant Premiums[3]	0.00	0.00	0.00	−0.17	−0.23	−0.29	−0.36	−0.45	−0.49	−0.53	−0.58	−0.69	−3.10
PSRHBF Share of Annuitant Premiums	0.00	0.00	0.00	−0.17	−0.23	−0.29	−0.36	−0.45	−0.49	−0.53	−0.58	−0.69	−3.10
FEHB and Federal Share USPS Premiums[3]	0.00	0.00	0.00	−0.09	−0.09	−0.10	−0.10	−0.10	−0.11	−0.11	−0.12	−0.28	−0.83
Payments for NP annuitant premiums	0.00	0.00	0.00	−0.06	−0.07	−0.07	−0.07	−0.08	−0.08	−0.09	−0.09	−0.20	−0.61
Federal Share of USPS Annuitant Premiums	0.00	0.00	0.00	−0.03	−0.03	−0.03	−0.03	−0.03	−0.03	−0.03	−0.03	−0.08	−0.21
Employee and Annuitant Share of Premiums	0.00	0.00	0.00	−0.26	−0.26	−0.25	−0.25	−0.25	−0.25	−0.24	−0.23	−0.76	−1.98
Postal employee share PSHB premiums[2]	0.00	0.00	0.00	−0.10	−0.11	−0.12	−0.13	−0.14	−0.15	−0.16	−0.17	−0.34	−1.09
Postal annuitants share PSHB premiums[2]	0.00	0.00	0.00	−0.11	−0.12	−0.14	−0.15	−0.16	−0.17	−0.18	−0.19	−0.37	−1.22
Non-Postal employee share FEHB premiums[3]	0.00	0.00	0.00	−0.04	−0.04	−0.04	−0.04	−0.05	−0.05	−0.05	−0.05	−0.12	−0.36
Non-Postal annuitant share FEHB premiums[3]	0.00	0.00	0.00	−0.03	−0.03	−0.03	−0.03	−0.04	−0.04	−0.04	−0.04	−0.09	−0.28
Postal annuitant premiums for Medicare B[1a]	0.00	0.00	0.00	0.03	0.05	0.08	0.11	0.13	0.16	0.19	0.23	0.16	0.98

The estimated costs in this table were aggregated from multiple, independent analyses conducted by separate agencies, and are intended only to represent the directional flow of costs between various stakeholders. Due to the differences in assumptions and methodology employed by each agency (as detailed below), the cumulative impacts represented in this table do not directly align with the general expectation, as detailed in the narrative below, that aggregate premium payments will be lower post-PSRA due to the transfer of costs to drug manufacturers via mandatory Part D discounts. All estimates are based on coverage provisions as of 2023 and *do not* reflect expected changes to pharmaceutical coverage from the Inflation Reduction Act or Carrier Letter Number 2023–04, the 2023 FEHB Call Letter.

Sources and methodology:

[1] Projected Medicare costs for additional Part B and Part D enrollment were provided by CMS.

[a] Part B projections were based on an assumption that about 7,000 new retirees plus spouses would enroll in Part B in 2025, and growth would be consistent with aged enrollment. Additionally, CMS assumed that roughly 14,000 existing retirees would enroll in 2025, which would degrade over time due to deaths. Expected costs and premiums for additional enrollees were assumed to be consistent with current average Part B beneficiaries.

[b] CMS estimated additional Part D costs based on projected annual headcounts of Postal Service annuitants. Annual headcounts were estimated using the 2021 Postal Service annuitant enrollment total (approximately 515,000) and applying an annual growth rate based on the number of new postal retirees in 2021. Growth estimates were trended by the projected annual growth in overall Part A and/or Part B enrollment and were decremented yearly by the annual mortality rates from SSA for ages 70–75. Using this methodology, CMS estimated that approximately 603,000 postal retirees would join Part D in 2025 and that this population would grow to 797,000 by 2032. To project annual Part D spending on Postal retirees, CMS assumed a 90/10 split between PDP–EGWP and MAPD–EGWP, and annual costs consistent with current beneficiaries in each of these enrollment categories.

[2] Based on estimates provided by USPS actuaries and budget analysts. Projected savings on PSHB premiums are based on the expected reduction in the portion of retirees' medical costs that will be paid by PSHB plans, which is expected to lower overall costs in the combined pool of annuitants and employees and reduce premiums. USPS assumed that 30% of grandfathered annuitants would enroll in Part B during the SEP, resulting in 30,000 new enrollments in 2025. Annual projections for current and annuitant Postal enrollee populations were based on mortality and retirement projections for the postal population, which were developed by OPM.

[3] Estimates from OPM Office of Administration (OA) Budget Summary as of January 2023. Assumed 30% of grandfathered annuitants and family members would join during SEP and stable population of total annuitants from 2025–2032 (annual new retirees + family members ≈ deaths in Postal annuitant population). Differential costs of FEHB and PSHB population was estimated using age distribution in the two populations, which skews slightly higher for Postal, and historical average costs by age band for the joint FEHB population. OA estimates a 5.8% reduction in average PSHB premiums beginning in 2025, which is attributed to the Part B and Part D requirements, and a 0.4% reduction in average FEHB premiums. Annual projections assumed a 4.8% medical inflation rate.

The mandatory Medicare Part B enrollment for all future Postal Service Medicare covered annuitants enrolled in PSHB starting in 2025, as well as the optional Part B enrollment for current annuitants who are entitled to Part A, will shift a portion of Government share of premium costs for these individuals away from the Postal Service and will shift some of their healthcare costs to Medicare.

Medicare Part B enrollment and the shift of healthcare costs to Medicare will lower the aggregate costs among the PSHB population as Medicare will cover a larger portion of healthcare costs for Postal Service annuitants and family members that would have previously been covered by a plan. Given that premiums are based on average per member costs of the combined pool of

[14] FEHB Program Carrier Letter Number 2023–02, *FEHB and Medicare Part D Prescription Drug Coordination* (published January 25, 2023), available at *https://www.opm.gov/healthcare-insurance/carriers/fehb/2023/2023-02.pdf.*

annuitants and employees, this will likely result in lower premiums for PSHB plans compared to current FEHB premium amounts. This will reduce costs for the Postal Service and Postal Service employees. Currently in FEHB, approximately 75% of retirees from the Postal Service are enrolled in Medicare Part B and pay the Part B premium. Some of the 25% of the retirees from the Postal Service without Medicare Part B may decide to enroll in Part B to coordinate with their PSHB coverage that starts in 2025. Those individuals and their family members will incur an increased cost for Part B premium that they otherwise would not incur if the retiree chose not to enroll in Part B. Because these individuals will ultimately be subject to premiums for both Medicare and PSHB plans, on net their premiums may be higher than FEHB premiums. At the same time, being covered by Medicare in conjunction with a PSHB plan may also reduce out-of-pocket expenses (*e.g.,* co-payments and co-insurance) for Postal Service annuitants compared to those that would otherwise have been incurred. In addition, because Medicare will pay primary for the costs of medical coverage, for those enrolled in Part B, costs of coverage are expected to be lower for the PSHB Program and could result in lower PSHB premiums than they would have been without the integration of Medicare. Furthermore, we anticipate that some PSHB plans will reimburse all or part of Part B premiums, as is currently the case with some FEHB plans.

As required in the PSRA, the Postal Service will need to pay to HHS the monthly late enrollment penalties for any Medicare Part B enrollments that occur during the 2024 SEP. These late enrollment penalties are assessed to enrollees as a monthly increase in Medicare Part B premiums. We estimate that approximately 100,000 Postal Service annuitant aged 65+ currently enrolled in the FEHB Program are not enrolled in Medicare Part B and, thus, would be eligible for the SEP. For these individuals, the late enrollment penalties will be paid by the Postal Service.

Uncertainty and Directional Effects Related to Enrollment, Utilization, and Carrier Participation

The summary above is based on baseline assumptions that plan enrollment, carrier participation, and healthcare utilization will remain consistent following implementation of the PSHB Program. It is likely that implementation of the PSHB Program and the additional Medicare enrollment requirements will impact some or all of these baseline assumptions, which will have downstream effects for cost and utilization within both the PSHB and FEHB populations. The magnitude and directionality of these effects will depend on several factors that are presently uncertain.

Individual carriers will likely weigh the costs and benefits of offering FEHB plans and PSHB plans. Shifting enrollment numbers and additional implementation costs may lead some carriers to scale back or discontinue offering both FEHB and PSHB plans. This would impact the number of available plan options for both PSHB and FEHB enrollees, as well as the likelihood that enrollees will be able to remain enrolled in a plan with the same carrier and have a consistent choice of plans and options from year to year. However, as noted below, it is likely that the PSRA will increase the total number of plans covering the Postal Service and non-Postal Service population notwithstanding that plan choices for each population may vary.

PSHB enrollees required to enroll in Medicare Part B would be subject to additional premiums, which may impact the likelihood of their enrollment in PSHB plans. It is estimated that around 25% of Postal Service annuitants who are otherwise eligible for Part B are not currently enrolled. It is possible they declined Part B coverage because they were satisfied with their FEHB coverage or felt that the additional Medicare premium costs were too high, although it is also possible that they were not fully aware of the benefits of Medicare enrollment on their overall health care expenses over the course of their lifetimes. Assuming that a similar percentage of future Postal Service annuitants would have made a similar determination, these individuals may now be required to enroll as a condition of PSHB eligibility. This may result in some Postal Service annuitants dropping PSHB coverage altogether if they determine that PSHB and Part B coverage together is unaffordable or duplicative for their health care circumstances, though this number may be limited since it would require those annuitants to forgo PSHB coverage for the rest of their lifetimes unless individuals enroll in a Medicare Advantage plan. This could potentially result in adverse selection within the PSHB plans, referring to the tendency for individuals with higher health risks to disproportionately elect more generous coverage. Ultimately, this would increase the average risk and costs within the PSHB enrolled population, creating upward pressure on premiums. Additionally, some carriers may elect not to offer or discontinue PSHB plans if they anticipate or experience lower than expected enrollment.

The additional Medicare Part B and Part D coverage may also induce a moral hazard effect due to the more robust coverage and lower cost-sharing. Moral hazard refers to the tendency of individuals to increase health care utilization and spending in response to greater coverage or lower out-of-pocket costs. If an individual is required to enroll in Medicare, they may feel more compelled to utilize the benefits, increasing overall health care consumption. This effect could increase utilization of both necessary and unnecessary health services upon introduction of increased coverage and lower cost sharing. Increased utilization among these individuals would increase the overall per member costs within the PSHB plans which may result in higher premiums and potentially impact health outcomes.

Because not all carriers will offer both FEHB plans and PSHB plans, the result is smaller risk pools within each plan option, which could lead to greater uncertainty with respect to costs. With smaller risk pools, each enrollee's health status has a larger impact on total costs. This can create greater variability in annual premiums. Smaller risk pools increase individual plans' exposure to high-cost outlier events, as there are fewer low or average-cost enrollees to offset these costs. Administrative costs would also be spread across smaller risk pools. To ensure financial solvency in such scenarios, plans may seek to price this additional risk exposure into premiums, resulting in an increase in the aggregate costs for all PSHB plan and FEHB plan enrollees compared to the baseline.

At present, there remains a great deal of uncertainty with respect to the longer-term impacts on plan enrollment, carrier participation, plan design, and plan premiums. It is possible that a number of FEHB Carriers will elect not to participate in the PSHB Program or to drop their current FEHB plan offerings. Consolidation within the FEHB and PSHB markets would likely benefit larger carriers and may yield some efficiencies through greater economies of scale, although on aggregate, it is expected that PSHB implementation will result in a greater number of total plans across both the FEHB and PSHB Programs and increased administrative costs and premiums. Fewer options within the PSHB Program may also simplify plan choice for employees and

annuitants, saving time on plan comparisons.

Enrollment in the PSHB Program, particularly among individuals who are required to enroll in Medicare Part B, is also uncertain. For future Postal Service annuitants, the requirement to enroll in Part B after retirement represents an additional cost. This will likely factor into individual retirement planning decisions and could potentially lead to employees remaining in the workforce longer to delay these additional costs. Likewise, lower-risk individuals may determine that their Medicare coverage, including Part B coverage is sufficient for their health care needs and opt out of PSHB enrollment. These aspects could impact PSHB Program risk pools and influence carriers' decisions on whether to continue offering plans in the PSHB Program. Each of these scenarios could trigger potential downstream effects on utilization and premiums and will be important to monitor.

F. Alternatives

There are no feasible alternatives to the final rule as it implements section 8903c, as added by the PSRA, which establishes the PSHB Program and is mandated by the law. Therefore, OPM does not have the discretion to forego issuing regulations altogether. However, we considered alternatives to certain aspects of this regulation.

Initial Enrollment in the PSHB Program and Medicare Part B

OPM recognizes that, for a small portion of Postal Service annuitants and their family members who take advantage of the Medicare Part B SEP from April 1 to September 30, 2024, there may be confusion about having two separate health plan enrollment opportunities given that the PSHB Program Open Season for plan year 2025 will occur from November 11 through December 9, 2024. As with FEHB plans, however, OPM's rate review process for PSHB plans will not be completed until September 2024, which makes simultaneous enrollment in Medicare Part B and PSHB plans impossible. If OPM were to open PSHB plan enrollment at the same time as the Medicare SEP, without completing the PSHB rate review process, enrollees would be selecting PSHB plans without knowing the monthly cost of their PSHB plan premium, which does not resolve the conflict.

We explored an opportunity for Postal Service annuitants to ''pre-enroll'' in PSHB plans prior to OPM completing its PSHB rate review process. Combining the opportunity to pre-enroll in a PSHB plan with the Medicare SEP would allow Postal Service annuitants to complete both actions simultaneously. Alternatively, Postal Service annuitants could be automatically enrolled in a PSHB plan at the same time they enroll in Medicare Part B. Automatic pre-enrollment in PSHB would relieve these Postal Service annuitants from two separate enrollment periods. However, we found both of these options would be undesirable for enrollees and their family members for several reasons.

Allowing individuals to pre-enroll in PSHB plans during the SEP means they would sign up for a plan without knowing their PSHB premium obligation. Similarly, because OPM will not have certified the PSHB plans by the time the Medicare SEP occurs, there would be no way for an individual to know whether a given carrier will be participating in the PSHB Program for the next plan year, let alone what the final contract would look like. In general, while allowing those annuitants taking advantage of the Medicare SEP to simultaneously pre-enroll in a PSHB plan seems like it could reduce confusion and frustration from having two separate enrollment obligations, the timing of simultaneous PSHB pre-enrollment and the Medicare SEP would mean choosing a PSHB plan with unknown benefits and premiums and likely having to review the selection again during the PSHB Open Season period to ensure that the plan an individual pre-enrolled in actually makes sense for them once plan details are finalized and approved by OPM.

Much of the rationale for considering PSHB plan pre-enrollment can be achieved by providing information about automatic enrollment to Postal Service employees, Postal Service annuitants, and their family members. Postal Service annuitants who wish to keep their plan or take as little action as possible can have their needs met as easily with automatic enrollment after Open Season ends instead of OPM implementing a new pre-enrollment or automatic pre-enrollment. In addition, under 5 CFR 890.301(f)(2), the OPM Director has the authority to modify the dates for Open Season or hold additional Open Seasons. These authorities and flexibilities exist under current regulations and may be exercised without needing to make any specific provisions under this rulemaking.

Centralized Enrollment

OPM is developing a centralized enrollment system simultaneously with the implementation of the PSHB Program. As explained above, the centralized enrollment system will shift certain responsibilities from the employing office to a new system which will function as an electronic enrollment solution for all PSHB stakeholder groups. Developing a centralized enrollment system for the PSHB Program allows OPM to take advantage of IT solutions and create a modern enrollment system for Postal Service employees, Postal Service annuitants, and their family members. OPM considered maintaining the existing enrollment processes that apply to enrollment in FEHB plans but ultimately determined that the establishment of the PSHB provided an ideal opportunity to utilize new technologies and centralization processes that will improve the experience of PSHB stakeholders.

PSHB Plan Coverage Effective Date

OPM considered keeping the effective date of coverage for coverage under PSHB Plans as the first day of the first pay period of the calendar year for Postal Service employees, as it is for FEHB Plans. Keeping the same effective date of coverage for PSHB Plans as the effective date of coverage for FEHB Plans that Postal Service employees are familiar with would not result in implementation costs or risk confusing existing enrollees.

The benefits of a January 1 effective date, however, outweigh the costs and risks of implementation and educating enrollees, as implementation costs are incurred only one time and after several years there will be little to no ongoing enrollee education needs. Conversely, the benefits of the January 1 date will remain indefinitely. A calendar year start date is convenient and is consistent with the industry standard and many similar programs, including health savings accounts, the Federal Employees Dental and Vision Insurance Program, and the cutoff date for certain exceptions to the Medicare Part B enrollment requirement for Postal Service Medicare covered annuitants and their covered members of family who qualify for an exception.

Regulatory Review

OPM has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Office of Management and Budget has determined that this

rule is a ''significant regulatory action'' under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094.

Regulatory Flexibility Act

The Director of OPM certifies this regulation will not have a significant economic impact on a substantial number of small entities.

Federalism

OPM has examined this rule in accordance with Executive Order 13132, Federalism, and has determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or Tribal governments.

Civil Justice Reform

This regulation meets the applicable standard set forth in Executive Order 12988, Civil Justice Reform.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending by State, local, and Tribal governments in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold was approximately $183 million. This final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*) requires rules (as defined in 5 U.S.C. 804) to be submitted to Congress before taking effect. OPM will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this action before its effective date, as required by 5 U.S.C. 801. OMB's Office of Information and Regulatory Affairs has determined that this rule meets the criteria in 5 U.S.C. 804(2).

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35)

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB Control Number.

In the interim final rule, OPM requested comment on what, if any, information collection activities may be required by this rulemaking, including any comments on whether to create a new information collection or revise the information collection for SF–2809, *Health Benefits Election Form,* under OMB Control number 3206–0160. A commenter recommended that OPM update the existing Standard Form (SF) 2809 for Postal Service employees and Postal Service annuitants rather than developing a new form under PSHB to accommodate the needs of the PSHB Program. OPM agrees with this suggestion and will update the SF–2809 to include PSHB enrollments. OPM notes that there is a corresponding health benefits election form for retirees, OPM 2809 (OMB control number 3206–0141). OPM will also update the OPM–2809 to include PSHB enrollments. The revised forms would be made available prior to Open Season for the PSHB Program, which will begin on November 11, 2024. OPM is publishing a separate notice regarding modifications to these forms and will provide opportunities to comment as required by the PRA. An initial notice of proposed changes to these information collections with a 60-day comment period is published elsewhere in this issue of the **Federal Register**. In that notice, in addition to the changes to the forms, OPM proposes to combine OMB Control number 3206–0160 and OMB Control number 3206–0141 into a single information collection.

The information collection for form SF–2809 (OMB Control Number 3206–0160) is currently approved with an estimated public burden of 9,000 hours. The information collection (OMB Control number 3206–0141) associated with that form is currently approved with an estimated public burden of 11,667 hours.

A list of routine uses associated with these forms can be found in the Privacy Act System of Records Notice (SORN), OPM/CENTRAL 1 Civil Service Retirement and Insurance, available at *https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-central-1-civil-service-retirement-and-insurance-records.pdf.*

Participants in the 6-month Medicare Part B SEP will use form CMS 40B, Application for Enrollment in Medicare—Part B (Medical Insurance) (OMB control number 0938–1230) to enroll in Medicare Part B.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Postal Service employees, Reporting and recordkeeping requirements, Retirement.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

For reasons stated in the preamble, OPM is adopting the interim rule amending 5 CFR part 890 published on April 6, 2023, at 88 FR 20383, as final with the following changes:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246 (b) of Pub. L. 105–33, 111 Stat. 251; Sec. 890.111 also issued under 36 U.S.C. 5522; Sec. 890.112 also issued under 2 U.S.C. 2051; Sec. 890.113 also issued under section 1110 of Pub. L. 116–92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301 also issued under 26 U.S.C. 9801; Sec. 890.302(b) also issued under 42 U.S.C. 300gg–14; Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c–1; subpart L also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064 (5 U.S.C. 5561 note); subpart M also issued under 10 U.S.C. 1108 and 25 U.S.C. 1647b; and subpart P issued under 5 U.S.C. 8903c.

Subpart P—Postal Service Health Benefits Program

■ 2. Revise § 890.1604 to read as follows:

§ 890.1604 Medicare enrollment requirement for certain Postal Service annuitants and eligible family members.

(a) *Annuitant.* A Postal Service annuitant who is entitled to Medicare Part A must be enrolled in Medicare Part B to enroll or continue enrollment in a health benefits plan under this subpart, except as otherwise provided by paragraph (d)(1) of this section.

(b) *Member of family.* A Postal Service Medicare covered annuitant's member of family who is entitled to Medicare Part A must be enrolled in Medicare Part B to be covered or continue coverage in a health benefits plan under this subpart, unless:

(1) The Postal Service Medicare covered annuitant is excepted from the requirement to enroll in Medicare Part B as provided by paragraphs (d)(1)(i) through (v) of this section; or

(2) The member of family is excepted from the requirement to enroll in

Medicare Part B as provided by paragraphs (d)(2)(i) through (iv) of this section.

(c) [Reserved]

(d) *Exceptions.* The Medicare Part B enrollment requirements provided in paragraphs (a) and (b) of this section do not apply:

(1) To a Postal Service Medicare covered annuitant who—

(i) Was a Postal Service annuitant on or before January 1, 2025, and who was not both entitled to Medicare Part A and enrolled in Medicare Part B on January 1, 2025;

(ii) Was a Postal Service employee and was 64 years of age or older on January 1, 2025;

(iii) Resides outside the United States (which includes the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands), provided that the individual demonstrates such residency;

(iv) Is enrolled in health care benefits provided by the Department of Veterans Affairs (VA) under 38 U.S.C. chapter 17, subchapter II, including individuals who are not required to enroll in the VA's system of patient enrollment referred to in 38 U.S.C. 1705(a), subject to the documentation requirements in paragraph (e)(2) of this section; or

(v) Is eligible for health services from the Indian Health Service, subject to the documentation requirements in paragraph (e)(3) of this section.

(2) To a Medicare covered member of family who—

(i) Is eligible for PSHB coverage under the PSHB enrollment of a Postal Service Medicare covered annuitant who is not required to enroll in Medicare Part B, as provided in paragraphs (d)(1)(i) through (v) of this section;

(ii) Resides outside the United States (which includes the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands), provided that the individual demonstrates such residency;

(iii) Is enrolled in health care benefits provided by the VA under 38 U.S.C. chapter 17, subchapter II, including individuals who are not required to enroll in the VA's system of patient enrollment referred to in 38 U.S.C. 1705(a) to receive VA hospital care and medical services, subject to the documentation requirements in paragraph (e)(2) of this section; or

(iv) Is eligible for health services from the Indian Health Service subject to the documentation requirements in paragraph (e)(3) of this section.

(e) *Documentation requirements.* To qualify for an exception under paragraph (d) of this section, a Postal Service Medicare covered annuitant, or a Medicare covered member of family must meet one of the following documentation requirements:

(1) Documentation or information in a form, manner, and frequency as prescribed by OPM demonstrating qualification, satisfactory to the Postal Service, for the exceptions at paragraph (d)(1)(iii) or (d)(2)(ii) of this section;

(2) Documentation from the Department of Veterans Affairs in a form, manner, and frequency as prescribed by OPM demonstrating the individual meets an exception identified in paragraph (d)(1)(iv) or (d)(2)(iii), of this section; or

(3) Documentation from the Indian Health Service (IHS) in a form, manner, and frequency as prescribed by OPM in consultation with IHS demonstrating the individual meets an exception identified in paragraph (d)(1)(v) or (d)(2)(iv) of this section.

(f) *Notification of non-enrollment in Part B.* A Postal Service Medicare covered annuitant or a Medicare covered member of family who is required to be enrolled in Medicare Part B must promptly notify the Postal Service or OPM, in writing, if they choose not to enroll in or to disenroll from Medicare Part B as described in § 890.1608(e).

(g) *Effect of non-enrollment in Part B.* Failure to enroll or disenrollment from Medicare Part B will have the effect of a termination of PSHB coverage, as described in § 890.1608(b).

■ 3. Amend § 890.1606 by revising paragraph (e) to read as follows:

§ 890.1606 Opportunities to enroll, change enrollment, or reenroll; effective dates.

* * * * *

(e) Under this subpart, an enrollment, change of enrollment, or reenrollment made during Open Season takes effect on January 1 of the next year.

* * * * *

[FR Doc. 2024–09565 Filed 5–3–24; 8:45 am]

BILLING CODE 6325–63–P

DEPARTMENT OF ENERGY

10 CFR Chapter III

RIN 1901–ZA02

Interpretation of Foreign Entity of Concern

AGENCY: Office of Manufacturing and Energy Supply Chains (MESC), U.S. Department of Energy.

ACTION: Notification of final interpretive rule.

SUMMARY: On December 4, 2023, the U.S. Department of Energy (DOE or the Department) published in the **Federal Register** for public comment a proposed interpretive rule on DOE's interpretation of the statutory definition of ''foreign entity of concern'' (FEOC) in the Infrastructure Investment and Jobs Act, also known as the Bipartisan Infrastructure Law (BIL), which applies to multiple programs related to the battery supply chain. This statutory definition provides that, among other criteria, a foreign entity is a FEOC if it is ''owned by, controlled by, or subject to the jurisdiction or direction of a government of a foreign country that is a covered nation.'' In this final interpretive rule, DOE responds to public comments, clarifying the term ''foreign entity of concern'' by providing interpretations of the following key terms: ''government of a foreign country;'' ''foreign entity;'' ''subject to the jurisdiction;'' and ''owned by, controlled by, or subject to the direction.''

DATES: This final interpretive rule is effective May 6, 2024.

FOR FURTHER INFORMATION CONTACT: Widad Whitman, U.S. Department of Energy, Office of Manufacturing and Energy Supply Chains at Email: *FEOCguidance@hq.doe.gov,* Telephone: (202) 586–3302.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Purpose

Section 40207 of BIL (42 U.S.C. 18741) provides DOE $6 billion to support domestic battery material

processing, manufacturing, and recycling. Section 40207(b)(3)(C) directs DOE to prioritize material processing applicants that will not use battery material supplied by or originating from a ''foreign entity of concern'' (FEOC). Similarly, section 40207(c)(3)(C) directs DOE to prioritize manufacturing applicants who will not use battery material supplied by or originating from a FEOC and prioritize recycling applicants who will not export recovered critical materials to a FEOC. FEOC is defined in BIL section 40207(a)(5). The relevant paragraph lists five grounds upon which a foreign entity is considered a FEOC, described in subparagraphs (A) through (E). Subparagraphs (A), (B), and (D) address entities designated as foreign terrorist organizations by the Secretary of State, included on the Specially Designated Nationals and Blocked Persons List (SDN List) maintained by the Department of the Treasury's Office of Foreign Assets Control (OFAC), and alleged by the Attorney General to have been involved in various illegal activities, including espionage and arms exports, for which a conviction was obtained, respectively. Subparagraph (C) states that a foreign entity is a FEOC if it is ''owned by, controlled by, or subject to the jurisdiction or direction of a government of a foreign country that is a covered nation (as defined in [10 U.S.C. 4872(d)(2)]).'' The ''covered nations'' are the People's Republic of China (PRC), the Russian Federation, the Democratic People's Republic of North Korea, and the Islamic Republic of Iran (10 U.S.C. 4872(d)(2)). BIL section 40207(a)(5) provides no further definition of the term ''foreign entity'' or of the terms used in subparagraph (C).

Subparagraph (E) of BIL section 40207(a)(5) provides an additional means by which an entity may be designated to be a FEOC: a foreign entity is a FEOC if it is ''determined by the Secretary [of Energy], in consultation with the Secretary of Defense and the Director of National Intelligence, to be engaged in unauthorized conduct that is detrimental to the national security or foreign policy of the United States.'' The Secretary of Energy has not exercised this authority, as of this date.

In addition to affecting which entities DOE will prioritize as part of its BIL section 40207 Battery Materials Processing and Battery Manufacturing and Recycling Grant Programs, the ''Foreign Entity of Concern'' term is cross-referenced in section 30D of the Internal Revenue Code (IRC) (26 U.S.C. 30D), as amended by the Inflation Reduction Act of 2022 (IRA). Section 30D provides a tax credit for new clean vehicles, including battery electric vehicles. Section 30D(d)(7) excludes from the definition of ''new clean vehicle'' ''(A) any vehicle placed in service after December 31, 2024, with respect to which any of the applicable critical minerals contained in the battery of such vehicle (as described in [section 30D(e)(1)(A)]) were extracted, processed, or recycled by a [FEOC] (as defined in section 40207(a)(5) [of BIL] (42 U.S.C. 18741(a)(5))), or (B) any vehicle placed in service after December 31, 2023, with respect to which any of the components contained in the battery of such vehicle (as described in section 30D(e)(2)(A)) were manufactured or assembled by a [FEOC] (as so defined).''

On December 4, 2023, DOE published in the **Federal Register** its notice of proposed interpretive rule and request for comments related to the definition of FEOC contained in section 40207(a)(5) of BIL (88 FR 84082). The comment period closed on January 3, 2024.

After careful consideration of available information related to the battery supply chain and comments received, DOE is now issuing this final guidance regarding which foreign entities qualify as FEOCs, under BIL 40207(a)(5)(C), as a result of being ''owned by, controlled by, or subject to the jurisdiction or direction of a government of a foreign country that is a covered nation.'' For the purposes of this document, DOE uses the term ''interpretive rule'' and ''guidance'' interchangeably. At a future date, DOE may decide to initiate a separate rulemaking to implement the Secretary's ''determination authority'' contained in BIL section 40207(a)(5)(E) (42 U.S.C. 18741(a)(5)(E)).

To get the benefit of input from the public and interested stakeholders, the Department specifically requested comments on its proposed interpretation of the terms discussed in its proposed interpretive rule (88 FR 84082). The proposed interpretive rule was intended to solicit public feedback on DOE's interpretation to better understand stakeholder perspectives prior to implementation of finalized guidance. The Department considered all comments received during the public comment period and modified its proposed approach, as appropriate, based on public comment as described in section III of this document.

This final guidance proceeds as follows: Section II of this document provides a discussion of comments received and DOE's response to those comments; section III of this document provides an explanation of final interpretation and changes from the proposed interpretive rule; section IV of this document provides information on Regulatory Review of this interpretive guidance; section V of this document provides DOE's final interpretive rule on the definition of Foreign Entity of Concern; and section VI of this document provides the approval of the Office of the Secretary.

II. Discussion of Comments

A. Summary of Comments

DOE received 84 comment submissions in response to the proposed interpretive rule. Comments were received from original equipment manufacturers; cell producers; materials suppliers; component suppliers; trade organizations; a nonprofit organization; a consultant; foreign governments; and individuals. Forty-two—half of the total comments received—were from anonymous sources. Several comments included confidential business information, along with a non-confidential version to be uploaded to the docket for public viewing. Additionally, at the request of the governments of the Republic of Korea, Chile, and Australia, DOE met with delegations from each country. Meeting notes of these ex parte communications have been posted to the public docket. Commenters generally expressed support for the issuance of guidance, welcoming additional clarity on the definition of the term ''foreign entity of concern.'' Many comments raised specific concerns about the feasibility of compliance without bright-line administrable standards to govern which entities qualify as FEOCs. Many other submissions raised specific concerns about rules that too narrowly construe the term FEOC, raising concerns about manipulation of the battery supply chain by covered nations. Other submissions were more general in nature and did not provide specific comments on the proposed interpretive rule itself. All submissions were carefully reviewed, and DOE thanks the public for its engagement. DOE's responses to comment within the scope of this interpretive rule have been grouped by the topic area to which they pertain and are summarized as follows.

B. Foreign Entity

Comment: Multiple commenters sought clarity on how the guidance intends to treat a U.S.-headquartered company with its principal place of business in the United States but operating in a covered nation. Specifically, the commenters questioned whether such a U.S. entity's operations within a covered nation can be considered a FEOC under the guidance

even if the U.S. entity does not fall into the definition of ''foreign entity.''

Response: The guidance includes in the definition of ''foreign entity'' any ''partnership, association, corporation, organization, or other combination of persons organized under the laws of or having its principal place of business in a foreign country.'' If a U.S.-headquartered company has operations in a foreign country but has not organized under the laws of that country, then the guidance would not consider them to be a foreign entity. However, entities that operate within covered nations are typically required to be organized under the laws of that nation, and if that is the case, then such entities will be considered foreign entities, and thus subject to the jurisdiction of the covered nation's government. In this scenario, even though the operations of the U.S. entity located in the covered nation are considered a FEOC, this designation would not flow back to the U.S. entity's operations in the United States or other third-party countries.

C. Government of a Foreign Country

Comment: One commenter requested that DOE provide a definitive list of individuals who are considered to be current or former senior government officials and therefore considered part of the ''government of a foreign country.'' The commenter argued that determining which officials are considered ''senior'' and whether their family members hold interests in a company will not always be readily apparent.

Response: While DOE understands the commenter's concern, DOE declines to make this change. Compiling a complete list of current and former senior government officials would prove challenging given that the list would likely be subject to frequent change, difficult to predict, and very likely underinclusive. Furthermore, DOE does not have the resources to do so for every company that may be in the battery supply chain; however, individual participants in the battery supply chain will be in a position to individually analyze their specific upstream suppliers and ask those suppliers to provide information necessary for such an evaluation. DOE's guidance provides additional clarity for such evaluation by identifying markers of when an individual official should be considered ''senior,'' and in the case of the People's Republic of China (PRC), identifying particular Chinese Communist Party (CCP) entities whose current and former members should be considered senior foreign political figures.

Comment: Several other commenters requested that DOE provide greater clarity for the definition of ''senior foreign political figure,'' particularly regarding whether (a) there is a time period that may pass after which a former official can no longer be considered a part of the government of a foreign country; (b) what level an official must be to be considered ''senior;'' and (c) for the PRC, whether ''senior foreign political figure'' is limited to individuals with membership on the CCP entities identified in the guidance.

Response: There is no designated amount of time for how long an individual may be a former official and avoid being considered a ''senior foreign political figure.'' The concerns that arise from representing the government in a senior role and from membership on the CCP bodies identified in the guidance, for which former membership is considered, do not dissipate over time just because an individual no longer represents that government or political body.

The standard for determining whether a particular individual is a ''senior'' figure under the guidance is whether the individual exercises ''substantial authority over policy, operations, or the use of government-owned resources.'' In the context of the PRC, the guidance identifies particular CCP entities whose members should be considered to be senior officials of a ''dominant or ruling foreign political party.'' These bodies do not constitute all senior foreign political figures in the PRC, however. Apart from roles within a dominant political party, a senior official who works for the government of a covered nation in an official capacity, whether at a government ministry, for a state-owned enterprise (SOE), or within the military, may also be considered a ''senior foreign political figure.'' DOE declines to specify particular government positions that qualify as ''senior,'' but believes the standard provided (*i.e.,* ''a position of substantial authority over policy, operations, or the use of government-owned resources'') provides a reasonable standard with which to evaluate companies in the battery supply chain.

Comment: Other commenters argued that a determination of senior political figure ownership and involvement in private companies would be unduly onerous and may not be feasible. Relatedly, one commenter asked for greater clarity on what level of diligence and processes companies are expected to undertake to determine whether individuals or their family members who control entities within their supply chain qualify as senior foreign political figures.

Response: DOE's guidance has been drafted to provide a reasonable interpretation of the statutory definition of FEOC contained in 42 U.S.C. 18741(a), while taking into account administrability concerns. While outside the scope of this guidance, for the purposes of determining eligibility for the 30D tax credit, the Treasury Department's final regulations on Clean Vehicle Credits under Sections 25E and 30D; Transfer of Credits; Critical Minerals and Battery Components; Foreign Entities of Concern published elsewhere in this issue of the **Federal Register** and associated guidance (Rev. Proc. 2023–38) identify due diligence measures, including the potential for attestations of compliance from companies within a manufacturer's supply chain, that can be used to provide reasonable assurance that an entity's supply chain is free of FEOCs, including control by senior foreign political figures.

Comment: One commenter noted that the proposed interpretive rule suggests that local or subnational government-owned enterprises are considered to be part of the ''government of a foreign country'' and questioned whether all SOEs should be considered part of the ''government of a foreign country'' such that an entity controlled by an SOE at a level of 25% or more would also be a FEOC.

Response: DOE agrees that all SOEs, whether local or national, should be considered to be instrumentalities of a national or subnational government, and thus part of the ''government of a foreign country.'' As such, a national SOE's voting rights, equity interests, or board seats in an entity can be combined with a local SOE's ownership of the same entity to reach the 25% FEOC threshold for control of that entity.

Comment: One commenter asked for clarity as to whether, with respect to the PRC, a ''dominant or ruling political party'' in the interpretation of ''government of a foreign country'' refers only to the central party, or to local party apparatuses as well.

Response: The guidance includes local and subnational government officials in the definition of government of a foreign country, and therefore senior government officials at the local and subnational level should be considered to be part of the government of a foreign country. When it comes to senior officials from a dominant or ruling party, DOE's final interpretive guidance also makes clear that the list of specific CCP entities that are

considered part of the ''government of a foreign country,'' includes current, but not former, members of local or provincial Chinese People's Political Consultative Conferences (CPPCC).

D. Subject to the Jurisdiction

Comment: One commenter urged DOE to clearly define the term ''principal place of business'' in the guidance.

Response: DOE intends for the term ''principal place of business'' to be interpreted consistent with standard practice. The guidance is informed by the United States Supreme Court's formulation in *Hertz Corp.* v. *Friend,* in which a principal place of business is considered to be the ''place where a corporation's officers direct, control, and coordinate the corporation's activities [and] in practice it should normally be the place where the corporation maintains its headquarters—provided that the headquarters is the actual center of direction, control, and coordination, *i.e.,* the 'nerve center.' '' 559 U.S. 77, 92–93 (2010).

Comment: Multiple commenters argued that all subsidiaries of FEOCs should be considered FEOCs themselves, even when the parent entity is only a FEOC via jurisdiction due to it being headquartered within a covered nation.

Response: DOE declines to make this change. DOE's interpretive guidance is intended to clarify the statutory terms in a way that gives effect to the purpose of the statutory provisions to which it applies. The term FEOC within section 40207, as it applies to both DOE's battery materials processing and battery manufacturing and recycling grant programs and to the 30D tax credit, is intended to both reduce reliance upon covered nations in the battery supply chain and provide a pathway for companies in the United States and third-party countries to increase production of critical minerals, battery components, and battery materials. At this time, DOE concludes that United States or third-party country subsidiaries of entities that are headquartered within a covered nation do not necessarily pose the same risk to the battery supply chain as subsidiaries that are FEOCs by virtue of the government of a covered nation holding, directly or indirectly, 25% or more of the equity interests, board seats, or voting rights of the subsidiary. This is due to: (a) their location within the United States or third-party countries; and (b) the lack of direct control by the government of a covered nation. In addition, DOE's interpretation serves the intended purpose of the statute by providing a pathway for the onshoring and friend-shoring of critical minerals, battery components, and battery materials. This contrasts with the primary purpose of the CHIPS and Science Act of 2022, and the implementation of the Department of Commerce's substantially similar FEOC provision, which concerns the prevention of transfers of semiconductor technology to covered nation governments.

Comment: More than one of the commenters that urged that all subsidiaries of FEOCs be considered FEOCs themselves, expressed concern that companies headquartered in the PRC, even when privately held with no formal control by the government of the PRC, may receive significant government subsidy, grants, and debt financing to pursue expansion outside of the PRC. One of these commenters urged DOE to aggressively assess whether such companies are actually private or are engaged in activities designed to avoid FEOC designation.

Response: DOE considered whether to expand the definition of ''control'' under this interpretive rule to incorporate companies that are controlled by the government of a covered nation by virtue of significant investments by that government of the kind identified by the commenters (*e.g.,* subsidies, grants, or debt financing) from the government of a covered nation. However, DOE has not yet identified a sufficiently bright-line rule for such investments that would be administrable by entities in the battery supply chain or by vehicle manufacturers. Accordingly, DOE declines to make this change to the interpretive guidance at this time. With respect to its evaluation of applications for domestic battery material processing, manufacturing, and recycling grants under section 40207 of BIL, DOE notes that it will conduct a holistic risk evaluation process related to research, technology, and economic security. Such evaluation will include consideration of financial support by countries of concern, including the PRC. In addition, DOE may consider government investment as part of its exercise of the Secretary of Energy's authority under BIL section 40207(a)(5)(E) to designate an entity a FEOC if it is ''engaged in unauthorized conduct that is detrimental to the national security or foreign policy of the United States.'' Furthermore, DOE will continue to monitor the battery supply chain market and may consider revisiting this issue in the future through updated interpretive guidance defining control by the government of a covered nation based on significant investments from that government. Any information that may assist DOE in monitoring the battery supply chain market may be submitted to the email address identified in the ''For Further Information'' section of this document.

E. Owned by, Controlled by, or Subject to the Direction

Comment: Several commenters asked whether, when calculating an entity's voting rights, equity interests, or board seats held by the government of a covered nation, the guidance requires that these calculations be made in combination or independently.

Response: DOE responds with the following clarification. The 25% threshold applies to each metric independently, not in combination. For example, and assuming no other relevant circumstances, if an entity has 20% of its voting rights, 10% of its equity interests, and 15% of its board seats each held by the government of a covered nation, these percentages would not be combined to equal 45% control, but would each be evaluated independently, resulting in the entity being controlled at the level of the highest metric (*i.e.,* 20%) and thus not considered a FEOC. That said, DOE recognizes that significant levels of government control in all three metrics may still raise concerns. As such, as indicated above in response to a previous comment, DOE may incorporate such considerations into its evaluation of applications for grants under section 40207 of BIL, through utilization of the Secretary's authority under BIL section 40207(a)(5)(E), or through revisions to the interpretive guidance upon evidence of evasive gamesmanship with respect to the 25% threshold.

Comment: One commenter asked for greater clarity on what constitutes voting rights, equity interests, and board seats for the purposes of calculating whether a 25% controlling interest exists. Specifically, the commenter asked (a) whether DOE intended to refer to ''traditional voting rights belonging to common stockholders or the voting rights of owners'' or to ''the voting rights of a board;'' (b) how to calculate the value of an individual board seat; and (c) what constitutes equity interests for the purposes of the guidance.

Response: As previously stated, DOE notes that each of these metrics of control is intended to be calculated independently. For ''voting rights,'' DOE intends to refer to the voting rights of owners, as suggested by the commenter. This means that the voting power of owners of different types of stock, to the

extent this information is reasonably ascertainable, should be considered in calculating whether a FEOC controls 25% of the voting rights in an entity. For ''board seats,'' DOE intends for the value of a board seat to equal the value of its voting power on the board. So, if one board seat is held by a representative of the government of a covered nation and that seat holds 25% of the board voting power, then that entity would be considered a controlled FEOC. For ''equity interests,'' DOE intends to refer to percent value of the ownership interest, to include capital or profit interests and contingent equity interests, in the company held by an individual or entity, with the amount of contingent interest that can be reasonably determined included for the purpose of determining FEOC compliance.

Comment: Several commenters raised concerns that the analysis required to evaluate the FEOC compliance of a manufacturer's supply chain, including the voting rights, board seats, and equity interests for privately held companies, will be unduly burdensome and create administrability problems. Other commenters, however, stated that the FEOC guidance is stringent but, for the most part, workable.

Response: DOE's guidance has been drafted to give a reasonable interpretation to the statutory definition of FEOC contained in 42 U.S.C. 18741(a), while taking into account administrability concerns. The due diligence measures required for determining FEOC compliance for purposes of determining eligibility for the 30D tax credit and for DOE's BIL 40207 grant programs are outside the scope of this guidance.

Comment: One commenter stated that the 25% threshold for control is too bright-line and will allow an entity to drop its covered nation government ownership stake to 24.9% to avoid being deemed a controlled FEOC. Several other commenters stated their support for the 25% bright-line threshold and the guidance's alignment with the Department of Commerce's FEOC definition in its Final Rule on Preventing the Improper Use of CHIPS Act Funding (CHIPS Rule) as published in the **Federal Register** on September 25, 2023 (88 FR 65600).

Response: DOE declines to make a change. The guidance attempts, to the greatest degree possible, to establish bright-line rules to allow individual entities seeking to take advantage of BIL section 40207 and IRC section 30D to readily evaluate whether their upstream suppliers should or should not be considered FEOCs. Without that clarity, individual entities would be unable to properly evaluate their supply chains. To the extent that an entity changes its ownership structure to fall below the 25% threshold, DOE views such restructuring as a desirable dilution of covered nation government control, consistent with the purposes of the FEOC restrictions in BIL section 40207 and IRC section 30D, as DOE understands them.

Comment: Similarly, another commenter stated that DOE's interpretation of indirect control allows for an entity to alter its ownership structure to skirt the FEOC ban, by nesting control and allowing control to defuse through levels of subsidiaries.

Response: DOE declines to make a change. First, not all ownership stakes dilute in a tiered ownership structure. Specifically, DOE notes that the guidance makes clear that the controlling stake of a parent company with 50% or more interest in a subsidiary does not attenuate. Thus, the covered nation government's level of control would not attenuate in a situation where there exist tiers of subsidiaries that are owned at a level of 50% or more. Second, DOE's approach to calculating indirect control recognizes the reality that, in the case of multiple tiers of minority control by a covered nation government, the actual ability of the covered nation government to influence the operations of a subsidiary may become materially attenuated.

Comment: One commenter asked for clarification on why DOE used the parenthetical phrase ''(including the government of a foreign country that is a covered nation)'' in the interpretation of ''control,'' since the focus of the guidance relates to control by the government of a covered nation.

Response: The interpretation of ''control'' in the guidance is meant to encompass both situations where the government directly controls an entity and when the government may indirectly control an entity through another entity that is not itself the government of a covered nation. In addition, the ''control'' definition is also embedded into the interpretation of ''foreign entity,'' to identify situations where a U.S. entity is considered to be ''foreign'' as a result of control. The parenthetical is intended to make clear that ''control'' refers to both direct and indirect control by the government, and control within the interpretation of ''foreign entity.''

Comment: Several commenters asked for clarification on how to evaluate levels of control within a joint venture. Specifically, the commenters questioned whether a joint venture should be evaluated using the licensing and contracting provision of the guidance or if joint ventures should be evaluated solely under the 25% control prong.

Response: DOE responds by clarifying that whether a FEOC holds a controlling interest in a JV entity (through voting rights, equity interests, or board seats) is determined under the 25% control threshold. Thus, a separate entity that exists as a 50–50 JV, in which one of the members of the JV is a FEOC, would be considered to be a FEOC. In a situation where a FEOC maintains less than 25% control of a JV, the JV agreement would not confer ''effective control'' of the JV entity unless, by its terms, it gives a FEOC the right to determine the quantity or timing of production; to determine which entities may purchase or use the output of production; to restrict access to the site of production to the contractor's own personnel; or the exclusive right to maintain, repair, or operate equipment that is critical to production.

Comment: One commenter asked for clarification as to whether the ''effective control'' definition only applies when the other entity (licensor/contractor) is a FEOC.

Response: DOE responds that the ''effective control'' definition in the guidance is only relevant as it relates to licenses and contracts with an entity considered to be a FEOC. The language of the guidance has been edited to clarify.

Comment: Multiple commentors asked for clarification on whether the ''effective control'' test in the definition of ''owned by, controlled by, or subject to the direction'' applies only when the licensor or contractor is a FEOC because it is subject to at least 25% control by the government of a covered nation or also when the licensor or contractor is a FEOC due to being ''subject to the jurisdiction'' of a covered nation.

Response: DOE responds by clarifying that an entity can be subject to effective control through a license or contract with any entity that is deemed a FEOC, whether via the 25% threshold for control or via jurisdiction. The proximity of a FEOC to the government of a covered nation, even when the government does not have a controlling stake in the company, raises similar concerns in the context of a license or contract with a non-FEOC, and the non-FEOC should retain the identified rights to avoid effective control by the FEOC.

Comment: One commenter suggested that DOE modify the fifth right to be reserved within a license or contract with a FEOC, which requires that IP and technology that is the subject of the

contract be accessible to the non-FEOC entity ''notwithstanding any export control or other limit on the use of intellectual property imposed by a covered nation subsequent to execution.'' The commenter suggested that the provision could be interpreted to call for the defiance of foreign laws.

Response: To ensure that a license or contract with a FEOC does not result in effective control, a non-FEOC should reserve the listed rights at the time of entering into the license or contract. DOE's view is that new export controls would not be applicable to IP that has already been transferred, *i.e.,* IP licenses with an effective date prior to implementation of a new export control. That said, it is not DOE's intent that this language place a manufacturer in the position of having to violate a foreign law. Therefore, DOE has edited the fifth right to state that the parties to the given license or contract commit that the non-FEOC party will retain access to and use of any intellectual property, information, and data critical to production ''for the duration of the contractual relationship.''

Comment: One commenter requested confirmation on their understanding of the first and fifth rights identified by DOE to be retained by a non-FEOC entity entering into a license or contract with a FEOC. Specifically, the commenter stated its understanding that the first right would allow the non-FEOC entity to acquire information from the FEOC related to the quantity of critical minerals or components necessary to manufacture a battery or battery component, and the fifth right would allow the non-FEOC entity to obtain assistance from the FEOC in operating, maintaining, and repairing equipment critical to production.

Response: The commenter is correct that the non-FEOC entity would be able to obtain information and assistance from the FEOC as described above. The determining factor as to whether the retained rights have prevented ''effective control'' by a FEOC under the guidance is whether the non-FEOC entity has the right of access and the authority to make decisions. In order to fully exercise those rights, however, it may be necessary for the non-FEOC entity to obtain information and assistance from the FEOC entity.

Comment: In the context of the ''effective control'' definition and the safe harbor rights identified in the guidance, one commenter requested that DOE provide a limited exception or transition period for licenses and contracts that were signed between enactment of the IRA and the issuance of DOE's proposed interpretive guidance, if the non-FEOC entity can establish that the FEOC entity does not have effective control through alternate means.

Response: DOE's guidance is limited to providing an interpretation of the statutory term ''foreign entity of concern,'' and related terms. Whether to provide an exception or transition period to eligibility for a particular program or incentive is out of scope of this interpretive guidance.

F. Other Comments

i. General Comments Related to Proposed Interpretive Rule

Comment: Several commenters urged DOE to create a definitive list of entities considered to be FEOCs.

Response: DOE declines to make this change. The criteria for ''foreign entities of concern'' were articulated in the Infrastructure Investment and Jobs Act (IIJA). DOE recognizes that, for some of the criteria, in particular the criteria related to foreign entities that have been alleged by the Attorney General to have been involved in certain activities for which a conviction was obtained, there may not be a consolidated, readily available list. For the criteria that are the subject of this guidance (*i.e.,* a foreign entity that is ''owned by, controlled by, or subject to the jurisdiction or direction of the government of a covered nation''), DOE is not in a position to provide a comprehensive list of every entity that qualifies as a FEOC. Providing a definitive list of FEOCs could result in attempts to evade the rule through corporate restructuring that does not change actual control and would be overly burdensome on DOE to create and maintain such a list for the entire battery supply chain. Accordingly, the guidance provides standards to assist companies in determining whether the particular entities in their battery supply chain are FEOCs. These companies are better positioned than DOE to conduct due diligence on and obtain certifications from entities within their supply chain, with whom they maintain a contractual relationship. DOE expects that, given the guidance provided in this final interpretive rule, relevant entities can exercise appropriate diligence to identify entities that fall within the criteria articulated in the IIJA.

Comment: Several commenters urged DOE to establish a voluntary pre-review process to allow manufacturers to submit to DOE potential licenses and contracts with FEOCs to determine whether it would lead to effective control by the FEOC. Several of the commenters also requested that such a pre-review process be structured in a confidential manner.

Response: While DOE requested comment on the desirability of establishing and the potential structure of a pre-review process for licenses and contracts, DOE is declining to establish such process at this time. Instead, as established in the Treasury Department's 30D rule and associated guidance, DOE will play a pivotal role in reviewing all of the documentation that is provided to the IRS for the purpose of determining eligibility for the 30D tax credit. DOE's review of licenses and contracts for effective control will take place through that process.

Comment: Multiple commenters urged DOE to use the determination authority provided in section 40207(a)(5)(E) of BIL to allow the Secretary of Energy, in consultation with the Secretary of Defense and the Director of National Intelligence, to designate an individual entity as a FEOC ''engaged in unauthorized conduct that is detrimental to the national security or foreign policy of the United States.''

Response: DOE responds that it continues to consider whether and how to use the determination authority in BIL section 40207(a)(5)(E).

ii. Comments Related to Treasury's 30D Rule

Comment: One commenter urged DOE to clearly define the terms of ''critical minerals,'' ''components,'' and ''materials'' in this guidance.

Response: DOE declines to make this change. The definitions identified by the commenter are relevant to DOE's interpretative guidance only insofar as it applies to eligibility for the 30D tax credit. The Treasury Department has defined these terms in the relevant regulations.

Comment: Several commenters suggested that the U.S. Government should consider providing extensions of time for compliance with FEOC sourcing rules or waivers of any penalties involving 'unintentional' transactions with entities later determined to be FEOCs as the industry tries to implement these new rules. Another commenter expressed strong support for phasing out the Treasury Department's transition rule for non-traceable critical minerals.

Response: DOE's guidance is limited to providing an interpretation of the statutory term ''foreign entity of concern,'' and related terms. As such, comments related to extensions of time to allow for a transition period, waiver of penalties associated with an

unintentional interaction with a FEOC, or transition rule phase-outs are outside the scope of this interpretive guidance.

Comment: One commenter expressed concerns that the Federal government has failed to provide a harmonized definition of the term ''foreign entity of concern,'' specifically noting its belief that DOE and the Treasury Department, for the purposes of the 30D tax credit, do not have a common definition of FEOC.

Response: DOE and the Treasury Department have harmonized their FEOC definitions for the purposes of implementing the 30D tax credit, as Treasury has incorporated DOE's FEOC guidance into its 30D rule.

Comment: One commenter expressed concern that some critical minerals producers would not be able to certify compliance with FEOC rules because they use a mixture of ingredients from FEOC and non-FEOC sources that cannot be separated physically.

Response: DOE's guidance is limited to providing an interpretation of the statutory term ''foreign entity of concern,'' and related terms. This comment is out of scope of this interpretive guidance.

Comment: Several commenters requested clarification from DOE as to what sort of documentation and materials DOE would deem sufficient to certify FEOC compliance with the Internal Revenue Service for the purposes of the 30D tax credit and for the battery ledger identified in the Treasury Department's 30D rule. For instance, one commenter asked whether a guarantee letter from a third-party manufacturer or supplier that confirms it is a non-FEOC is sufficient to substantiate its non-FEOC status to the IRS.

Response: DOE's guidance is limited to providing an interpretation of the statutory term ''foreign entity of concern'' and related terms, and this comment is outside the scope of this interpretive guidance. The due diligence measures required for determining FEOC compliance for purposes of determining eligibility for the 30D tax credit and for DOE's BIL 40207 grant programs are outside the scope of this guidance.

iii. Comments Related to the Inflation Reduction Act

Comment: DOE received several comments, both positive and negative, about the relative merits of the Inflation Reduction Act. Some of these commenters stated that the IRA will support energy reliability, clean energy production, and a variety of other goals. Other commenters stated that IRA provisions limiting eligibility for government incentives (*e.g.,* excluding new clean cars from eligibility if they source from FEOCs) is discriminatory, protectionist, and violates basic principles of the World Trade Organization.

Response: DOE notes that all of these comments are directed at the underlying statute, which is outside the scope of this interpretive guidance.

III. Explanation of Final Interpretation and Changes From the Proposed Interpretive Rule

A. Purpose

The term FEOC, as used in both BIL section 40207 and IRC section 30D, is intended to address upstream supply chains of individual entities that may benefit from direct or indirect Federal government financial support. As such, the interpretations proposed here are intended to be structured as, to the greatest degree possible, bright-line rules that allow individual entities to readily evaluate whether their supply chain includes FEOCs. In the case of the Battery Materials Processing and Battery Manufacturing and Recycling Grants programs in BIL section 40207, a bright-line rule will afford eligible entities using their grants for battery materials processing or advanced battery component manufacturing greater clarity in avoiding using battery materials supplied by or originating from a FEOC; similarly, such a rule will afford those eligible entities using their grants for battery recycling greater clarity in avoiding the export of recovered critical materials to a FEOC.

B. Foreign Entity

DOE's final interpretive rule does not make any changes to its interpretation of the term ''foreign entity.'' To be considered a FEOC under BIL section 40207(a)(5) (42 U.S.C. 18741(a)(5)), the statute requires that the entity be a ''foreign entity.'' However, section 40207 does not define ''foreign entity.''

The interpretation of ''foreign entity'' in this final guidance aligns closely with the definition of ''foreign entity'' contained in the 2021 National Defense Authorization Act (NDAA) (15 U.S.C. 4651(6)), which informs certain Department of Commerce programs related to semiconductors. Both the interpretation in this guidance and the 2021 NDAA definitions define foreign entities to include three main categories of entities: (1) a government of a foreign country and a foreign political party; (2) a natural person who is not a lawful permanent resident of the United States, citizen of the United States, or any other protected individual (as such term is defined in 8 U.S.C. 1324b(a)(3) (addressing unfair immigration-related employment practices)); or (3) a partnership, association, corporation, organization, or other combination of persons organized under the laws of or having its principal place of business in a foreign country.

DOE's interpretation specifically provides that entities organized under the laws of the United States that are subject to the ownership, control, or direction of another entity that qualifies as a foreign entity will also qualify as ''foreign entities'' for the purposes of BIL section 40207(a)(5)(C). The 2021 NDAA definition of foreign entity allows for U.S. entities to be considered foreign in this way and also provides an additional list of criteria by which such persons may be considered foreign due to their relationship with the three main categories of foreign entities. While these criteria are relevant for the purposes of the Department of Commerce programs at issue, which are primarily concerned with preventing the transfer of semiconductor technology to covered nation governments, DOE assesses that the criteria are not necessary for the purpose of evaluating covered nation-associated risk to the battery supply chains, because the natural persons and corporate entities that are relevant to the battery supply chain are already encompassed in the identified criteria for ''foreign entity.'' DOE's interpretation ensures that the government of a covered nation cannot evade the FEOC restriction simply by establishing a U.S. subsidiary, while otherwise maintaining ownership or control over that subsidiary.

C. Government of a Foreign Country

DOE's final interpretive rule makes minor, clarifying changes to its interpretation of the term ''government of a foreign country.'' The term ''government of a foreign country'' is a term used to determine whether an entity is ''owned by, controlled by, or subject to the jurisdiction or direction of a government of a foreign country.'' It is also used in the interpretation of ''foreign entity'' in paragraph (i) of section V.B of this document.

DOE's interpretation of the term ''government of a foreign country'' contained within this notice includes subnational governments, which can have significant ownership or control of firms in the vehicle supply chain. In the covered nations at issue here, there exist many subnational and local government-owned entities, that play a large role in their nation's economies,

and local SOEs are a large driver of regional economies. This term also includes instrumentalities, which include separate legal entities that are organs of a state but where ownership may be unclear, such as a utility or public financial institution. This interpretation aligns with the definition of ''foreign government'' promulgated by the Department of the Treasury in its regulations implementing the Committee on Foreign Investment in the United States (CFIUS) program (31 CFR 800.221). That definition includes ''national and subnational governments, including their respective departments, agencies, and instrumentalities.''

DOE's interpretation of the term ''government of a foreign country'' also includes senior foreign political figures. This inclusion recognizes the reality of government influence over business entities in covered nations, which is often exercised through individuals representing the government on corporate boards or acting at the direction of the government or to advance governmental interests when serving as an equity owner or through voting rights in an otherwise privately held business. This interpretation aligns with the Defense Department's National Industrial Security Program Operating Manual (NISPOM) regulatory definition of ''foreign interest'' (32 CFR 117.3) and associated ''foreign ownership, control or influence'' (FOCI) regulations (32 CFR 117.11), which recognize as FOCI the influence of a representative of a foreign government with the power to direct or decide issues related to a U.S. entity. In addition, in order to deal with the situation in which officials leave their official positions in order to exert the same type of influence on behalf of the government, the interpretation also includes former senior government officials and former senior party leaders. Inclusion of former officials is consistent with regulatory definitions in other contexts. As stated in response to comments above, the guidance does not limit the ''former'' designation to a particular period of time, as the concerns arising from membership on the CCP bodies identified below, do not dissipate over time just because an individual no longer serves as a member of that body. For example, the Bank Secrecy Act (BSA) private banking account regulations (relating to due diligence program requirements for private banking accounts established, maintained, administered, or managed in the United States for foreign persons) administered by the Department of the Treasury's Financial Crimes Enforcement Network (FinCEN) include both current and former officials in the definition of ''senior foreign political figure'' (31 CFR 1010.605(p)). Those regulations provide further interpretation of the term ''senior official'' that DOE has also included to provide additional clarity.

DOE's final interpretive rule clarifies that ''senior foreign political figure'' includes both individuals who are senior officials in the government and senior officials within a dominant or ruling political party, as well as family members of such individuals. In the specific context of the PRC, DOE considers ''senior foreign political figure'' to include (a) individuals currently or formerly in senior roles within the PRC government, at the central and local levels; (b) individuals currently or formerly in senior roles within the Chinese Communist Party (CCP) and bodies and commissions under the Central Committee; (c) current and former members of the CCP Central Committee, the Politburo Standing Committee, the Politburo, the National People's Congress and Provincial Party Congresses, and the national Chinese People's Political Consultative Conference (CPPCC); and (d) current but not former members of local or provincial CPPCCs.

Finally, the inclusion of immediate family members of senior foreign political figures in the interpretation of ''government of a foreign country'' aligns with the BSA private banking regulation. Those regulations include the immediate family members of a senior foreign political figure in their definition of ''senior foreign political figure'' (31 CFR 1010.605(p)(1)(iii)). Immediate family members in those regulations mean spouses, parents, siblings, children, and a spouse's parents and siblings (31 CFR 1010.605(p)(2)(ii)).

D. Subject to the Jurisdiction

DOE's final interpretive rule does not make any changes to its interpretation of the term ''subject to the jurisdiction.'' If an entity is ''subject to the jurisdiction'' of a government of a foreign country that is a covered nation, the entity is a FEOC. DOE's interpretation provides an objective standard, consistent with the common understanding of ''jurisdiction,'' rather than a subjective standard that relies upon an individual nation's understanding of its own jurisdictional reach. As such, the interpretation first recognizes that any organization formed under the laws of the government of a covered nation is a national of that nation and therefore subject to its direct legal reach. *Cf.* 28 U.S.C. 1332(c)(1) (noting that, for the purposes of diversity jurisdiction, ''a corporation shall be deemed to be a citizen of every . . . foreign state by which it has been incorporated and of the . . . foreign state where it has its principal place of business''). In addition and as stated above in response to comments, determining an entity's principal place of business under the guidance should be guided by the United States Supreme Court's formulation in *Hertz Corp.* v. *Friend,* in which a principal place of business is considered to be the ''place where a corporation's officers direct, control, and coordinate the corporation's activities [and] in practice it should normally be the place where the corporation maintains its headquarters—provided that the headquarters is the actual center of direction, control, and coordination, *i.e.,* the 'nerve center.' '' 559 U.S. 77, 92–93 (2010).

Second, DOE's interpretation accounts for the fact that several critical segments of the battery supply chain today are predominantly processed and manufactured within covered nation boundaries,[1] and recognizes that a covered nation will be able to exercise legal control (potentially forcing an entity to cease production or cease exports) over an entity with respect to any critical minerals that are physically extracted, processed, or recycled, any battery components that are manufactured or assembled, and any battery materials that are processed within those boundaries, even if the entity is not legally formed under the laws of the covered nation. *See* Fourth Restatement (Foreign Relations) (2018) section 408 (stating that ''[i]nternational law recognizes a state's jurisdiction to prescribe law with respect to persons, property, and conduct within its territory''). At the same time, DOE's interpretation recognizes that such an entity, which is not legally formed in a covered nation but has production activities *inside* a covered nation, may also have separate production activities that occur *outside* the covered nation. In that case, the covered nation does not have jurisdiction over those outside production activities. Therefore, under the guidance, an entity that is not legally incorporated in a covered nation could nevertheless be considered a FEOC under the jurisdiction prong with respect to the particular critical minerals, battery components, or battery materials that are subject to the jurisdiction of a covered nation. But the entity would not be considered a FEOC

[1] *100-day-supply-chain-review-report.pdf* (*whitehouse.gov*).

with respect to its activities related to other critical minerals, battery components, or battery materials that are not subject to the jurisdiction of a covered nation.

Finally, when an entity is a FEOC due to it being ''subject to the jurisdiction'' of a covered nation, subsidiaries of the FEOC are not automatically considered to be FEOCs themselves based solely on their parent being a covered nation jurisdictional entity. A subsidiary entity would be considered a FEOC itself, however, if it is also either (1) ''subject to the jurisdiction'' of the covered nation, pursuant to section V.D of this document, or (2) ''controlled by'' a covered nation government (including via direct or indirect control, such as through joint ventures, or via contracts that confer effective control to a FEOC), pursuant to section V.E of this document.

DOE's interpretation is supported by statutory and regulatory choices made in similar contexts, including: the 2021 NDAA definition of ''foreign entity'' (15 U.S.C. 4651(6)); and the NISPOM regulatory definition of ''foreign interest'' (32 CFR 117.3). The interpretation of ''subject to the jurisdiction'' provides clarity to original equipment manufacturers (OEM) that removing FEOCs from their supply chain will require removal of any critical minerals, battery components, and battery materials that are directly produced within the boundary of a covered nation.

E. Owned by, Controlled by, or Subject to the Direction

DOE's interpretive rule is largely consistent with the proposal but makes some clarifying edits in response to comments. If an entity is ''owned by, controlled by, or subject to the direction'' (hereinafter ''control'') of a government of a foreign country that is a covered nation, the entity is a FEOC. The term is also used in paragraph (iv) of DOE's interpretation of foreign entity to account for situations where a U.S. entity is sufficiently controlled to be considered foreign. DOE's interpretation provides for both (1) control via the holding of 25% or more of an entity's board seats, voting rights, or equity interest, and (2) control via license or contract conferring rights on a person that amount to a conferral of control.

As previously stated in response to comments, DOE considered whether to expand the definition of ''control'' under this interpretive rule to incorporate companies that are controlled by the government of a covered nation by virtue of significant investments by that government of the kind identified by commenters (*e.g.,* subsidies, grants, or debt financing). However, DOE has not yet identified a sufficiently bright-line rule for such investments that would be administrable by vehicle manufacturers in the context of the Treasury Department's 30D tax credit. Accordingly, DOE declines to make a change to the interpretive guidance at this time, but may incorporate consideration of such government investments into its evaluation of applications for domestic battery material processing, manufacturing, and recycling grants under section 40207 of BIL, or through utilization of the Secretary's exercise of her authority under BIL section 40207(a)(5)(E) to designate an entity a FEOC if it is ''engaged in unauthorized conduct that is detrimental to the national security or foreign policy of the United States.'' Furthermore, DOE will continue to monitor the battery supply chain market and may consider revisiting this issue in the future through updated interpretive guidance defining control by the government of a covered nation based on significant investments from that government. Any information that may assist DOE in monitoring the battery supply chain market may be submitted to the email address identified in the ''For Further Information'' section of this document.

i. Control via 25% Interest

DOE's interpretation of control is informed by careful analysis of corporate structure within the battery supply chain. In the battery industry, the primary methods by which a parent entity, including the government of a foreign country, exercises control over another entity is through voting rights, equity interests, and/or its boards of directors. Parent entities may exercise control via majority equity interest, voting rights, or board seats, and also through minority holdings. Furthermore, parent entities may act in concert with other investors to combine minority holdings in order to exercise control. As a result, an effective measure of control is one that considers multiple permutations of majority and minority holdings of equity interest, voting rights, and board seats that can cumulatively confer control. In response to comments, DOE's final interpretation clarifies that each of these metrics—voting rights, equity interests, and board seats—are evaluated independently. As noted above, and assuming no other relevant circumstances, if an entity has 20% of its voting rights, 10% of its equity interests, and 15% of its board seats each held by the government of a covered nation, these percentages would not be combined to equal 45% control, but would result in the entity being controlled at the level of the highest metric (*i.e.,* 20%), and thus, not considered a FEOC. That said, DOE recognizes that significant levels of government control in all three metrics may still raise concerns. As such, as indicated above in response to comments, DOE may incorporate such considerations into its evaluation of applications for grants under section 40207 of BIL, through utilization of the Secretary's designation authority under BIL section 40207(a)(5)(E), or through revisions to the interpretive guidance upon evidence of evasive gamesmanship with respect to the 25% threshold.

While there are several prominent companies within the battery supply chain that are majority-owned by covered nation governments, particularly in the upstream mining segment, the predominant form of state ownership and influence in most segments of the battery supply chain is through minority shareholding, voting rights, or board seats. DOE has evaluated a range of supply chain entities for which covered nation governments and officials with cumulative holdings between 25% and 50% have meaningful influence over corporate decision-making, even in cases of subsidiary entities operating in other jurisdictions and in the case of multiple minority shareholders acting in concert. However, DOE's assessment of the battery supply chain strongly suggests that minority control can attenuate with multiple tiers of separation between the state and the firm performing the covered activity.

DOE recognizes that a bright-line metric for control will be necessary to ensure that OEMs can feasibly evaluate the presence of FEOCs within their supply chains. Informed by empirical evidence in the battery supply chain and choices made in other regulatory contexts, as discussed further below, DOE's interpretation establishes a 25% threshold and guidance on calculating the attenuation of control in a tiered ownership structure. In the case of majority control by a covered nation government, that control is not diluted such that outright ownership (50%+) confers full control. This ensures that a covered nation government is still considered to control, indirectly, a majority-owned subsidiary of a government-controlled company. However, multiple layers of minority control by a government may become so attenuated that an entity would no longer be classified as a FEOC. This

bright-line threshold and guidance on how to calculate control will enable an evaluation of battery supply chains and facilitate any required reporting or certification of whether that supply chain includes products produced by a FEOC. This same analysis applies to joint ventures, such that if the government of foreign country that is a covered nation controls, either directly or indirectly, 25% or more of a joint venture, then that joint venture is a FEOC.

DOE's interpretation is supported by choices made in a variety of statutory and regulatory regimes, while the identified methods of control account for specific circumstances present in the battery industry. DOE takes a broad approach to the interests that count towards the 25% threshold, considering board seats, voting rights, or equity interest. This is consistent with FOCI regulations, which evaluate ownership based on equity ownership interests sufficient to provide ''the power to direct or decide issues affecting the entity's management or operations'' (32 CFR 117.11(a)(1)). The interpretation that the interests of two entities with an agreement to act in concert may be combined to establish a controlling interest is similar to concepts in Securities and Exchange Commission rules defining beneficial ownership in instances of shareholders acting in concert (17 CFR 240.13d–5) and CFIUS regulations that consider arrangements to act in concert to determine, direct, or decide important matters affecting an entity as one means by which two or more entities may establish control over another entity (31 CFR 800.208(a)). Different thresholds of control are used in different statutory and regulatory contexts (*see, for example,* 26 U.S.C. 6038(e)(2), (3) (defining control with respect to a corporation to mean actual or constructive ownership by a person of stock possessing more than 50% of the total combined voting power of all classes of stock entitled to vote or 50% of the total value of shares of all classes of stock of a corporation, and control with respect to a partnership to generally mean actual or constructive ownership of a more than 50% capital or profit interest in a partnership); and 26 U.S.C. 368(c) (defining control with respect to certain corporate transactions to mean the ownership of stock possessing at least 80% of the total combined voting power of all classes of stock entitled to vote and at least 80% of the total number of shares of all other classes of stock of the corporation)). However, there are a number of analogous regulatory contexts in which a 25% threshold for considering an entity controlled is used. For instance, the Department of Commerce's CHIPS Rule, implementing a very similar FEOC provision, uses a 25% threshold with respect to voting interest, board seats, or equity interest. The State Department, in its International Traffic in Arms Regulation (ITAR) regulations, established a presumption of foreign control where foreign persons own 25% or more of the outstanding voting securities of an entity, unless one U.S. person controls an equal or larger percentage (22 CFR 120.65). FinCEN's BSA private banking account regulations (31 CFR 1010.605(j)(1)(i)) and Beneficial Ownership Reporting Rule (31 CFR 1010.380(d)) also contain 25% ownership thresholds. *See also* 15 CFR 760.1(c) (defining ''controlled in fact'' using a 25% threshold for cases where no other person controls an equal or larger percentage of voting securities). In some of these other contexts, the 25% calculation is based on a particular form of control (*e.g.,* only voting rights). DOE's interpretation broadens the ways in which an entity can be controlled at a 25% level, because doing so accords with statutory concerns related to the corporate structure of the battery industry.

In response to comments above, DOE also clarified that ''equity interests'' refers to all ownership interests, including capital or profit interests and contingent equity interests. ''Contingent equity interests'' is a defined term in the CFIUS regulations (31 CFR 800.207), and DOE intends for the concept of contingent equity interests in the interpretive rule to be understood largely consistent with the CFIUS regulations. For the purpose of determining FEOC compliance, the amount of the contingent interest that can be reasonably determined, as understood in 31 CFR 800.308(a)(3), should be included in the 25% control calculation, without consideration of whether conversion is imminent or within the control of the equity-owning entity as set forth in 31 CFR 800.308(a)(1–2).

DOE's interpretation of indirect control includes guidance on how to calculate the attenuation of control in a tiered ownership structure. In the case of majority control at any level, that control is not attenuated such that outright ownership (50%+) confers full control. The proposed approach recognizes the reality that a parent entity that holds a majority of the voting rights, equity interests, or board seats in a subsidiary has unilateral control over that subsidiary and can direct that subsidiary's ability to exercise influence and control over its own subsidiaries. However, in the case of multiple tiers of minority control by a government, the actual ability of the government to influence the operations of a subsidiary may become materially attenuated. This understanding of how to calculate a parent entity's indirect ownership and control of sub-entities is similar to OFAC's 50% Rule, under which ''any entity owned in the aggregate, directly or indirectly, 50% or more by one or more blocked persons is itself considered to be a blocked person.'' *See* U.S. Dept. of the Treasury, Revised Guidance on Entities Owned by Persons Whose Property and Interests in Property are Blocked (Aug. 13, 2014).

As previously stated, when calculating whether an entity is a FEOC based on whether the government of a covered nation directly or indirectly holds 25% or more of its voting rights, equity interest, or board seats, DOE's interpretation would not factor in any voting share, equity interest, or board seats held by an entity that is a FEOC solely by virtue of being subject to the covered nation's jurisdiction.

The following scenarios illustrate indirect control in a multi-tiered ownership structure, which could contain more tiers than illustrated here. For simplicity, these examples only evaluate control via voting rights and assume no other relevant circumstances.

1. If Entity A cumulatively holds 25% of Entity B's voting rights, then Entity A directly controls Entity B. If Entity B cumulatively holds 50% of Entity C's voting rights, then Entities B and C are treated as the same entity, and Entity A also indirectly controls Entity C.

○ If Entity A is the government of a foreign country that is a covered nation, Entities B and C are both FEOCs.

2. If Entity A cumulatively holds 50% of Entity B's voting rights, then Entity A is the direct controlling ''parent'' of Entity B, and Entities A and B are treated as the same entity. If Entity B cumulatively holds 25% of Entity C's voting rights, then Entity C is understood to be directly controlled by Entity B and indirectly controlled by Entity A.

○ If Entity A is the government of a foreign country that is a covered nation, Entities B and C are both FEOCs.

3. If Entity A cumulatively holds 25% of Entity B's voting rights, then Entity A directly controls Entity B. If Entity B cumulatively holds 40% of Entity C's voting rights, then Entity B directly controls Entity C. However, because Entity A does not hold 50% of the voting rights of Entity B, and Entity B does not hold 50% of the voting rights of Entity C, Entity A's indirect control

of Entity C is calculated proportionately (25% × 40% = 10%). Based on that proportionate calculation, Entity A will be considered to hold only a 10% interest in Entity C, which is insufficient to meet the 25% threshold for control contemplated under this proposed guidance.

○ If Entity A is the government of a foreign country that is a covered nation, Entity B is a FEOC. But Entity A holds only a 10% interest in Entity C, which is less than the 25% threshold requirement to deem Entity C controlled by Entity A. Therefore, Entity C is not a FEOC via the indirect control of Entity A.

ii. Control via Licensing and Contracting

DOE is concerned that if its interpretation of the term ''control'' covered only direct and indirect holding of board seats, voting rights, and equity interest by the government of a covered nation, then a government may seek to evade application of the rule by instead exercising its control over a FEOC that enters into a license or contract with a non-FEOC entity such that the non-FEOC serves as the producer of record while the FEOC maintains effective control over production. Because such arrangements would defeat congressional intent, DOE's interpretation of ''control'' includes ''effective control'' through contracts or licenses with a FEOC that warrant treating the FEOC as if it were the true entity responsible for any production. DOE's interpretive rule clarifies that ''effective control'' through a license or contract can be exercised by any entity designated as a FEOC, whether through 25% control by the government of a covered nation or through jurisdiction. The proximity of a FEOC to the government of a covered nation, even when the government does not have a controlling stake in the company, raises similar concerns in the context of a license or contract with a non-FEOC, and the non-FEOC should retain the identified rights to avoid effective control by the FEOC.

Many contractual and licensing arrangements do not raise these concerns. Therefore, to provide a reasonably bright-line test for evaluation of battery supply chains that may include numerous contracts and licenses, DOE's interpretation in section V.E of this document contains a safe harbor for evaluation of ''effective control.'' A non-FEOC entity that can demonstrate that it has reserved certain rights to itself or another non-FEOC through contract would not be deemed to be a FEOC solely based on its contractual relationships.

DOE also recognizes that even if an entity's contractual relationship with a FEOC confers effective control over the production of particular critical minerals, battery components, or battery materials, for purposes of determining eligibility for the 30D tax credit and for and DOE's BIL 40207 grant program, the contracting entity would not necessarily be controlled by the government of a covered nation for critical minerals, battery components, or battery materials that were not produced pursuant to that contract or license. Therefore, under the guidance, an entity could be considered a FEOC with respect to the particular critical minerals, battery components, or battery materials that are effectively produced by the FEOC under a contract or license but not with respect to other critical minerals, battery components, or battery materials that are produced by the entity outside the terms of the contract or license with a FEOC.

The concept that an entity can be controlled via contract is supported by choices made in various regulatory contexts, including CFIUS regulations that include an understanding that control can be established via contractual arrangements to determine, direct, or decide important matters affecting an entity (31 CFR 800.208(a)). Further, intellectual property can be licensed restrictively, or even misused, to give the intellectual property owner rights beyond the typical ability to exclude others from making, using, selling, and/or copying the intellectual property for a limited time. In this scenario, even if a non-FEOC entity owns a facility, which is not separately 25% controlled by the government of a covered nation, the facility and/or its operations could still be effectively controlled by a FEOC licensor or contractor through other mechanisms. Accordingly, DOE's definition of effective control identifies criteria that would indicate that a license or contract provides the licensor or contractor with the ability to make business or operational choices that otherwise would rest with the licensee or principal. The criteria selected reflect various known mechanisms in restrictive or overreaching licenses, such as lack of access by the licensee or principal to information and data (*e.g.,* control parameters or specification and quantities of material input for equipment) that are necessary to operate equipment critical to production at necessary quality and throughput levels. This lack of access could be tantamount to the licensor or contractor having effective control over the licensee or principal.

IV. Regulatory Review

DOE considers this guidance to be a final interpretive rule under the Department's authority to interpret section 40207(a)(5) of the Infrastructure Investment and Jobs Act (42 U.S.C. 18741(a)(5)). As an interpretive rule, this rule is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(A)). Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis (5 U.S.C. 603(a), 604(b)).

This interpretive rule is significant guidance under Executive Order 12866 because of the substantial public interest and policy importance with respect to the interpretation of the definition of a FEOC. It also affects a variety of entities and other Federal agencies. This interpretive rule has, thus, been reviewed by the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA).

The Department has determined that this final interpretive rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on the public that would be considered information collections requiring approval by the OMB in accordance with the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Finally, as required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this interpretive rule prior to its effective date. The report will state that OIRA has determined that the rule does not meet the criteria set forth in 5 U.S.C. 804(2).

V. Final Interpretive Rule on the Definition of Foreign Entity of Concern

A. Overview

DOE clarifies the term ''foreign entity of concern'' by providing interpretations for the following terms within BIL section 40207(a)(5)(C) (42 U.S.C. 18741(a)(5)(C)): ''foreign entity;'' ''government of a foreign country;'' ''subject to the jurisdiction;'' and ''owned by, controlled by, or subject to the direction.'' These terms are interpreted separately, recognizing that the terms have unique meaning. DOE also interprets additional terms as necessary to provide clarity.

For DOE's final guidance, an entity is determined to be a FEOC under BIL section 40207(a)(5)(C) if it meets the definition of a ''foreign entity,'' (section V.B of this document) and either is ''subject to the jurisdiction'' of a covered nation government (section V.D of this

document) or is ''owned by, controlled by, or subject to the direction'' (section V.E of this document) of the ''government of a foreign country'' (section V.C of this document) that is a covered nation.

B. Foreign Entity

DOE interprets ''foreign entity'' to mean:

(i) A government of a foreign country;

(ii) A natural person who is not a lawful permanent resident of the United States, citizen of the United States, or any other protected individual (as such term is defined in 8 U.S.C. 1324b(a)(3));

(iii) A partnership, association, corporation, organization, or other combination of persons organized under the laws of or having its principal place of business in a foreign country; or

(iv) An entity organized under the laws of the United States that is owned by, controlled by, or subject to the direction (as interpreted in subsection E) of an entity that qualifies as a foreign entity in paragraphs (i)–(iii).

C. Government of a Foreign Country

DOE interprets ''government of a foreign country'' to mean:

(i) A national or subnational government of a foreign country;

(ii) An agency or instrumentality of a national or subnational government of a foreign country;

(iii) A dominant or ruling political party (*e.g.,* Chinese Communist Party (CCP)) of a foreign country; or

(iv) A current or former senior foreign political figure.

Senior foreign political figure means (a) a senior official, either in the executive, legislative, administrative, military, or judicial branches of a foreign government (whether elected or not), (b) a senior official of a dominant or ruling foreign political party, and (c) an immediate family member (spouse, parent, sibling, child, or a spouse's parent and sibling) of any individual described in (a) or (b). In order to be considered ''senior,'' an official should be or have been in a position of substantial authority over policy, operations, or the use of government-owned resources.

D. Subject to the Jurisdiction

DOE interprets that a foreign entity is ''subject to the jurisdiction'' of a covered nation government if:

(i) The foreign entity is incorporated or domiciled in, or has its principal place of business in, a covered nation; or

(ii) With respect to the critical minerals, components, or materials of a given battery, the foreign entity engages in the extraction, processing, or recycling of such critical minerals, the manufacturing or assembly of such components, or the processing of such materials, in a covered nation.

E. Owned by, Controlled by, or Subject to the Direction

DOE interprets that an entity is ''owned by, controlled by, or subject to the direction'' of another entity (including the government of a foreign country that is a covered nation) if:

(i) 25% or more of the entity's board seats, voting rights, or equity interest, with each metric evaluated independently, are cumulatively held by that other entity, whether directly or indirectly via one or more intermediate entities; or

(ii) With respect to the critical minerals, battery components, or battery materials of a given battery, the entity has entered into a licensing arrangement or other contract with another entity (a contractor) that entitles that other entity to exercise effective control over the extraction, processing, recycling, manufacturing, or assembly (collectively, ''production'') of the critical minerals, battery components, or battery materials that would be attributed to the entity.

Cumulatively held. For the purposes of determining control by a foreign entity (including the government of a foreign country), control is evaluated based on the combined interest in an entity held, directly or indirectly, by all other entities that qualify under the above interpretation of ''foreign entity.'' Additionally, if an entity that qualifies as a ''government of a foreign country that is a covered nation'' enters into a formal arrangement to act in concert with another entity or entities that have an interest in the same third-party entity, the cumulative board seats, voting rights, or equity interests of all such entities are combined for the purpose of determining the level of control attributable to each of those entities.

Indirect control. For purposes of determining whether an entity indirectly holds board seats, voting rights, or equity interest in a tiered ownership structure:

- If a ''parent'' entity (including the government of a foreign country) directly holds 50% or more of a ''subsidiary'' entity's board seats, voting rights, or equity interest, then the parent and subsidiary are treated as equivalent in the evaluation of control, as if the subsidiary were an extension of the parent. As such, any holdings of the subsidiary are fully attributed to the parent.
- If a ''parent'' entity directly holds less than 50% of a ''subsidiary'' entity's board seats, voting rights, or equity interest, then indirect ownership is attributed proportionately.

Section III.E.i of this document, contains multiple examples illustrating how to determine when an entity is indirectly controlled under this interpretive rule.

Effective control means the right of the FEOC contractor, whether the entity is a FEOC via 25% control or via jurisdiction, in a contractual relationship to determine the quantity or timing of production; to determine which entities may purchase or use the output of production; to restrict access to the site of production to the contractor's own personnel; or the exclusive right to maintain, repair, or operate equipment that is critical to production.

In the case of a contract with a FEOC, a contractual relationship will be deemed to not confer effective control to the FEOC if the applicable agreement(s) reserves expressly to one or more non-FEOC entities all of the following rights:

(i) To determine the quantity of critical mineral, component, or material produced (subject to any overall maximum or minimum quantities agreed to by the parties prior to execution of the contract);

(ii) To determine, within the overall contract term, the timing of production, including when and whether to cease production;

(iii) To use the critical mineral, component, or material for its own purposes or, if the agreement contemplates sales, to sell the critical mineral, component, or material to entities of its choosing;

(iv) To access all areas of the production site continuously and observe all stages of the production process; and

(v) At its election, to independently operate, maintain, and repair all equipment critical to production and to access and use any intellectual property, information, and data critical to production, for the duration of the contractual relationship.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notification of final interpretive rule.

Signing Authority

This document of the Department of Energy was signed on April 18, 2024, by Giulia Siccardo, Director, Office of Manufacturing and Energy Supply Chains, pursuant to delegated authority

from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 22, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–08913 Filed 5–3–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF THE TREASURY

Office of Financial Research

12 CFR Part 1610

Ongoing Data Collection of Non-Centrally Cleared Bilateral Transactions in the U.S. Repurchase Agreement Market

AGENCY: Office of Financial Research, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Financial Research (the ''Office'') within the U.S. Department of the Treasury (''Treasury'') is adopting a final rule (the ''Final Rule'') establishing a data collection for certain non-centrally cleared bilateral transactions in the U.S. repurchase agreement (''repo'') market. This collection requires daily reporting to the Office by certain brokers, dealers, and other financial companies with large exposures to non-centrally cleared bilateral repo (''NCCBR''). The collected data will be used to support the work of the Financial Stability Oversight Council (the ''Council''), its member agencies, and the Office to identify and monitor risks to financial stability.

DATES:

Effective date: July 5, 2024.

Compliance Dates: See the amendment to 12 CFR 1610.11(e).

FOR FURTHER INFORMATION CONTACT: Michael Passante, Chief Counsel, Office of Financial Research, (202) 921–4003, *michael.passante@ofr.treasury.gov,* Sriram Rajan, Associate Director of Financial Markets, Office of Financial Research, (202) 594–9658, *sriram.rajan@ofr.treasury.gov,* or Laura Miller Craig, Senior Advisor, Office of Financial Research, (202) 927–8379, *laura.craig@ofr.treasury.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

The Office is adopting the Final Rule to establish an ongoing data collection for certain non-centrally cleared bilateral transactions in the U.S. repo market. The Final Rule will require reporting by certain covered reporters for repo transactions that are not centrally cleared and have no tri-party custodian. The purpose is to enhance the ability of the Council, Council member agencies, and the Office to identify and monitor risks to financial stability. Under the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''), the Office is authorized to issue rules and regulations to collect and standardize data that supports the Council in fulfilling its duties and purposes, such as identifying risks to U.S. financial stability. In a 2022 statement on nonbank financial intermediation, the Council supported a recommendation that the Office consider ways to obtain better data on the NCCBR market segment, and in July 2022 and February 2024, the Office consulted with the Council on efforts to collect NCCBR data.[1]

This collection requires reporting on NCCBR transactions, which currently comprise the majority of repo activity by several key categories of financial companies, such as hedge funds. This collection will provide visibility and transparency into a crucial segment of the U.S. repo market, the one remaining market segment for which transaction-level data is not available to regulators.[2]

Collection of information on the NCCBR segment of the repo market is critical to understanding potential financial stability risks. The data to be collected under the Final Rule will enable the Office to monitor risks in this market. Because the Council's duties relate to monitoring and responding to potential financial stability risks, the collection will support the Office's statutory mandate to support the work of the Council.

The Office issued its Notice of Proposed Rule Making (''NPRM'' or ''proposed rules'') for a 60-day public comment period, ending on March 10, 2023.[3] In response, the Office received more than 30 comment letters conveying a range of perspectives.[4] Although the majority of commenters supported the proposed collection, noting the potential benefits to the monitoring of risks to financial stability, several identified issues that the Office has addressed in the discussion below and, in some cases, through regulatory text changes reflected in the Final Rule. In making these changes, the Office intends to minimize the burden of the Final Rule while ensuring that the purposes of the collection as expressed in the NPRM and below are met.

Since the publication of the NPRM, two new regulations were adopted that are relevant to the Office's collection. The Office believes that one of these will materially affect this collection. On December 13, 2023, the U.S. Securities and Exchange Commission (SEC) adopted rules under the Securities Exchange Act of 1934 (''Exchange Act'') to amend the standards applicable to covered clearing agencies for U.S. Treasury securities. The final rules require that every direct participant of the covered clearing agency submit for clearance and settlement all repo activity collateralized by U.S. Treasury securities to which it is a counterparty (the ''SEC's central clearing rules'').[5] On February 6, 2024, the SEC also adopted new rules to further define the phrase ''as part of a regular business'' as used in the statutory definitions of ''dealer'' and ''government securities dealer.''[6] The Office has considered the likely

[1] Financial Stability Oversight Council Statement on Nonbank Financial Intermediation. February 4, 2022. *https://home.treasury.gov/news/press-releases/jy0587;* Meeting minutes. FSOC, July 28, 2022, page 7; Readout: Financial Stability Oversight Council Meeting on February 23, 2024. *https://home.treasury.gov/news/press-releases/jy2122.*

[2] Hempel, Samuel, R. Jay Kahn, Vy Nguyen, and Sharon Y. Ross. ''Non-centrally Cleared Bilateral Repo.'' OFR Blog. Office of Financial Research. August 24, 2022. *https://www.financialresearch.gov/the-ofr-blog/2022/08/24/non-centrally-cleared-bilateral-repo/.*

[3] Department of the Treasury. *Collection of Non-centrally Cleared Bilateral Transactions in the U.S. Repurchase Agreement Market.* Proposed Rule, 88 FR 1154 (January 9, 2023). *https://www.federalregister.gov/d/2022-28615,* hereafter cited as 88 FR 1154.

[4] Comment letters to the proposed rules may be found at *https://www.regulations.gov/document/TREAS-DO-2023-0001-0001/comment.*

[5] Securities and Exchange Commission. *Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule with Respect to U.S. Treasury Securities.* Final Rule, 89 FR 2714 (January 16, 2024). *https://www.federalregister.gov/d/2023-27860.*

[6] Securities and Exchange Commission. *Further Definition of ''As a Part of a Regular Business'' in the Definition of Dealer and Government Securities Dealer in Connection with Certain Liquidity Providers.* Final Rule, 89 FR 14938 (Feb. 29, 2024). (''Further Definition of 'As a Part of a Regular Business' '') *https://www.federalregister.gov/d/2024-02837.*

impact of these rules on its NCCBR collection, as described below.

II. Background and Description of the Final Rule

The following discussion summarizes the proposed rules, the comments received, and the Office's responses to those comments, including modifications reflected in the Final Rule.

II(a) Structure of the Repo Market and Purpose of the Final Rule

As noted in the NPRM, the collection of data pursuant to this Final Rule will support the Council, its member agencies, and the Office in carrying out their responsibilities through the use of the data to identify and monitor potential financial stability risks in the U.S. repo market.

The repo market can be divided into four segments, which span the different combinations of centrally cleared and non-centrally cleared, tri-party, and bilateral repo.[7] For three of these segments, data are currently collected by regulators. The collection under the Final Rule has been designed to fill a critical gap in regulators' information on the overall repo market by collecting data on the NCCBR segment, the last segment for which regulators do not have a transaction-level data source.

As noted in the NPRM, the need for a collection of data on this segment of the market to assist policymakers' understanding of the repo market has been recognized by the Council since 2016, when it first called for the Office to establish a permanent repo data collection.[8] This lack of visibility was felt acutely following two recent episodes of stress in repo markets. The first of these recent episodes involved a spike in repo market rates in September 2019 and the second a decline in Treasury prices, which spilled over to the repo market through higher rates, in March 2020. For both of these episodes, substantial portions of activity in these crucial funding markets could not be observed. In the wake of these episodes, market participants and the official sector have pointed to this segment as a critical blind spot in a market that plays a key role in financial stability.[9]

Both of these episodes illustrate that the NCCBR market segment may be subject to the systemic vulnerabilities discussed below and perhaps has become even more central to the functioning of U.S. securities and short-term funding markets. Though these vulnerabilities are present to a greater or lesser extent across the four segments of the repo market, certain characteristics of the NCCBR segment may be especially prone to such vulnerabilities and exacerbate the risks in other segments.

II(b) NCCBR Market Segment Characteristics That May Increase Financial Stability Risks

In the NPRM, the Office noted the framework set forth in its centrally cleared repo rule[10] for understanding activity in the overall repo market and the associated vulnerabilities across five functions that repo provides: (1) a low-risk cash investment, (2) monetization of assets, (3) transformation of collateral, (4) facilitation of hedging, and (5) more generally, a support for secondary market liquidity and pricing efficiency.[11]

Certain characteristics of the NCCBR market segment may increase the potential for risks to financial stability relative to other segments. However, data gaps have limited the ability of financial regulators to monitor risks and vulnerabilities in this segment. Additionally, because abrupt changes in these characteristics can have financial stability consequences, addressing data gaps is important.

The NPRM highlighted collateral risk as a key motivation for the collection. The NCCBR market segment generally involves riskier collateral than other repo segments, because centrally cleared markets are limited to Fedwire-eligible collateral, such as Treasuries and agency bonds. Data from the Federal Reserve Bank of New York's Primary Dealer Statistics show that 95% of primary dealer repo lending against non-Fedwire-eligible collateral (including asset-backed securities, corporate debt, and other securities) is conducted through the NCCBR market segment. These collateral types are riskier than Treasury and agency securities. Supported by riskier collateral, the NCCBR market segment may be more exposed to the risks associated with monetizing assets.

The NCCBR market segment also has counterparty complexity that warrants attention. Many counterparties in this market are not as active in the centrally cleared or tri-party repo markets, which are market segments about which more data are available to financial regulators. The NCCBR market segment facilitates a large amount of cash borrowing by highly leveraged entities such as hedge funds.[12] As a result, financial regulators and market participants do not have sufficient information on the overall complexity and extent of hedge funds' daily repo borrowing to assess potential risks. For instance, financial regulators did not have access to sufficient data to understand the risk management practices of Long-Term Capital Management (LTCM).[13] LTCM, a hedge fund that failed in 1998, built up large counterparty exposures through NCCBR.[14] The firm conducted its repo and reverse-repo transactions with 75 different counterparties, many of which were reportedly unaware of the nature of LTCM's total exposure. These large exposures created through repo were a key source of systemic stress from LTCM's failure, as liquidations of the

[7] 88 FR 1154, 1156, citing Kahn, R. Jay, and Luke M. Olson. ''Who Participates in Cleared Repo?'' Brief no. 21–01, Washington, DC: Office of Financial Research, 2021. For more background, see Baklanova, Viktoria, Adam Copeland, and Rebecca McCaughrin. ''Reference Guide to U.S. Repo and Securities Lending Markets.'' Working Paper no. 15–17, Washington, DC: Office of Financial Research, 2015.

[8] Financial Stability Oversight Council. *2016 Annual Report,* page 14, Washington, DC: FSOC, 2016. *https://home.treasury.gov/system/files/261/FSOC-2016-Annual-Report.pdf.*

[9] Logan, Lorie K. ''Treasury Market Liquidity and Early Lessons from the Pandemic Shock.'' Remarks, Brookings-Chicago Booth Task Force on Financial Stability Meeting, 2020; International Monetary Fund. 2020. ''United States: Financial Sector Assessment Program Technical Note: Risk Oversight and Systemic Liquidity;'' Liang, Nellie, and Pat Parkinson. ''Enhancing Liquidity of the U.S. Treasury Market Under Stress.'' Working Paper no. 72, Washington, DC: Brookings Hutchins Center on Fiscal and Monetary Policy, 2020; BlackRock. 2020. ''Lessons from COVID–19: Market Structure Underlies Interconnectedness of the Financial Market Ecosystem.'' BlackRock ViewPoint; Bank Policy Institute. 2020. ''Necessary Dimensions of a Holistic Review of the Meltdown of U.S. Bond Markets in March;'' Citadel Securities. 2021. ''Enhancing Competition, Transparency, and Resiliency in U.S. Financial Markets;'' Feldberg, Greg. ''Fixing Financial Data to Assess Systemic Risk.'' Brookings Economic Studies, 2020; Brookings Hutchins Center on Fiscal and Monetary Policy. 2021. ''Report of the Task Force on Financial Stability.''

[10] Department of the Treasury. *Ongoing Data Collection of Centrally Cleared Transactions in the U.S. Repurchase Agreement Market.* Final Rule, 84 FR 4975 (Feb. 20, 2019). *https://www.federalregister.gov/d/2018-14706.*

[11] 88 FR 1154, 1157. *https://www.federalregister.gov/d/2022-28615.*

[12] Hempel, Samuel, R. Jay Kahn, Vy Nguyen, and Sharon Y. Ross. 2022. ''Non-centrally Cleared Bilateral Repo.'' August 24, 2022. The OFR Blog. Office of Financial Research. *https://www.financialresearch.gov/the-ofr-blog/2022/08/24/non-centrally-cleared-bilateral-repo/.*

[13] ''Long-Term Capital Management: Regulators Need to Focus Greater Attention on Systemic Risk: Report to Congressional Requesters,'' United States. General Accounting Office, 1999.

[14] Parkinson, Patrick M. ''Report on Hedge Funds, Leverage, and the Lessons of Long-Term Capital Management. Testimony, U.S. House, May 6, 1999, Congress, Washington, DC: Federal Reserve Board, 1999. *https://www.federalreserve.gov/boarddocs/testimony/1999/19990506.htm;* Dixon, Lloyd, Noreen Clancy, and Krishna B. Kumar. 2012. *Hedge Funds and Systemic Risk.* Santa Monica, California: RAND Corporation. *http://www.jstor.org/stable/10.7249/j.ctt1q60xr.11.*

underlying collateral in bankruptcy could have resulted in significantly depressed prices and broader market disruptions.[15] While transparency into other segments of the repo market has increased since 1998, the NCCBR market segment has remained opaque.

NCCBR market participants engage in varying risk management conventions, but insufficient information regarding these conventions is available to enable an assessment of their efficacy. These conventions include, but are not limited to, margining and settlement practices. For instance, the variation in margining practices across competing intermediaries may create competitive pressures that drive margins to lower levels than what prudent risk management would indicate.[16] There may also exist widely subscribed margining practices which could exacerbate financial stability vulnerabilities in times of stress. For instance, the cross-margining of repo, derivatives, and futures exposures could result in lower precautionary risk buffers, even in the presence of leverage, than if cross-margining practices were not in place. In times of stress, inadequate margins may be insufficient to buffer payment failures between firms and can result in consequential financial contagion. Additionally, risks exist in relation to operational aspects of the transaction lifecycle. For instance, the Treasury Market Practices Group found that settlement practices vary widely and expressed concern that ''bespoke bilateral processes may reflect differences in the level of understanding among market participants of the inherent risks of Securities Financing Transaction (SFT) clearing and settlement.'' [17] Collectively, NCCBR risk management concerns interrelationships between firms within this and other markets and spans risks that are not uniquely contained in the NCCBR segment.

Activity across the different segments of the repo market is linked. For example, the NCCBR market segment can serve as a close substitute for centrally cleared bilateral repo. This is particularly the case in the sponsored segment of the market for customers that are not direct clearing members of the Fixed Income Clearing Corporation (FICC), a subsidiary of the Depository Trust & Clearing Corporation, such as hedge funds and money market funds. These customers can participate in transactions with clearing members and have such transactions submitted to FICC for central clearing. As a result, migration to and from sponsored repo is also an area of interest for regulators concerned with a proper assessment of dealer balance sheets. Activity may move between sponsored repo and NCCBR in times of stress or in response to incentives created by financial reporting dates. Dealers' decisions to transact in NCCBR or in sponsored repo may also be affected by factors that affect the degree to which various constraints are binding for the dealers, including regulatory ratios and counterparty credit limits. Examples of these factors include changes in the supply of cash to the repo market from money market funds and the netting benefits provided by sponsored repo. To understand these shifts between NCCBR and sponsored repo, data on outstanding commitments in the NCCBR market segment are required.

The development of guaranteed repo is another factor that may affect flows between NCCBR and sponsored repo. A guaranteed repo is a repo in which the performance of one or both counterparties are guaranteed by a third-party guarantor. This is typically, but not exclusively, used to account for potential variation in value of the collateral provided by the cash borrower. Because guaranteed repo replicates the profile of offsetting legs of the same repo transaction with different counterparties yet has different balance sheet implications, guaranteed repo may be an alternative to sponsored repo. Since guaranteed repos would represent a similar exposure to offsetting repo transactions, it is essential to include these activities in this collection to gain a full understanding of the NCCBR segment of the repo market.

In addition to the specific data gaps noted above, because the NCCBR market segment has no central counterparty or tri-party custodian and due to the lack of transparency, lack of standardized risk management practices, the presence of riskier collateral underlying some trades, and counterparties with large exposures in the market, these data will provide insights into potential financial system vulnerabilities.[18] Many of the counterparties involved in the NCCBR segment, such as non-banks and non-primary dealers, are difficult to monitor with existing regulatory collections. Transaction-level data will provide the official sector with the granularity necessary to understand the exposures of market participants on a high-frequency basis. This is essential in a market where monthly or quarterly reporting may not provide timely indications of future stress or provide detailed data on recent periods of stress. Additionally, data on collateral will enable regulators to monitor exposures to particular classes of securities, margining practices that protect participants from fluctuations in collateral values, and the potential transmission of stress from the repo markets to securities markets or other markets. Timestamps and details of trading venues will allow regulators to monitor activity in a market that is often segmented and in which intraday liquidity concerns can play a key role in the creation or propagation of stress.

Thus, the collection of transaction-level data on the NCCBR segment of the repo market marks a significant step in carrying out the Council's recommendation to expand and make permanent the collection of data on the U.S. repo market.[19] It will assist the Council's effective identification and monitoring of emerging threats to the stability of the U.S. financial system by closing the remaining gap in coverage of the U.S. repo market, following the Office's previous rulemaking on the centrally cleared repo market. By collecting data from certain brokers, dealers, and other financial companies with more than $10 billion in extended guarantees and outstanding NCCBR cash borrowing, the Office initially expects to observe more than 90% of NCCBR transactions by volume, with approximately 40 covered reporters in Category 1 (as discussed below) expected at the time of publication of the Final Rule.

II(c) Effects of Recent Regulations on the Office's Collection

On December 13, 2023, the SEC adopted a final rule on central clearing in the U.S. Treasury market, and on February 12, 2024, the SEC adopted a

[15] Parkinson, Patrick M. ''Report on Hedge Funds, Leverage, and the Lessons of Long-Term Capital Management.'' Testimony, U.S. House, May 6, 1999, Congress, Washington, DC: Federal Reserve Board, 1999.

[16] See also Group of Thirty Working Group on Treasury Market Liquidity. *U.S. Treasury Markets: Steps Toward Increased Resilience.* Washington, DC: Group of Thirty, G30, 2021, which notes that competitive pressures in the repo market can often ''drive haircuts down (sometimes to zero).''

[17] Treasury Market Practices Group. ''TMPG Releases Updates for Working Groups on Clearing and Settlement Practices for Treasury SFTs, Treasury Market Data and Transparency.'' Press Release, November 5, 2021: TMPG. *https://www.newyorkfed.org/medialibrary/Microsites/tmpg/files/PressRelease_110521.pdf.*

[18] Schulhofer-Wohl, Sam; McCormick, Matthew. 2022. ''Expanded central clearing would increase Treasury market resilience.'' Dallas Fed Economics, December 23, 2022. *https://www.dallasfed.org/research/economics/2022/1223.*

[19] Financial Stability Oversight Council. 2016 Annual Report, page 14, Washington, DC: FSOC, 2016. *https://home.treasury.gov/system/files/261/FSOC-2016-Annual-Report.pdf.*

final rule expanding dealer registration. This section discusses the effects of these rules on the Office's collection under the Final Rule.

II(c)(1) SEC's Central Clearing Rules

The SEC's central clearing rules, adopted December 13, 2023, are designed to facilitate additional clearing of transactions involving U.S. Treasury securities. The rules require covered clearing agencies in the U.S. Treasury market to require that any direct participant of such covered clearing agency submit for clearance and settlement all the eligible secondary-market transactions to which the direct participant is a counterparty.[20] The compliance date for the SEC's requirements for the central clearing of repo transactions is June 30, 2026. After that date, the Office anticipates that a large portion of Treasury repo transactions will migrate from the NCCBR segment to the centrally cleared segments.

The Office has considered the effect of the SEC's central clearing rules on the riskiness of transactions that will remain in the NCCBR segment, the size of the NCCBR segment, the Office's coverage of the NCCBR segment, and the Office's coverage of repo transactions overall.

The Office expects transparency and financial stability of the repo market to improve following the implementation of the SEC's central clearing rules. However, the Office's collection will continue to be essential for monitoring a substantial portion of the riskiest trades in the repo market and will provide visibility into a segment that may grow and change in response to future developments.

Impact on the riskiness of NCCBR transactions: One reason that the collection of data from the NCCBR segment will remain important is that this segment will retain substantially all of the risks described above. While Treasury repo trades by financial companies that are members of covered clearing agencies will largely be centrally cleared as a result of the SEC's central clearing rules, the remaining trades will likely be riskier, such as those backed with lower-quality collateral or those with smaller, riskier financial companies that currently cannot be members of clearing agencies. Because the FICC is limited to Fedwire-eligible collateral, considerable volume in the NCCBR segment is backed by collateral that is generally considered to be riskier, such as private-label asset backed securities (ABS) and corporate debt.[21] [22] This collateral will comprise a larger share of the NCCBR segment after the migration of Treasury repo to central clearing. Similarly, the FICC imposes certain limits on direct membership that ensure only sounder counterparties can become direct and sponsoring members. Thus, after the SEC's central clearing rules are fully implemented, the remaining trades in the NCCBR segment will generally be conducted by riskier counterparties.

Impact on the size of the NCCBR segment: The Office expects the size of the NCCBR segment to shrink significantly when most Treasury -collateralized repo activity moves to central clearing. Although there is uncertainty associated with the effect of the SEC's central clearing rules on the structure of the repo market, the Office expects the rules to change the scope of the transactions reported under the Final Rule due to the reduction in the total volume of transactions in the NCCBR segment. In the NPRM, the Office estimated that the proposed rules' coverage of the NCCBR segment would be greater than 90%; using the same methodology, this segment coverage would decline to 75% after implementation of the SEC's central clearing rules.

However, because the NCCBR segment will materially change following full implementation of the SEC's central clearing rules, different estimation methodologies might be warranted. Accordingly, the Office developed two additional estimates. The first estimate assumes that all Treasury-collateralized repo activity moves into central clearing following full implementation of the SEC's central clearing rules. The second estimate assumes a modest amount of Treasury-collateralized repo remains in NCCBR. Certain exemptions to the SEC's central clearing rules make this modest amount realistic, as discussed below.

In the first estimate, the collection would cover 56% of the remaining NCCBR segment volume. The Office believes that this scenario is unlikely because it assumes that all Treasury repo will migrate to central clearing. In the second estimate, the collection would cover 75% of NCCBR volume if as little as 15% of the Treasury volume remains in the NCCBR segment. The assumption that 15% of volume remains is reasonable because certain Treasury-collateralized repo transactions are exempt from the SEC central clearing rules, including certain inter-affiliate trades. The Office's 2022 NCCBR pilot data collection suggests that the percentage of total NCCBR trading volume that is inter-affiliate may be much greater than 15%.

In addition, other Treasury repo transactions may be exempt from central clearing because they are not allowed under the FICC's sponsored clearing model. For example, trades with embedded optionality, such as open repos, are not allowed in sponsored repo, and it is uncertain how many of those trades will remain in the NCCBR segment after full implementation of the SEC's central clearing rules. Exceptions to the SEC's central clearing rules could therefore result in the collection covering more than 75% of the remaining NCCBR volume.

Under these two estimates, the NCCBR market segment would shrink from $2.3 trillion daily outstanding volume as of Q4 2021 to between roughly $300 billion and $600 billion daily outstanding volume. Although this will be a significant reduction in the size of the NCCBR segment, the Office believes a market of this size is large enough to warrant continued monitoring in light of the risks particular to this segment, as highlighted above and considered further below. A number of multibillion-dollar market segments are important to financial stability and are subject to reporting. For example, the Office currently collects information on the centrally cleared tri-party segment of the market, conducted under FICC's General Collateral Finance (GCF) Repo Service, which had $450 billion outstanding on January 22, 2024. While the GCF segment is similar in magnitude to what the Office projects for the NCCBR collection subsequent to the implementation of the SEC's central clearing rules, collateral quality is much lower in the NCCBR segment, because GCF is limited to Treasury and agency collateral. Further, counterparty risk in NCCBR is higher both because of the presence of a central counterparty in

[20] The definition of the term ''eligible secondary market transaction'' lists certain transactions that may be excluded from central clearing. Two notable exclusions are inter-affiliate trades and trades in which the direct member is a facilitator or agent rather than a direct counterparty. 89 FR 2829, *https://www.federalregister.gov/d/2023-27860.*

[21] For more detailed information on the use of non-Treasury collateral in the NCCBR market segment, see Baklanova, Caglio, Cipriani, and Copeland. ''The Use of Collateral in Bilateral Repurchase and Securities Lending Agreements.'' Federal Reserve Bank of New York Staff Reports, no. 758, 2016: *https://www.newyorkfed.org/medialibrary/media/research/staff_reports/sr758.pdf;* Hempel, Kahn, Paddrik, and Mann. 2023. ''Why is so much Repo Not Centrally Cleared?'' Brief no. 23–01, Washington, DC: Office of Financial Research, May 12, 2023: *https://www.financialresearch.gov/briefs/2023/05/12/why-is-so-much-repo-not-centrally-cleared/.*

[22] FICC is currently the sole provider of clearance and settlement services for U.S. Treasury securities.

GCF and because FICC imposes limits on direct membership.

Additionally, although the sizes of exposures to the NCCBR segment are likely to be smaller once the SEC's central clearing rules are implemented, exposures of this scale can still pose risks to financial stability. For example, the Council's Hedge Fund Working Group found that the failure of Archegos Capital, which had approximately $30 billion in capital borrowed through total return swaps that are in many ways similar to NCCBR transactions, ''transmitted material stress to large, interconnected financial institutions.'' [23]

Impact on the collection's coverage of the NCCBR segment: As stated above, the Office expects that the collection will cover between 56% and 75% of the transaction volume that remain in the NCCBR market segment. Because overall volumes in the NCCBR segment will decrease, the Office also expects the number of covered reporters to decrease. The Office estimates the number of covered reporters to decrease from 40 to 6 to 15, respectively, under the two estimates described above.

Notwithstanding these changes, the Office believes collecting this data remains important. The remaining entities in this market will continue to be the largest participants in the repo market, and this market will still make up a material portion of their balance sheets, so capturing this exposure will be important for monitoring how financial stress in the NCCBR segment might spill over into the other segments of the repo market. The Office continues to view the $10 billion exposure threshold as a reasonable size for a financial company to be considered material in this segment and notes that although the NPRM included a question on this threshold, no commenters expressed concern with this number. Additionally, the Office believes that reporting by Category 1 and Category 2 covered reporters (as discussed below) with exposures above this threshold will provide material coverage of the NCCBR segment to monitor risks without imposing undue reporting burdens on the industry.

As further support for maintaining the $10 billion materiality threshold proposed in the NPRM, the Office notes that even exposures below the $10 billion threshold can have financial stability consequences, especially in short-term funding markets such as the repo market where run risk is present. For instance, the run on the Reserve Primary Fund, a money market mutual fund that failed to redeem investors at the $1.00 net asset value per share in September 2008 following the collapse of Lehman Brothers, was triggered by the fund's exposure to $785 million of commercial paper issued by Lehman Brothers. This exposure was far less than the Office's aggregate repo cash borrowing threshold of $10 billion in NCCBR, yet the Reserve Primary Fund contributed materially to a crisis of confidence in the financial system. The risks were illustrated by a 2013 study that found an additional 20 money market mutual funds faced par redemption challenges similar to the Reserve Primary Fund during the same week.[24] While those money market mutual fund exposures may have varied, the financial instability resulted from a source much smaller than the materiality threshold in the Final Rule.

Impact on the Office's overall coverage of the repo market: The combination of the SEC's central clearing rules and the Office's NCCBR data collection will significantly improve visibility into transactions that currently take place in the NCCBR segment. While the SEC's rules will have the effect of channeling more Treasury repo transactions into central clearing, the Office's Final Rule will cover data gaps that currently exist and could develop in NCCBR. Additionally, the Final Rule will provide transparency with respect to potential future market changes. An example of such a change is guaranteed repo, which could emerge as an alternative to centrally cleared repo. The Final Rule will provide insight into any changes in the size of the NCCBR market segment. Further, the Final Rule will provide transparency into repo activity involving collateral that is not eligible for central clearing. Therefore, after the implementation of the SEC's central clearing rules, the NCCBR collection will continue to fill a critical data gap because without the collection, regulators would have limited insight into risks in this segment.

II(c)(2) SEC's Expansion of Dealer Registration Requirements

On February 6, 2024, the SEC adopted new rules to further define the phrase ''as a part of a regular business'' as used in the statutory definitions of ''dealer'' and ''government securities dealer.'' [25] These new rules could affect the collection under the Final Rule because, as described in the NPRM and below, registered dealers and government securities dealers are subject to the requirement to report their transactions to the Office if their NCCBR activity exceeds the materiality threshold in the Final Rule. While the SEC's recent amendments will expand the population of dealers and government securities dealers, those changes are unlikely to expand the number of NCCBR covered reporters at this time, because companies that are newly defined as dealers or government securities dealers are unlikely to pass the materiality threshold in the Final Rule. The Office expects that substantially all newly registered dealers and government securities brokers and dealers will be either principal trading firms (PTFs) or hedge funds employing high-frequency trading (HFT) strategies. In both cases, these firms employ strategies that involve rapid trading throughout the day, matching buyers and sellers, and exploiting spreads between bid and ask prices. For firms that do not carry significant inventories, like some PTFs or HFTs, participation in repo is likely negligible since they have no inventories to fund. As a result, the Office expects that few, if any, of the additional firms registering as dealers or government securities dealers under the SEC's recent amendments will be subject to NCCBR reporting, so the implementation of these SEC rules should have limited effect on the NCCBR collection.

II(d) Uses of the Data Collection

The data to be collected pursuant to the Final Rule will be used by the Office to fulfill its purpose, responsibilities, and duties under Title I of the Dodd-Frank Act, including improving the Council's and Council member agencies' monitoring of the financial system and identification and assessment of potential financial stability risks. The data reported in this collection will facilitate the identification and evaluation of potential repo market vulnerabilities and trends that could be destabilizing or indicate stresses in the financial system. For example, risks might be reflected in indicators of the volume or cost of funding in the repo market, differentiated by the type and credit quality of participants, quality of underlying collateral, and tenor of

[23] Financial Stability Oversight Council Press Release, February 4, 2022: *https://home.treasury.gov/news/press-releases/jy0587* (accessed January 24, 2024).

[24] McCabe, P.E., Cipriani, M., Holscher, M. and Martin, A., 2013. ''The Minimum Balance at Risk: A Proposal to Mitigate the Systemic Risks Posed by Money Market Funds.'' Brookings Papers on Economic Activity, 2013(1), pages 211–278.I think.

[25] Further Definition of 'As a Part of a Regular Business,' 89 FR 14938. *https://www.federalregister.gov/d/2024-02837*.

transactions. Analyzing the collateral data from this collection together with other available data will enable a clearer understanding of collateral flows in securities markets and associated potential financial stability risks.

One use of the data will be to monitor the transition between the time that the NCCBR collection commences and when, under the SEC's central clearing rules, certain Treasury repo trades will be required to migrate to central clearing.[26] The NCCBR collection will provide contemporaneous information to regulators and policymakers on the progress of market participants in moving to central clearing. Because the SEC's central clearing rules will involve significant changes in market structure and there is uncertainty regarding how markets will respond to its implementation, this information on progress and risks associated with the transition will be invaluable.

The Office may also use the data to sponsor and conduct additional research. This research may include using these data to help fulfill the Office's duties and purposes under the Dodd-Frank Act relating to the responsibility of the Office's Research and Analysis Center to support the Council.[27] For example, access to data on NCCBRs will allow the Office to conduct research related to the Council's monitoring of potential risks arising from securities financing activities and nonbank financial companies.

As noted in the NPRM, and consistent with the Dodd-Frank Act, the Office may share the data collection and information with the Council, Council member agencies, and the Bureau of Economic Analysis and will also make the data available to the Council and member agencies as necessary to support their regulatory responsibilities. The NPRM also noted that data and information shared as described above must be maintained with at least the same level of security as used by the Office and may not be shared with any individual or entity without the permission of the Council. Such sharing will be subject to the confidentiality and security requirements of applicable laws, including the Dodd-Frank Act.[28] Pursuant to the Dodd-Frank Act, the submission of any non-publicly available data to the Office under this collection will not constitute a waiver of or otherwise affect any privilege arising under federal or state law to which the data or information is otherwise subject.[29]

After consulting with Council member agencies as consistent with the Dodd-Frank Act, the Office further advised in the NPRM that certain data, including aggregate or summary data from this collection, may be provided to financial industry participants and the general public to increase market transparency and facilitate research on the financial system. In doing so, it is important that intellectual property rights are not violated, business confidential information is properly protected, and the sharing of such information poses no significant threats to the U.S. financial system.[30]

Commenters identified concerns about data privacy and security, anonymization, and aggregation of the data when disclosing data as described above. One commenter encouraged the Office to require in the Final Rule that data be anonymized and aggregated prior to being disclosed to the public. One commenter stated that anonymization and aggregation of publicly reported data was required to prevent covered reporters from violating privacy regulations or contractual confidentiality terms. Other commenters indicated that disclosure of data not anonymized or aggregated could lead to negative effects for markets and market participants and depending on the timing and nature of the disclosure, disclosure of even aggregate repo transactions could inadvertently reveal proprietary information of financial companies. One comment letter recommended that the Office consult in advance with market participants regarding the timing and granularity of any disclosure. Another commenter recommended that public disclosure occur after two business days from the date of the report.

The Office reiterates that data will be available to the public and financial industry participants only to the extent that intellectual property rights are not violated, business confidential information is properly protected, and the sharing of such information poses no significant threats to the U.S. financial system.[31] The Office further confirms that it will not disclose raw data to the public and that any work product disclosed to the public will consist only of anonymized, aggregated, or otherwise masked data.

One comment letter requested that the Office clarify how it will anonymize the aggregated data for public reporting. The Office employs a number of techniques to protect underlying raw data from public disclosure, including the use of anonymization, summaries, aggregation, masking, compliance with applicable data security and privacy laws, and compliance with internal review and approval protocols designed to protect the underlying data from public disclosure.

One commenter recommended that when sharing data from the collection with other regulators, the Office should make clear that the information is confidential and subject to all applicable laws and regulations regarding subsequent sharing of the information. The commenter also recommended that Office employees and consultants be subject to additional confidentiality requirements regarding the use or dissemination of data collected under the Final Rule. Another comment letter requested that the Office specify any IT security protocols that will be used to guarantee the security of the data that will be collected. The Office has a statutory responsibility to ensure that data collected by the Office is kept securely and protected from unauthorized disclosure; and data shared with other regulatory agencies must be maintained with at least the same level of security as is used by the Office.[32] Additionally, for purposes of preventing unauthorized access to data or loss of data, the Federal Information Security Modernization Act of 2014 (FISMA) requires that federal agencies, including the Office and federal regulatory agencies, provide information security protections commensurate with the risk and magnitude of harm resulting from unauthorized access, use, or disclosure of information collected by or on behalf of an agency. The information collected pursuant to the Final Rule will be handled in accordance with the Office's data access, security, and control policies and procedures. The Office will comply with applicable privacy and data protection laws and regulations, including but not limited to FISMA, and will require that any regulatory agencies that receive business confidential information utilize appropriate confidentiality and security protocols in

[26] The Final Rule requires that a ''covered reporter whose volume falls below the $10 billion threshold for at least four consecutive calendar quarters would have its reporting obligations cease.'' As a result, the Office expects to collect data from approximately 40 reporters until as late as June 2027, 12 months after the SEC's June 30, 2026, compliance date for central clearing of Treasury repo trades.

[27] 12 U.S.C. 5344(c) discusses the various uses of data by the Office's Research and Analysis Center, and 12 U.S.C. 5344(b) discusses the duties of the Office's Data Center, on behalf of the Council.

[28] 12 U.S.C. 5343(b), 5344(b)(3).

[29] 12 U.S.C. 5322(d)(5).

[30] 12 U.S.C. 5344(b)(6).

[31] 12 U.S.C. 5344(b)(6).

[32] 12 U.S.C. 5343(b)(1) and 12 U.S.C. 5344(b)(3).

compliance with FISMA and other applicable laws.

III. Collection Design

The regulatory text lists the requirements specifically relevant to this collection. This includes a table describing the data elements that covered reporters will be required to submit. As outlined below, the Office is publishing reporting instructions and technical guidance on the Office's website regarding matters such as data submission mechanics and formatting in connection with the Final Rule.

III(a) Scope of Entities

The Final Rule establishes the scope of entities subject to reporting. Specifically, reporting is required by financial companies (as defined in the Final Rule) that fall within either of two categories:

- *Category 1:* a securities broker, securities dealer, government securities broker, or government securities dealer whose average daily outstanding commitments to borrow cash and extend guarantees in NCCBR transactions with counterparties over all business days during the prior calendar quarter is at least $10 billion,[33] and
- *Category 2:* any financial company that is not a securities broker, securities dealer, government securities broker, or government securities dealer and that has over $1 billion in assets or assets under management, whose average daily outstanding commitments to borrow cash and extend guarantees in NCCBR transactions, including commitments of all funds for which the company serves as an investment adviser, with counterparties that are not securities brokers, securities dealers, government securities brokers, or government securities dealers over all business days during the prior calendar quarter is at least $10 billion.

The Office intends to consider a financial company to have assets or assets under management exceeding $1 billion if the company meets one or more of the following criteria:

- if the firm is an investment adviser registered pursuant to the Investment Advisers Act of 1940 provides continuous and regular supervisory or management services to securities portfolios valued in the aggregate at $1 billion or more in assets under that law;
- if the firm files a required disclosure of its balance sheet with a federal or state financial regulator and has more than $1 billion in assets under any such disclosure;
- if the firm discloses its assets to investors or creditors in audited financial statements, and has more than $1 billion in assets under that disclosure;
- if the firm has disclosed assets in filings with the Internal Revenue Service and has more than $1 billion in assets under that disclosure.

As noted in the NPRM, the Office distinguishes between assets and assets under management in the criteria above in light of the manner in which an agent acts on the part of other parties. Investment advisers provide investment management services as fiduciaries, using a wide variety of models and vehicles. They engage in activities such as entering into repo, acting as cash borrowers, and buying and selling derivatives on behalf of clients. These activities can take place at the managed fund or portfolio level or at the adviser level with the resulting trades subsequently allocated to their managed funds or portfolios. Unlike other financial companies, the value of these assets is not fully reflected on the balance sheet of the adviser. As a result, the use of assets under management better represents the market value of investment activities provided and should be used in the threshold computation.

The Office received several comments relating to investment advisers within the framework of the proposed rules. One commenter stated that reporting by an investment adviser based on its aggregate assets under management is inappropriate, as investment advisers merely execute investment strategies on behalf of their managed funds, with each fund having an individualized strategy that may include repo transactions. It further stated that trading of fund assets and positions is never executed with the adviser as the principal obligor, but rather must be allocated to the appropriate fund as the principal obligor. The commenter suggested that the Office instead use the assets under management of individual funds since, notwithstanding any execution of trades on a bunched or similar basis, each individual fund is the principal obligor, and the investment adviser must act consistent with each fund's investment strategy. As the commenter acknowledged, trading may be executed on a bunched basis across multiple funds to obtain consistent pricing for each fund with allocation to individual funds to follow, consistent with the Office's stated reasoning for aggregating assets across funds in the calculation of assets under management. These transactions are conducted on the adviser level, and the Office believes that limiting the threshold calculation to individual funds would lead to an incomplete picture of the repo market, because the data would no longer contain the necessary context for determining the financial stability risks implied by an investment adviser's transactions. For example, margining practices are a risk the collection may be used to monitor. Since haircuts are a transaction term often negotiated at the level of the investment adviser, it is important to have the full set of transactions negotiated with a given haircut to assess the riskiness of margining practices. For these reasons, the Office does not consider the issue of principal obligor status to be important for the purposes of this type of monitoring.

Another commenter asserted that investment advisers to private funds are already subject to significant oversight and compliance obligations and, in the context of systemic risk, report extensive information on Form PF regarding collateral and counterparty exposures, among other information. They also stated that the scope of entities covered by the proposed rules would result in duplicative and costly reporting requirements on investment advisers, which, in turn, would dilute the quality of the data reported and increase costs to funds' investors. However, although investment advisers may be subject to other oversight and compliance obligations as noted in the NPRM, based on its review of existing data collections, the Office has found no other transaction-level, daily collection of this data. Moreover, commenters on the NPRM did not identify a duplicative data collection at this level of granularity and frequency that would otherwise enable the Office adequately to monitor financial stability risks in this market.

Another commenter similarly suggested that registered investment advisers (RIAs) be excluded from eligibility for Category 2 reporting, and that Category 1 be extended to include banking entities. The commenter stated that if Category 1 were to be extended in such a manner, an RIA would be unlikely to undertake covered transactions with a financial company that was not in Category 1, and as a result, the inclusion of RIAs in Category 2 would be redundant. It also asserted that if Category 1 were not extended to include banking entities, the potential for an RIA to become subject to Category

[33] The terms broker and dealer are defined in 15 U.S.C. 78c(a)(4) and (5), respectively. Broker and dealer registration requirements are contained in 15 U.S.C. 78o. The terms government securities broker and government securities dealer are defined in 15 U.S.C. 78c(a)(43) and (44), respectively. Government securities broker and government securities dealer registration requirements are contained in 15 U.S.C. 78o–5.

2 reporting could lead to Category 2 entities generally preferring to transact with Category 1 entities (where this does not impact the price at which they transact), leading to distortions. Accordingly, it suggested that excluding RIAs from Category 2 would not ultimately reduce the effectiveness of the Office's data collection. However, this commenter provided no data to support this assertion, and the Office sees such concerns about trading preferences as speculative in nature. In relation to this commenter's proposal to extend the definition of Category 1 covered reporters, the Office has declined to add banking entities to the enumerated categories of entities contained in Category 1, as discussed below. Additionally, given the gaps in visibility into this market, the risks from leveraged funds that are operated by RIAs, and the potential for future developments in this market that shift activity away from traditional intermediaries, the Office continues to view the collection of data from RIAs as essential to its ability to effectively monitor financial stability risks.

Several commenters stated that inter-affiliate repo transactions should not be required to be reported and should not count toward the Category 1 and Category 2 covered reporter thresholds. One commenter noted that inter-affiliate transactions occur for operational reasons, and another commenter noted that these transactions are typically risk transfers with no market impact. They additionally suggested that data on transactions between affiliates would not be useful for understanding the repo market. The Office believes that reporting on these trades can provide insight into the fragilities and sources of financing within entities and between financial companies. Additionally, in contrast to the views expressed by the commenters, recent research shows that transactions between affiliates can play an important role in repo markets.[34] Information on these transactions is important for risk monitoring purposes. For instance, large transfers of cash from banks to affiliated dealers can indicate decreasing liquidity for dealers that could be an early warning indicator of stress. Another example of inter-affiliate transactions that are important to monitor from a financial stability perspective are those in which broker-dealers engage in centrally cleared trades on behalf of affiliated asset managers and then conduct back-to-back non-centrally cleared legs between the broker-dealers and the affiliated asset managers. While one commenter stated that collecting data on these types of transactions would be duplicative of information already collected by FICC, it is in fact an example of the importance of collecting inter-affiliate transactions, because exposures to repo would be incorrectly attributed to broker-dealer affiliates instead of asset managers without data on this back-to-back leg. As the Office's intention is to collect information on the full scope of financial activity in repo markets and inter-affiliate transactions are valuable for financial stability monitoring, inter-affiliate transactions are to be considered when calculating Category 1 and Category 2 reporting thresholds and should be reported.

Another commenter suggested that other categories of potential covered reporters be removed from the rules' coverage. The commenter stated that subjecting buy-side entities, such as advisers of private funds that predominantly enter into transactions with financial intermediaries like broker-dealers or banks or their affiliates, to reporting would be unwarranted. The Office understands that, at present, the majority of NCCBR transactions involving private funds, funds managed by RIAs, and other buy-side entities is likely conducted with Category 1 counterparties. However, as noted in the NPRM, without a comprehensive collection, the extent of transactions without a Category 1 counterparty is not knowable. Additionally, even if today it is unlikely that an investment adviser, adviser to a private fund, or other buy-side financial company would undertake a transaction with a non-Category 1 financial company, the NPRM explicitly noted the Office's intention to cover potential future changes in repo market structure. These may include peer-to-peer repo that bypasses Category 1 financial companies.

Another commenter suggested that money market funds and mutual funds be exempted from reporting because such funds do not generally enter repo transactions in the role of borrower and are unlikely to have outstanding commitments to borrow cash in the bilateral repo markets that meet the reporting threshold. The Office agrees that money market funds are generally unlikely to borrow cash in repo markets and generally do not play roles resembling intermediaries in these markets, and the Office does not generally expect money market funds to fall within the scope of Category 1 or Category 2. However, mutual funds have been known to borrow in repo markets. To the extent an adviser for mutual funds may manage a number of investment vehicles or relationships that in the aggregate could exceed the reporting threshold, including them in the data collection would enhance the ability of the collection to provide information regarding run risks and liquidity risks.[35]

Several commenters suggested that the Office add banks to the set of financial companies covered by Category 1. One commenter stated that while U.S. broker-dealers represent a significant proportion of market activity, sizable positions are also maintained by foreign and domestic banks, including U.S. branches of foreign banks. Another commenter stated that there would be duplicative reporting from asset managers and funds if banks are included in Category 1. The Office has attempted in the structure of the Final Rule to limit duplicative reporting by financial companies. For instance, the exclusion of brokers and dealers from the reporting threshold calculation for Category 2 limits the scope of Category 2 covered reporters. However, requiring Category 2 companies to remove transactions with Category 1 companies from their reports under the Final Rule could increase their reporting burdens. In some cases, determining whether a transaction has already been reported may be more costly for covered reporters than simply reporting the duplicate transaction. Additionally, the Office notes that reducing the potential for dual reporting by assigning reporting responsibility solely to the dealer would not be possible in cases where the dealer is not subject to reporting requirements, such as a dealer that is not a U.S. financial company. Therefore, in the interest of keeping the determination of reporting obligations clear, the Office will continue with the reporting structure as outlined in the NPRM.

Another commenter suggested that the reporting burden would be lower if banks were included in Category 1 because banks may be affiliated with other Category 1 covered reporters. Commenters noted that if banks were

[34] See Ricardo Correa, Wenxin Du, and Gordon Y. Liao, 2020. ''U.S. Banks and Global Liquidity,'' International Finance Discussion Papers 1289, Board of Governors of the Federal Reserve System (U.S.); and Cecilia R. Caglio, Adam Copeland, and Antoine Martin, 2021. ''The Value of Internal Sources of Funding Liquidity: U.S. Broker-Dealers and the Financial Crisis,'' Staff Reports 969, Federal Reserve Bank of New York.

[35] See Antoine Bouveret, Antoine Martin, and Patrick E. McCabe, 2022. ''Money Market Fund Vulnerabilities: A Global Perspective,'' Staff Reports 1009, Federal Reserve Bank of New York; and Antoine Bouveret and Jie Yu, 2021. ''Risks and Vulnerabilities in the U.S. Bond Mutual Fund Industry,'' Working Paper 21/109, International Monetary Fund.

included in Category 1, transactions with banks would be excluded from the Category 2 threshold calculation, making it less likely that certain financial companies would qualify as Category 2 covered reporters. Two comment letters also asserted that if Category 1 is not expanded to include banks, it could lead to migration of repo trades from other entities to Category 1 financial companies.

The NPRM included within Category 1 SEC-registered brokers, dealers, government securities brokers, and government securities dealers. While many repo transactions by financial companies occur with counterparties other than those types of entities included in Category 1, the Office believes that the vast majority of transactions occur with Category 1 entities.

Analysis by the Office of data from call reports suggests that over 90% of gross repo by U.S. depository institutions is conducted by depository institutions that are registered as government securities dealers. Therefore, as stated in the NPRM, the Office continues to believe that nearly all NCCBR trades are intermediated by either dealers or are intermediated by financial companies that may be required to report under the Category 1 criteria, such as government securities dealers.[36] As such, the Office believes that any duplicative reporting from asset managers and others resulting from the exclusion of banks from Category 1 would be minimal. Additionally, unless incorporated or organized under federal or state law, U.S. branches of foreign banks are not considered financial companies as defined under the Final Rule. As a result, submissions by Category 2 covered reporters under the Final Rule would be the only way these trades would be reported to the Office. Additionally, in relation to the repo activities for foreign banks, as the NPRM noted, because of the lack of transparency in the existing market and the possibility of trades that bypass traditional intermediaries,[37] it is essential to include financial companies that are large cash borrowers from sources other than Category 1 to ensure a robust framework for monitoring financial stability in the repo market going forward.

One commenter suggested that RIAs be excluded from the Final Rule if Category 1 were extended to include banking entities. The commenter also noted that it would be unlikely that a fund managed by an RIA would undertake a covered transaction with an entity that was not in Category 1 and therefore, the inclusion of RIAs in Category 2 would be redundant. As discussed above, the Office has not added banking entities to Category 1. Nevertheless, the Office understands that it may be likely that RIAs currently conduct the majority of their NCCBR transactions with Category 1 financial companies, including banking entities' affiliates that are registered government securities dealers. However, without a comprehensive data collection, the extent of transactions without a Category 1 counterparty is unknown. Additionally, even if it is unlikely a fund managed by an RIA would undertake a transaction with a non-Category 1 financial company, the Office in the NPRM explicitly stated its intention to cover potential future expansions in repo such as peer-to-peer repo that bypasses Category 1 financial companies. To the extent that funds managed by RIAs engage in repo transactions exclusively with Category 1 entities, they would not be covered reporters under Category 2. However, if RIAs were to be excluded entirely from the Final Rule, any transactions with counterparties outside of Category 1 would not be captured, leaving a crucial gap in the ability of regulators to effectively monitor financial stability risks in this market.

The same commenter asserted that banking entities should be added to Category 1 because the definition of ''financial company'' used in 12 U.S.C. 5381 is limited because it relates to the operation of the Orderly Liquidation Authority under Title II of the Dodd-Frank Act. As a result, the commenter stated, such term should instead reference the definition in 12 U.S.C. 5344. For the reasons stated above, the Office has declined to add banking entities to Category 1.

One commenter also requested clarification on several points of interpretation related to Category 1 financial companies. First, the commenter incorrectly asserted that the NPRM's preamble text indicated that the reporting requirements would only apply in the context of a covered reporter that is a cash borrower, and that they believed that the Office intended to limit Category 1 to the enumerated financial companies when acting as cash borrowers and requested confirmation of such an understanding. Notwithstanding the fact that the same section of the NPRM also explicitly included the extension of guarantees within the transactional threshold applicable to Category 1 financial companies, the regulatory text in both the NPRM and the Final Rule makes clear that Category 1 is not limited to financial companies when acting as cash borrowers, but also includes financial companies when extending guarantees.

Second, the commenter noted that one instance of the description of Category 1 financial companies in the preamble to the NPRM did not explicitly reference the $10 billion materiality threshold and asked whether the Office intended to include a materiality threshold in both categories of financial companies. The NPRM and the Final Rule make clear that the $10 billion threshold applies to both Category 1 and Category 2 financial companies.

Third, the commenter requested clarification as to whether Category 1 is intended to cover only principal transactions (and not agency transactions) by financial companies. Consistent with the explanation in the NPRM, the Category 1 calculation should include obligations of the financial company and guarantees extended by the financial company. For purposes of calculating the Category 1 threshold, a financial company should exclude transactions in which it acts as an agent—such that it incurs no obligation and extends no guarantee. Unlike investment advisers, the Office is not aware of dealers, brokers, government securities dealers, or government securities brokers that package their trades together with those of their clients that use the dealers or brokers as their agent. The case in which a Category 1 financial company acts as an agent for a customer but not as an investment adviser is therefore distinct from the case of investment advisers conducting batched trades on behalf of the funds they advise as described above.

Fourth, the commenter requested clarification as to whether, when a financial company is registered as a government securities broker or dealer for certain limited activities, the proposed rules would apply only to those certain limited activities of the registered financial company or whether all activity of the financial company would be captured by the Category 1 calculation. As set forth in the regulatory text in both the NPRM and the Final Rule, all commitments to borrow cash or extend guarantees in NCCBR transactions should be included in the determination of total commitments for the purposes of reporting, regardless of whether the firm is acting in its capacity as a government securities broker or dealer or in some other capacity. Similarly, all

[36] 88 FR 1154, 1163.

[37] Id.

commitments to borrow cash or lend cash in repo or transactions where guarantees are extended by the firm should be reported to the Office.

Finally, the commenter requested clarification, for the purpose of determining the $10 billion threshold in Category 2, about whether foreign banks and foreign broker-dealers should be treated as Category 1 financial companies and how transactions should be considered if the foreign entity is an affiliate of a U.S. bank or broker-dealer. As set forth in the Final Rule, for purposes of calculating the $10 billion threshold, potential Category 2 covered reporters should exclude repo borrowing and guarantees extended to counterparties that are securities brokers, securities dealers, government securities brokers, or government securities dealers (as each such term is defined in the Final Rule), regardless of whether those counterparties are Category 1 covered reporters. If a counterparty is an affiliate of a securities broker, securities dealer, government securities broker, or government securities dealer (as each such term is defined in the Final Rule), but is not one of these types of financial companies, transactions with the counterparty should be included in the calculation of the Category 2 threshold.

III(b) Scope of Transactions

Consistent with the NPRM, the Final Rule defines a non-centrally cleared bilateral repurchase agreement transaction as an agreement in which one party agrees to sell securities to a second party in exchange for the receipt of cash, and the simultaneous agreement of the former party to later reacquire the same securities (or any subsequently substituted securities) from that same second party in exchange for the payment of cash; or an agreement of a party to acquire securities from a second party in exchange for the payment of cash, and the simultaneous agreement of the former party to later transfer back the same securities (or any subsequently substituted securities) to the latter party in exchange for the receipt of cash. In all cases, the agreement neither involves a tri-party custodian nor is cleared through a central counterparty. This definition includes, but is not limited to, transactions that are executed under a Master Repurchase Agreement (MRA) or Global Master Repurchase Agreement (GMRA), or which are agreed to by the parties as subject to the provisions of 11 U.S.C. 559. Notwithstanding the above, transactions conducted under a Securities Lending Agreement (SLA), a Master Securities Lending Agreement (MSLA), or Global Master Securities Lending Agreement (GMSLA) are not considered repurchase agreements, nor are repurchase agreements arising from either participation in a commercial mortgage loan or the initial securitization of a residential mortgage loan. The Office has chosen to exclude SLA, MSLA, and GMSLA transactions from the Final Rule because reporting of data related to such transactions to the Office could be redundant (and therefore unnecessary) in light of the required reporting of securities lending information to a registered national securities association as provided for in the SEC's recent securities lending transparency rules.[38]

The NPRM requested comment on whether sell/buy-back transactions should be excluded from the Final Rule. While sell/buy-back agreements accomplish similar goals to repo transactions, the Office proposed not to include sell/buy-back agreements with the understanding that these agreements are recorded differently from MRA, GMRA, MSLA, and GMSLA agreements and may have different characteristics and names from the preceding types.[39] In response, one commenter noted that sell/buy-backs are now almost entirely documented (*e.g.,* under the Buy/Sell Back Annex to the GMRA and a similar annex to the SIFMA MRA). Further, this commenter noted that differences in methods of quoting and terminology of sell/buy-back agreements are legacies that are insubstantial and have dwindled in importance. Excluding sell/buy-backs from the Final Rule could be costly in requiring covered reporters to distinguish between nearly identically documented agreements and might also enable covered reporters to avoid disclosing a transaction by executing such economically similar transactions under a different form of agreement. Therefore, sell/buy-back agreements are included within the scope of transactions covered under the Final Rule.

Several commenters posed questions regarding guarantees, specifically with respect to the calculation of reporting thresholds and whether various guarantee arrangements fall within the scope of reporting. As noted in the NPRM, the extension of a guarantee to a repo transaction replicates the profile of traditional repo intermediation by offsetting direct transactions with the counterparties to the guaranteed repo, and therefore its inclusion in the data collection is essential to providing regulators a complete picture of the repo market. Guarantees encompass any agreement pursuant to which a financial company that is not one of the two direct counterparties to a repo transaction commits to provide protection against the risk of a failure to perform for that repo transaction under the terms of the repo by one of the direct counterparties. For every transaction, including guaranteed repo transactions, all the data elements should be reported as detailed below and in the reporting instructions.

One commenter asked whether, for purposes of determining if a financial company has met the position thresholds to be a covered reporter, the financial company should aggregate the repos in which the firm is a cash borrower together with the repos for which the firm is a guarantor on behalf of a cash borrower, and whether a separate file should be submitted for guarantee arrangements. The same commenter also asked whether a firm would be considered a covered reporter if its repo cash borrowings exceed the applicable threshold for the prior quarter, but the firm does not guarantee any repos (or the firm's repo guarantees do not exceed the applicable threshold). Data on guarantee arrangements should be submitted in the same file. The $10 billion threshold for Category 1 or Category 2 is calculated based on the aggregate combined amount of a financial company's cash borrowings in NCCBR transactions and the guarantees extended by the financial company in NCCBR transactions.

One commenter asked whether the $10 billion threshold calculation include repo transactions with and guarantees extended to affiliates. A repo transaction or an extension of a guarantee to an affiliate creates an exposure of the covered reporter to its affiliate. The resulting risks are within scope of the Final Rule's purpose, and the transaction should be reported and included in the total transaction volume used for the Category 1 and Category 2 thresholds.

Another commenter asked whether indemnified repo entered into as part of cash collateral reinvestment associated with securities lending should be included under guarantees. Because these transactions replicate the profile of offsetting legs between a securities lender and the securities lending agent and between the securities lending agent and a third party, and because the resulting risks are within scope of the Final Rule's purpose, this would be reported to the Office. However, the commenter asserted that nearly all of

[38] Securities and Exchange Commission. *Reporting of Securities Loans,* Final Rule, 88 FR 75644 (Nov. 3, 2023). *https://www.federalregister.gov/d/2023-23052.*

[39] 88 FR 1154, 1164.

the indemnified repo is done with Category 1 financial companies as counterparties or is centrally cleared. The Office notes that guarantees extended to centrally cleared repo transactions, sponsored repo transactions, and tri-party transactions are not covered by the scope of this Final Rule, and that transactions with Category 1 financial companies are not included in the calculation of reporting thresholds for Category 2 financial companies, reducing the potential for duplicative reporting associated with indemnified repo.

Two commenters requested clarification around whether ''shortfall guarantees,'' transactions in which a financial company offers a guarantee only on the uncollateralized portion of a repo, would be considered guarantees and if so, whether reporters should consider the full amount of the repo transaction being guaranteed or only the size of the shortfall guarantee when calculating their repo commitments. A shortfall guarantee replicates the exposure of an intermediary standing between a cash borrower and a cash lender, since repo transactions are all collateralized and the loss the intermediary is exposed to is the size of the uncollateralized portion of the repo transaction. As such, the resulting risks are within scope of the Final Rule's purpose and should be included in reporting and, since the exposure replicated is the same as the exposure the intermediary would undertake if it were intermediating the full amount of the transaction, the amount used to calculate a potential covered reporter's transaction volume should be the full amount. To illustrate, for $95 lent against a market value of $90 in collateral, the measurement of guarantee obligations used to calculate transaction volume should be reported as $95 rather than a shortfall exposure. Since the cash amount being guaranteed is the $95, rather than the shortfall value, this is considered the exposure for the purpose of the threshold calculation. This exposure would then be added to the total commitments by the borrower to borrow cash or lend cash in repo transactions for the purposes of calculating the total threshold based on repo exposure, and the repo transaction would be reported in the same file as other transactions. One of the commenters requested clarification on the manner by which a covered reporter should report the various data elements for a guarantee that does not have a specified cap, or a guarantee on behalf of a non-U.S. entity. For all guarantee transactions, regardless of the existence of any cap or whether the relevant entity is a U.S. entity, the reported data elements should cover the entirety of the underlying transaction.

The NPRM noted that some transactions covered under the proposed rules would likely be with counterparties outside of the United States, noting the potential benefit of greater information on cross-border exposures associated with repo borrowing and the concern of potential circumvention.[40] This would include transactions by the covered reporter settled internationally or denominated in currencies other than in U.S. dollars. Some commenters sought clarification of how the rules would apply to a U.S. branch of a foreign financial company, a foreign branch or affiliate of a U.S. financial company, or a transaction conducted internationally. As noted in the NPRM, the definition of ''financial company'' includes only entities that are incorporated or organized under Federal or state law, including subsidiaries. Entities that are not incorporated or organized under Federal or state law, or branches of entities that are not incorporated or organized under Federal or state law, are not subject to the Final Rule's reporting requirements. However, as stated in the NPRM, transactions conducted outside the United States by covered reporters are within scope, because their exclusion could allow covered reporters to avoid reporting by settling a transaction outside the U.S., and these transactions contain information on cross-border exposures that are relevant for financial stability monitoring.[41] Therefore, transactions conducted by financial companies (as defined in the Final Rule) that are settled or otherwise take place outside of the United States as well as transactions settled in currencies other than the U.S. dollar are included both in the transactions reported to the Office and in the volumes used to determine the Category 1 and Category 2 thresholds.

One commenter suggested that the rules should exclude transactions by non-U.S. sub-advisers under the management of a U.S. adviser as well as *de minimis* transactions between Category 2 financial companies denominated in currencies other than U.S. dollars. This commenter suggested these transactions be excluded from the collection because such information is not relevant to regulators' understanding of the U.S. repo market and *de minimis* transactions pose little systemic risk to the United States. Also, they suggested that the burden of reporting these transactions outweighs the benefit. The Office does not agree with these reasons. Financial companies can flexibly utilize financing from sources outside the United States as needed. Excluding transactions of a non-U.S. sub-adviser under the management of a U.S. adviser or transactions denominated in other currencies could eliminate important information about cross-border exposures relevant to financial stability. Additionally, the practice of structuring transactions into smaller cash amounts does not remove their relevance to financial stability analysis. As a result, the Office declines to exclude these transactions. These transactions should be included both in the transactions reported to the Office and in the volumes used to determine Category 1 and Category 2 disclosure thresholds.

III(c) Information Required

Pursuant to § 1610.11(c) of the Final Rule, covered reporters must submit information on all NCCBR transactions in which the covered reporter participates. The word ''all'' should be interpreted broadly; the set of transactions to be included in a covered reporter's disclosures is wider than that used to determine whether a financial company is a covered reporter. Transactions should be reported regardless of whether the covered reporter is a cash lender or cash borrower, a direct participant, guarantor, or other relevant third party. Further, covered reporters should report transactions in this market segment regardless of the tenor, optionality, or the collateral underlying the transaction. Additionally, covered reporters should report transactions regardless of the domicile of the other entities taking part in the transaction or the location in which the transaction is settled. Additionally, the covered reporter should report all transactions that occur within the larger organization (including affiliates and subsidiaries of the covered reporter) to which the covered reporter participates. Along the same lines, Category 2 reporters should report any transactions that occur with potential or actual Category 1 reporters.

III(c)(1) Line Items

The Final Rule requires reporting on NCCBR trades, including detailed reporting about the securities used to collateralize these trades and contractual details of the underlying repurchase agreements.

As adopted, the required data elements are listed in the table in section § 1610.11(c) of the Final Rule's

[40] 88 FR 1154, 1164.

[41] Id.

text. The table is tailored to capture information regarding covered transactions in a manner that the Office believes largely reflects the data generated by covered reporters in the ordinary course of business. This table lists each required element and a brief description of that element.

While commenters addressed the data elements in varying ways, for ease of reference, the following discussion follows the order of the data elements as they appear in the table of data elements in the NPRM. Additional instructions relating to data submission mechanics and the formatting of individual data elements will be contained in reporting instructions published concurrently with the Final Rule.

Cash Lender Name and Cash Borrower Name

One commenter suggested that these elements were unnecessary because the Legal Entity Identifiers (LEIs) of the cash lender and cash borrower were to be collected and, because LEIs are unambiguous values, LEIs should be sufficient to identify the parties to the transaction. LEIs are not available in every circumstance and the Office has therefore determined that the cash lender and cash borrower names should remain as required data elements.

Guarantee

Two commenters requested more guidance on the meaning of this element and the manner of reporting. Guarantees in the context of this element are to be understood as having the same meaning as stated above in section III.b ''Scope of Transactions.'' As proposed in the NPRM, guarantees must be reported simply with an indicator for whether the covered reporter issued a guarantee with respect to the transaction. The Office will provide further clarification on data submission mechanics in the reporting instructions.

Netting Set

Two commenters asked that this field be dropped from the collection. As discussed below in this section under ''Risk Management,'' the Office is not including the netting set data element in the collection at this time.

Transaction ID

One commenter asked for clarification of the word ''respondent'' in the data element explanation provided in the NPRM. This term means ''covered reporter'' in this instance, and the Office has made corresponding changes in the Final Rule.

Trading Platform

One commenter asked if this field would be a free-text field or if the Office would provide specific values for a covered reporter to select. It is a free-text field for the name of the trading platform used to perform/submit the corresponding transaction. The Office will provide examples in the reporting instructions.

End Date

One commenter asked for clarification on the use of this element in the cases of open and evergreen repos and made a suggestion about the ability to distinguish between open and evergreen repos. For the purposes of this collection, the Office will collect the Minimum Maturity Date for all transactions. To preserve the granularity between repos with different optionality structures, the Office will provide a field for special instructions, notes, or comments that should be used, among other things, to differentiate between these different transaction types. Examples and clarifications will be provided in the reporting instructions.

Cash Lender Internal Identifier and Cash Borrower Internal Identifier

One commenter requested clarification as to whether the cash lender internal identifier or cash borrower internal identifier should be reported when the covered reporter itself is the relevant counterparty. This field should always be reported, including when the covered reporter is the direct counterparty to the transaction. Covered reporters are free to develop their own internal identifiers for self-identification.

Start Leg Amount

One commenter suggested removing this element because some financial companies do not track this value on a historical basis and the Office would have this information previously reported by the firm (and associated to the same transaction identifier reported by the firm) as long as the firm was a covered reporter as of the inception of the repo. However, removing this field would mean that it would never be collected, even for the date the transaction was initiated. On this basis, the Office deems the suggestion unworkable. The element is retained in the collection.

Close Leg Amount

Two commenters questioned how to calculate this value for floating-rate repos. The Office clarifies in the Reporting Instructions that it does not expect this value to be calculated for floating-rate repos. The field should still be provided in accordance with the reporting instructions.

Current Cash Amount

One commenter requested that accrued interest not be included in daily reporting of this element or that including accrued interest in this field be optional, with the addition of another field for reporters to indicate whether accrued interest was included. The commenter stated that the Office could calculate the accrued interest data based on the start leg amount and the spread and benchmark for the applicable transaction identifier. The Office understands that this element is not solely composed of start leg cash value and accrued interest and may also contain other adjustments. Moreover, the purpose of this field is to collect the reporter's assessment of its current cash amounts without having to infer these adjustments. The Office therefore does not see the need for a separate data element and declines to change the reporting of the field.

Rate

One commenter requested confirmation that this field would be reportable for both fixed- and floating-rate repo transactions and, if so, whether a firm would report the sum of the benchmark rate and the spread in this field in the case of a floating-rate transaction. The Office will clarify this in the reporting instructions.

Floating Rate

One commenter requested clarification as to whether this field was intended to identify the benchmark used for determining the rate for the floating-rate transaction and if so, suggested renaming the field. The Office confirms that the identification of the benchmark name is the data to be reported and has made clarifying revisions in the Final Rule.

Securities Identifier Type

One commenter asked if this is a free-text field. It is not. The Office will enumerate the choices available for this field in the reporting instructions.

Securities Value at Inception

One commenter suggested removing this element because some financial companies do not track this value on a historical basis and the Office would have this information previously reported by the firm (and associated to the same transaction identifier reported by the firm) as long as the firm was a covered reporter as of the inception of the repo. However, removing this field

would mean that it would never be collected, even for the date the transaction was initiated. On this basis, the Office deems the suggestion unworkable. The element is retained in the collection.

Haircut

One commenter suggested removing this element because some financial companies do not track this value on a historical basis and that the Office would have this information previously reported by the firm (and associated with the same transaction identifier reported by the firm) as long as the firm was a covered reporter as of the inception of the repo. However, removing this field would mean that it would never be collected, even for the date the transaction was initiated. On this basis, the Office deems the suggestion unworkable. The element is retained in the collection.

As noted above, some commenters addressed data element issues on a more thematic basis. One commenter requested clarification as to whether matching unique transaction identifiers (UTIs) with a counterparty would be necessary for reporting. It is not contemplated for this collection that matching elements across reporters, including UTIs, will be necessary.

III(c)(2) Collateral Information

Several commenters stated that the collection of data should be restricted to transactions that use U.S. Treasuries as the underlying collateral, due to the operational complexity and burden of reporting trades backed by other collateral. Two of these commenters incorrectly asserted that the Office's interest in the proposed collection was driven solely by stability and liquidity in the U.S. Treasury securities market and that the operational build-out to cover non-U.S. dollar-denominated securities, U.S. agency debt, or U.S. corporate debt would provide questionable insight into overall systemic stability in U.S. or global financial markets. The collection is intended to fill a critical gap in regulators' information on the repo market by collecting data on the NCCBR market segment, in order to provide a comprehensive view of the last segment for which regulators do not have a transaction-level data source.[42] The NPRM specifically contemplated collateral other than U.S. Treasuries by noting the need to better understand collateral risk, which has implications for financial stability, and that the NCCBR market segment generally contains riskier collateral than other segments because the cleared market segments are limited to Fedwire-eligible collateral.[43]

As additionally noted in the NPRM, collecting data on collateral will provide valuable insight into financial stability matters because vulnerabilities associated with two of the five repo market functions–monetization of assets and transformation of collateral–allow for the propagation of shocks from the repo market to the secondary market for the underlying collateral or for a shock in one of these securities markets to propagate to the repo market and then potentially spread into other markets.[44] The collateral underlying a repurchase agreement is crucial to assessing the exposures and risk management in the repo market. Information about securities delivered into repo will allow the Office to assess common risk exposures across counterparties. The fields proposed will also allow the Office to assess the extent to which specific securities are tied to the repo market and therefore the potential for spillovers from the repo market into the underlying securities market, with potential effects on liquidity and price efficiency. The Office continues to believe that understanding paths of potential spillovers through various collateral classes is critical to monitoring stability in the repo market.

One commenter stated that there would be additional complexity of reporting trades that use other collateral on the basis that these trades are less standardized. While standardization is not the primary purpose of this collection, as noted in the NPRM, standardization in this decentralized market as a result of the Final Rule's reporting process may also improve the ability to reconcile records between financial companies in the event of severe market stresses.[45]

Additionally, the Office believes that the reporting thresholds established by the Final Rule will restrict the collection to large, sophisticated financial companies for which the cost of reporting information on all trades will be relatively minor. Further, as discussed below, the compliance timelines for both Category 1 and Category 2 covered reporters have been lengthened in the Final Rule compared to those proposed in the NPRM, which the Office believes will allow covered reporters ample time to set up and test for reporting.

Finally, one commenter suggested a staged approach to reporting, in which the collection is initially limited to trades backed by U.S. Treasury securities and would provide the Office with a significant portion of the remaining segment of the repo market for which it currently does not have information, without imposing unduly burdensome reporting obligations on market participants. It also asserted that such an approach would prove less disruptive to the orderly operation of the repo market and give the Office valuable information regarding the compliance costs of implementing a repo reporting regime before it imposes additional reporting obligations. For the same reasons as noted above, the Office has an interest in collecting data with respect to all types of collateral, and in light of the anticipated sophistication of covered reporters and the additional time provided for a newly qualifying financial company to begin reporting, the Office declines to adopt a two-stage reporting timeline with respect to collateral type. For all of the reasons noted above, the Office is not limiting the collection of data in the Final Rule only to those transactions that use U.S. Treasuries as the underlying collateral.

III(c)(3) Risk Management

In the NPRM, the Office proposed to collect information on a covered reporter's risk management practices. The Office sought to collect information on whether the covered reporter nets counterparty exposures across asset classes and instruments outside of repo and the terms on which netting occurs when the covered reporter does not net counterparty exposures across asset classes and instruments outside of repo.

The Office received two comments on its proposal to collect data on netting. One commenter stated that reporting the field as proposed was not workable because netting is not captured on a trade-by-trade basis and does not represent an economic term of a trade like the other proposed fields. It also stated that if the Office intends to review netting as it relates to capital, other existing rules govern the collections of that information by federal financial regulators.

The other commenter stated that given the various netting arrangements that could apply, reporting as proposed would require financial companies to make subjective and complex interpretations for each reported position. It also stated that netting could be based on a written agreement or the specific course of dealing and policies and procedures of each party. Finally, the commenter requested that the Office

[42] 88 FR 1154, 1156.

[43] 88 FR 1154, 1158.

[44] 88 FR 1154, 1157.

[45] 88 FR 1154, 1160.

provide additional clarity as to the specific types of netting that the Office intended to cover and how netting should be reported in order to achieve consistent reporting across covered reporters.

The Office has concluded that while additional information on netting arrangements, including cross-product margining, would be useful for financial stability monitoring, the range of netting practices and documentation, along with the resultant potential inconsistency in reporting, suggest that other means of gathering such information might be more effective. Therefore, the Final Rule does not include this field. However, the financial stability rationale for the collection of information on netting arrangements and other risk management practices was not contested by comment letters. Such a collection may be addressed by the Office in the future.

III(d) Submission Process and Implementation

In its NPRM, the Office stated that it was reviewing options for the submission process and implementation of the collection and, should the proposed rules be adopted, may require submission either through the Office or through a collection agent.[46]

Two commenters suggested that the Office consider using a collection agent, although they identified different candidates. Based on the Office's experience with the Ongoing Data Collection of Centrally Cleared Transactions in the U.S. Repurchase Agreement Market, the Office has determined it has the ability to efficiently manage the collection of data under the Final Rule. The Office has developed and launched a data collection utility and specifies under the Final Rule that covered reporters are required to submit data directly to the Office rather than through a collection agent. However, the Office reserves the option to designate a collection agent in the future.

One commenter requested clarification as to whether, when a firm reports data for a particular observation date, it should report its positions as of the close of business on that observation date, whether a repo that is opened and closed on the same day is reportable, and whether reporting applies only to U.S. business days. The Office has considered this issue and made changes to the regulatory text in the Final Rule to include the definition of a business day. In addition to transactions that are opened or rolled over, the NPRM was clear that transactions that open and close on the same day must be reported as part of that business day's data submission. The Final Rule also adds a definition of File observation date, and this definition is consistent with the usage in the NPRM.

One commenter asked whether a covered reporter's reporting responsibilities under the rules could be delegated to a counterparty or platform in order to manage reporting costs and provided an explanation of potential benefits of doing so. The Office distinguishes between trade-by-trade delegation to a counterparty or trading platform and delegation of its daily data submission (and any corrections thereto) to a provider of outsourced processing. The Office acknowledges that outsourcing certain business processes is an accepted industry practice for some financial companies, including those that may be covered reporters under the Final Rule. On the other hand, delegation that might spread the daily data submission of a covered reporter across several filings or from day to day among various entities is unworkable from an operational perspective and could create risks of errors in reported data. In light of these considerations, the Office will allow covered reporters to use a third party to submit data on their behalf, subject to the following constraints:

- The covered reporter may delegate a maximum of one third party at a time for daily file submission and corrections.
- The completed file is consistently submitted from a single source (either the covered reporter or the delegated third party), and the source may not change without advance notice to the Office.
- The covered reporter provides the Office at least 90 days advance notice of any proposed change to the submitter of the daily file.

Adherence to the above-listed constraints will allow covered reporters to use third parties to meet operational needs while furthering data quality. In any case, the covered reporter will remain fully responsible for the data submission and compliance with the Final Rule; any issues will be addressed directly between the covered reporter and the Office.

Under the NPRM, covered reporters were to submit the required data for each business day by 11 a.m. Eastern Time on the following business day. Several commenters stated that this reporting deadline should be extended for reasons of data quality and burden. One of these commenters also stated that financial companies also should have the ability to report between T+1 and T+3 because for some financial companies the positions would have matured off their system after T+1, and it would be difficult to determine what was outstanding three days before the filing deadline. Two commenters mentioned cross-border transactions as difficulties to T+1 reporting, with one commenter additionally asserting that a T+1 reporting requirement could discourage covered reporters from entering into NCCBR transactions, particularly with respect to repo transactions with non-U.S. counterparties.

Taking concerns regarding burdens and data quality and availability into account, the Office believes that 11 a.m. Eastern Time T+1 is an appropriate reporting deadline. Non-U.S. trades are likely to take place earlier in the 24-hour cycle than U.S. transactions, because most non-U.S. markets close earlier in the 24-hour cycle than U.S. markets, so for any given day a transaction on a foreign market already has more time for processing. Since this deadline occurs after most international financial exchanges have closed for the evening, the Office does not believe that this reporting cadence will materially affect choice of venue or otherwise distort the market.

Additionally, following the same logic out of consideration of the operating hours of international financial exchanges, the Final Rule defines ''business day'' as the period beginning at 6 p.m. Eastern Time on any day that the Fedwire Funds Service is open to 6 p.m. Eastern Time on the next day that the Fedwire Funds Service is open.[47] For example, the business day of January 24, 2024, began at 6 p.m. Eastern Time on January 23, 2024, and ended at 6 p.m. Eastern Time on January 24, 2024.

One commenter additionally noted the need for some covered reporters to build reporting systems to comply with the rules and therefore recommended T+3 should be used. The Office rejects this reasoning because a T+1 system should generally be similar in implementation to a T+3 system. Further, another commenter noted that existing systems for some covered reporters would be burdened by waiting until T+3 to report.

Overall, the Office has concluded that the T+1 proposal of the NPRM to be appropriate for both covered reporters

[46] 88 FR 1154, 1167).

[47] Refer to the schedule published on the *FRBservices.org* website, currently available at *https://www.frbservices.org/resources/financial-services/wires/operating-hours.html,* but subject to change.

and the Office. Allowing transactions to be submitted across multiple days would affect the ability of the Office to manage submissions, resubmissions due to errors, and overall data quality. This conclusion is based in part on the Office's experience with the cleared repo data collection, which has been that even a relatively high-volume system—one with more transactions per day than any one covered reporter under the Final Rule will have—works efficiently at a T+1 cadence.

The NPRM stated that if the proposal were to be adopted, the Final Rule would go into effect 60 days after its publication in the **Federal Register** and that covered reporters would be required to comply with the Final Rule 90 days after its effective date. The Office believed this implementation period would provide adequate time for covered reporters to comply with the proposed requirements but sought public comment on this matter.

Five commenters responded to the Office's questions related to the implementation timeline. Each requested more time to allow for building infrastructure and resources to meet compliance and reporting requirements. Several provided examples of activities that would need to be completed before compliance, such as changes to user interfaces, databases, and other existing systems, as well as implementing systems for processing rejections, resubmissions, and modifications and automating the process for generating and reporting the daily file.

Two of these commenters stated that the Office should allow 18 months for covered entities to begin reporting, in part due to the need to calculate the reporting thresholds. Both stated that the Office should consider a tiered or incremental approach for reporting, with one citing the European Securities and Markets Authority's (ESMA's) Securities Financing Transactions Regulation (SFTR) as an example. The other commenter recommended that the Office start with imposing a reporting obligation on Category 1 covered reporters, suggesting that after receiving their data for a period of time, the Office may learn that it has sufficient visibility into the repo market such that Category 2 entities would no longer need to report. Two of these commenters stated that the Office should allow 12 months for covered entities to begin reporting. Two commenters also pointed out that a longer implementation timeline was needed because the rules would add to several other global regulatory changes underway that will affect financial companies' reporting obligations. Several commenters tied their requests for additional implementation time to the date the Office finalizes technical specifications or reporting instructions that cover matters like report formats and connectivity protocols.

One commenter asserted as another reason for an extended reporting implementation timeline that the Office's collection of centrally cleared repo transactions allowed for a longer implementation timeframe while covering only a single reporting entity, as opposed to the multiple reporting parties expected under the Office's proposed collection of NCCBR transactions. However, the Office's centrally cleared repo collection is not an analogous basis for comparison. The Office's earlier collection required more than 70 data elements across three separate data file submissions. In comparison, this collection requires only a single data file to be submitted with 32 data elements.

Two commenters noted that the NPRM did not specify whether the Office or a collection agent would receive the data submissions. One asserted that once the collection agent is specified, the Office should issue technical details for notice and comment to maximize efficiency and consistency. The Office has previously engaged on these topics with market participants, regulators responsible for financial data collections, and industry associations through its NCCBR data collection and outreach pilot of 2022.[48] It is with this knowledge that the Office's Technical Guidance, including such matters as data submission mechanics and formatting, have been developed and are being published in concert with the Final Rule at *https://www.financialresearch.gov/data/non-centrally-cleared-bilateral-repo-data/.*

[48] The OFR secured the voluntary participation of nine dealers for its pilot data collection. These dealers include primary dealers and nonprimary dealers, bank affiliated and nonbank affiliated dealers, and both purely domestic dealers and dealers that are affiliates of foreign institutions. Hempel, Samuel J., R. Jay Khan, Robert Mann, and Mark Paddrik. 2022. The OFR Blog (blog). ''OFR's Pilot Provides Unique Window into the Non-centrally Cleared Bilateral Repo Market.'' December 5, 2022. *https://www.financialresearch.gov/the-ofr-blog/2022/12/05/fr-sheds-light-on-dark-corner-of-the-repo-market/.*

The Office does not intend to solicit additional public input on its Reporting Instructions nor its Technical Guidance at this time. These documents, along with the Final Rule, confirm that covered reporters will be required to submit their data directly to the Office. Additionally, the Technical Guidance will provide information on how to transmit data to the Office in the manner described in the Reporting Instructions.

Two commenters discussed the need for testing, with one requesting that the Office provide details regarding testing facilities and processes. This commenter further recommended that one month be allocated for testing submissions. The Office has considered this comment and will accept covered reporter data as of the Final Rule's effective date. The Office agrees that testing is important and expects that most covered reporters will use the time between the effective date and compliance date to submit data on a test basis. The Office encourages all covered reporters to test submissions as early as possible but at least 90 days before their compliance deadline.

The Office acknowledges that covered entities may need to establish or adapt their infrastructure to comply with their reporting obligations. However, as stated in the NPRM, the collection of these data is key to the Council's effective identification and monitoring of emerging threats to the stability of the U.S. financial system and any significant delay to reporting would hinder such efforts. To strike a balance in addressing these competing concerns, the Office is extending the amount of time that covered reporters have to comply with the Final Rule. The timeline has been extended in the Final Rule for Category 1 covered reporters by approximately 66%, from the proposed 90 days after the effective date to 150 days after the effective date, and for Category 2 covered reporters by 200%, from the proposed 90 days after the effective date to 270 days after the effective date. The Office believes that by extending the overall implementation timeline, as well as establishing staggered compliance dates, with an additional 120 days for Category 2 covered reporters compared to Category 1 covered reporters, it has appropriately addressed the identified concerns. The effective date of the rule remains as proposed at 60 days after the Final Rule is published.

TABLE 1—TIMELINE FOR FINANCIAL COMPANIES THAT MEET REPORTING THRESHOLDS AS OF THE EFFECTIVE DATE OF THE FINAL RULE

	Publication date	Effective date	Compliance date
Category 1 covered reporter	T	T+60 days	Effective Date + 150 days.
Category 2 covered reporter	T	T+60 days	Effective Date + 270 days.

One commenter requested clarification of the basis for determining whether financial companies meet reporting thresholds based on various compliance date scenarios. Consistent with the NPRM, the reporting threshold is met when a financial company's average daily total outstanding commitments to borrow cash and extend guarantees through NCCBR contracts over all business days during the prior calendar quarter is at least $10 billion.[49]

One commenter had questions about implementation time for financial companies that begin to meet reporting thresholds after the Final Rule's effective date. The NPRM stated that any financial company that becomes a covered reporter after the effective date of this section shall comply with the reporting requirements pursuant to this section on the first business day of the third full calendar quarter following the calendar quarter when such financial company becomes a covered reporter.[50] In light of the revised timeline for financial companies that qualify as covered reporters as of the Final Rule's effective date, and to improve consistency and clarity, the Office is also revising the timeline for financial companies that become covered reporters after the Final Rule's effective date. For a Category 1 company that becomes a covered reporter after the effective date, the compliance date has been revised to 150 days after the last day of the calendar quarter when the company becomes a covered reporter. For a Category 2 company that becomes a covered reporter after the Final Rule's effective date, the timeline has been revised to 270 days after the last day of the calendar quarter when the company becomes a covered reporter.

The Final Rule enumerates all compliance timelines in terms of days, and not quarters, to eliminate any confusion when interpreting the compliance timelines discussed above. Where the NPRM previously instructed financial companies that become covered reporters after the Final Rule's effective date to comply on the first business day of a quarter, the Final Rules will now articulate a compliance date that is a set number of days after the last day of the calendar quarter when such financial company becomes a covered reporter. The following table illustrates these timelines.

TABLE 2—TIMELINE FOR FINANCIAL COMPANIES THAT MEET REPORTING THRESHOLDS AFTER THE EFFECTIVE DATE OF THE FINAL RULE

	Last day of threshold quarter *	Compliance date
Category 1 covered reporter	T	T+150 days.
Category 2 covered reporter	T	T+270 days.

* The threshold quarter is the calendar quarter when the financial company first exceeds the thresholds stated in 12 CFR 1610.11(b)(2).

One commenter requested clarification on what happens when a covered reporter falls below the reporting thresholds and subsequently meets the thresholds again. As the NPRM stated, a covered reporter whose volume falls below the $10 billion threshold for at least four consecutive calendar quarters would have its reporting obligations cease.[51] However, if that same financial company once again meets the reporting threshold, it is subject to the same requirements as any financial company that becomes a covered reporter after the Final Rule's effective date, as illustrated in Figure 2.

As contemplated in the NPRM, the Office is publishing concurrently with the Final Rule specific reporting instructions and technical guidance on the Office's website at *https://www.financialresearch.gov/data/non-centrally-cleared-bilateral-repo-data/* regarding matters such as data submission mechanics and formatting. The Office may update these materials from time to time and will publish any updates on its website.

VI. Administrative Law Matters

VI(a) Paperwork Reduction Act

The information collection contained in the Final Rule has been reviewed and approved by the Office of Management and Budget (''OMB'') under OMB Control No. 1505–0279. In accordance with the requirements of the Paperwork Reduction Act (the ''PRA''), the Office may not conduct or sponsor, and a covered reporter is not required to respond to, an information collection unless it displays a currently valid OMB control number.

Commenters on the proposed rules generally acknowledged the need for the Office to collect certain information on repo transactions in support of the work of the Council, its member agencies, and the Office in connection with identifying and monitoring risks to financial stability.

Commenters also requested various modifications to, or relief from, aspects of the proposed rules that they stated would entail burdens that outweighed the benefits to the Office. This included recommendations from expected covered reporters for a phased implementation process over a longer period of time than the Office had proposed. However, none of the commenters provided comments, empirical data, estimates of costs or benefits, or other analyses directly addressing matters pertaining to the PRA discussion.

The Office's ability to collect non-centrally cleared repo data through this collection derives in part from the authority to promulgate regulations regarding the type and scope of financial transaction and position data from financial companies on a schedule determined by the Director of the Office

[49] 88 FR 1154, 1162.

[50] 88 FR 1154, 1170.

[51] 88 FR 1154, 1163.

in consultation with the Council.[52] In a 2022 statement on nonbank financial intermediation, the Council supported a recommendation made by the Council's Hedge Fund Working Group that the Office consider ways to collect NCCBR data[53] and, in July 2022 and February 2024, the Office consulted with the Council on efforts to collect NCCBR data.[54]

The Office also has authority to promulgate regulations pursuant to the Office's general rulemaking authority under Dodd-Frank Act section 153, which authorizes the Office to issue rules, regulations, and orders to the extent necessary to carry out certain purposes and duties of the Office.[55] In particular, the purposes and duties of the Office include supporting the Council in fulfilling its purposes and duties, and supporting Council member agencies, by collecting data on behalf of the Council and providing such data to the Council and Council member agencies, and standardizing the types and formats of data reported and collected.[56] The Office must consult with the Chairperson of the Council prior to the promulgation of any rules under section 153[57]—these consultations occurred both before and after the publication of the NPRM.

As noted above, commenters generally did not provide comments, empirical data, or other analyses directly addressing the Office's estimates in the PRA discussion. As outlined in detail above, the Final Rule incorporates changes from the proposed rules to provide for a phased implementation process over a longer period of time than the Office had proposed. However, this change does not impact the scope of financial companies subject to the requirements of the Final Rule, nor the estimated annual burden on a covered reporter once the Final Rule is fully implemented.

As a result, the Office's estimate of an annual burden of 756 hours per covered reporter remains unchanged. This figure is arrived at by estimating the daily reporting time to be approximately 3 hours for each submission and multiplying that figure by an average of 252 business days in a year, the typical number of days per year that do not fall either on weekends or on holidays widely observed by the market.

To estimate hourly wages for purposes of this Final Rule, the Office used data from the May 2022 Bureau of Labor Statistics Occupational Employment Statistics for credit intermediation and related activities (NAICS 522000). For hourly compensation, a figure of $91 per hour was used, which is an average of the 90th percentile wages in seven different categories of employment (compliance officers, accountants and auditors, lawyers, management occupations, financial analysts, software developers, and statisticians), plus an additional 44.5 percent to cover subsequent wage gains and non-wage benefits, which yields an estimate of $131 per hour.

In addition, and as described in the NPRM, each covered reporter must also obtain and maintain an LEI. Those costs have reduced since the publication of the NPRM, with the initial application now costing $50 and the annual renewal costing $40.

Using these assumptions, the Office estimates the recurring total estimated annual cost to a covered reporter is $99,076.

VI(b) Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (the ''RFA'') to address concerns related to the effects of agency rules on small entities.[58] The Office is sensitive to the impact its rules may impose on small entities. The RFA requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule for which general notice of proposed rulemaking is required, or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.[59] In accordance with section 3(a) of the RFA, the Office is certifying that the Final Rule will not have a significant economic impact on a substantial number of small entities.

As discussed above, this collection will apply to certain brokers, dealers, and other financial companies whose average daily outstanding commitments to borrow cash and extend guarantees in NCCBR with certain counterparties over all business days during the prior calendar quarter is at least $10 billion.

Under regulations issued by the Small Business Administration, a ''small entity'' includes those firms within the ''Finance and Insurance'' sector with asset sizes that vary from $15 million in assets up to $850 million in assets.[60] For purposes of the RFA, entities that are banks are considered small entities if their assets are less than or equal to $850 million. The level of the activity-based threshold under the Final Rule ensures that any respondent will be well beyond these small entity definitions.

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), it is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities.

VI(c) Congressional Review Act

This rule is not a major rule pursuant to the Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*

List of Subjects in 12 CFR Part 1610

Banks, Banking, Confidential business information, Securities.

For the reasons stated in the preamble, the Office of Financial Research amends 12 CFR part 1610 as follows:

PART 1610—REGULATORY DATA COLLECTIONS

■ 1. The authority citation for part 1610 continues to read as follows:

Authority: 12 U.S.C. 5343 and 5344.

■ 2. Add § 1610.11 to read as follows:

§ 1610.11 Non-centrally Cleared Bilateral Repurchase Agreement Data.

(a) *Definitions.* The terms used in this section have the following meanings:

Business day is the period beginning at 6 p.m. Eastern Time on any day that the Fedwire Funds Service is open to 6 p.m. Eastern Time on the next day that the Fedwire Funds Service is open.

Covered reporter means any financial company that meets the criteria set forth in paragraph (b)(2) of this section; provided, however, that any covered reporter shall cease to be a covered reporter only if it does not meet the dollar thresholds specified in paragraph (b)(2) of this section for at least four consecutive calendar quarters.

File observation date means the date on which any business day ends.

Financial company has the same meaning as in 12 U.S.C. 5341(2).

[52] 12 U.S.C. 5344(b)(1)(B)(iii).

[53] Financial Stability Oversight Council. ''Statement on Nonbank Financial Intermediation.'' Press Release, February 4, 2022: FSOC. *https://home.treasury.gov/news/press-releases/jy0587.* (accessed April 17, 2024)

[54] Financial Stability Oversight Council. Meeting minutes. FSOC, July 28, 2022, p. 7. *https://home.treasury.gov/system/files/256/FSOC_20220728_Minutes.pdf.*

[55] 12 U.S.C. 5343(a), (c)(1).

[56] 12 U.S.C. 5343(a). The Council's purposes and duties include identifying risks to U.S. financial stability; responding to emerging threats to the stability of the U.S. financial system; monitoring the financial services marketplace in order to identify potential threats to U.S. financial stability; making recommendations in such areas that will enhance the integrity, efficiency, competitiveness, and stability of the U.S. financial markets; and identifying gaps in regulation that could pose risks to the financial stability of the United States. 12 U.S.C. 5322(a).

[57] 12 U.S.C. 5343(c)(1).

[58] 5 U.S.C. 601 *et seq.*

[59] 5 U.S.C. 603(a).

[60] 13 CFR 121.201.

Government securities broker means any financial company registered as a government securities broker under the Securities Exchange Act of 1934.

Government securities dealer means any financial company registered as a government securities dealer under the Securities Exchange Act of 1934.

Investment adviser means any financial company registered as an investment adviser with the Securities and Exchange Commission under the Investment Advisers Act of 1940.

Non-centrally cleared bilateral repurchase agreement transaction means an agreement of one party to sell securities to a second party in exchange for the receipt of cash, and the simultaneous agreement of the former party to later reacquire the same securities (or any subsequently substituted securities) from that same second party in exchange for the payment of cash; or an agreement of a party to acquire securities from a second party in exchange for the payment of cash, and the simultaneous agreement of the former party to later transfer back the same securities (or any subsequently substituted securities) to the latter party in exchange for the receipt of cash. The agreement does not involve a tri-party custodian and is not cleared with a central counterparty. This definition includes, but is not limited to, transactions that are executed under a Master Repurchase Agreement (MRA) or Global Master Repurchase Agreement (GMRA), or which are agreed to by the parties as subject to the provisions of 11 U.S.C. 559. Notwithstanding the above, transactions conducted under a Securities Lending Agreement (SLA) or a Master Securities Lending Agreement (MSLA) are not considered repurchase agreements, nor are repurchase agreements arising from either participation in a commercial mortgage loan or the initial securitization of a residential mortgage loan.

Outstanding commitment means the amount of financial obligations entered into pursuant to any repurchase agreement that opens on any business day or is outstanding as of the end of any business day, including transactions which both opened and closed on the same business day. These financial obligations include all of those that exist prior to netting.

Securities broker means any financial company registered as a broker with the Securities and Exchange Commission under the Securities Exchange Act of 1934.

Securities dealer means any financial company registered as a dealer with the Securities and Exchange Commission under the Securities Exchange Act of 1934.

(b) *Purpose and scope*—(1) *Purpose.* The purpose of this data collection is to require the reporting of certain information to the Office about non-centrally cleared bilateral repurchase agreement transactions. The information will be used by the Office to fulfill its responsibilities under Title I of the Dodd-Frank Wall Street Reform and Consumer Protection Act, including support of the Council and Council member agencies by facilitating financial stability monitoring and research consistent with support of the Council and its member agencies.

(2) *Scope of application.* Reporting under this section is required by any financial company that participates in a non-centrally cleared bilateral repurchase agreement transaction and that is:

(i) A securities broker, securities dealer, government securities broker, or government securities dealer whose average daily outstanding commitments to borrow cash and extend guarantees in non-centrally cleared bilateral repurchase agreement transactions with counterparties over all business days during the prior calendar quarter is at least $10 billion, or

(ii) Any other financial company with over $1 billion in assets or assets under management whose average daily outstanding commitments to borrow cash and extend guarantees in non-centrally cleared bilateral repurchase agreement transactions, including commitments of all funds for which the company serves as an investment adviser, with counterparties that are not securities brokers, securities dealers, government securities brokers, or government securities dealers over all business days during the prior calendar quarter is at least $10 billion.

(c) *Data required.* (1) Covered reporters shall report trade and collateral information on all non-centrally cleared bilateral repurchase agreement transactions, subject to paragraph (c)(2) of this section, in accordance with the prescribed reporting format in this section.

(2) Covered reporters shall only report trade and collateral information with respect to any non-centrally cleared bilateral repurchase agreement transaction which opens on, or is outstanding at any time during the business day, including transactions which both opened and closed during the business day.

(3) Covered reporters shall submit the following data elements for all transactions:

TABLE 1 TO PARAGRAPH (c)(3)

Data element	Explanation
File observation date	The date on which the business day ends.
Covered reporter LEI	The Legal Entity Identifier of the covered reporter.
Cash lender LEI	The Legal Entity Identifier of the cash lender.
Cash lender name	The legal name of the cash lender.
Cash borrower name	The legal name of the cash borrower.
Cash borrower LEI	The Legal Entity Identifier of the cash borrower.
Guarantee	Indicator for whether the covered reporter issued a guarantee with respect to the transaction.
Transaction ID	The covered reporter-generated unique transaction identifier in an alphanumeric string format.
Unique transaction ID	If available, the Unique Transaction Identifier (UTI).
Trading platform	For transactions arranged using an outside vendor's platform, the provider of the platform.
Trade timestamp	The timestamp that the trade became an obligation of the covered reporter or the covered reporter's affiliate or subsidiary.
Start date	The start date of the repo.
End date	The date the repo matures.
Minimum maturity date	The earliest possible date on which the transaction could end in accordance with its contractual terms (taking into account optionality).
Cash lender internal identifier	The internal identifier assigned to the cash lender by the covered reporter, if the covered reporter is not the cash lender.
Cash borrower internal identifier	The internal identifier assigned to the cash borrower by the covered reporter, if the covered reporter is not the cash borrower.

TABLE 1 TO PARAGRAPH (c)(3)—Continued

Data element	Explanation
Start leg amount	The amount of cash transferred to the cash borrower on the open leg of the transaction at the inception of the transaction.
Close leg amount	The amount of cash to be transferred by the cash borrower on the end date of the transaction.
Current cash amount	The amount of cash to be transferred by the cash borrower, inclusive of principal, accrued interest and other adjustments, as of the end of the business day.
Start leg currency	The currency which is used in the Start leg amount field.
Rate	The rate of interest paid by the cash borrower on the transaction, expressed as an annual percentage rate on an actual/360-day basis.
Floating rate benchmark	The name of the benchmark interest rate upon which the transaction is based.
Floating rate reset frequency	The time period, in calendar days, describing the frequency of the floating rate resets.
Spread	The contractual spread over (or below) the benchmark rate referenced in the repurchase agreement.
Securities identifier type	The identifier type for the securities transferred between cash borrower and cash lender.
Security identifier	The identifier of securities transferred between the cash borrower and the cash lender in the repo.
Securities quantity	The number of units (e.g., shares, bonds, bills, notes) transferred to the cash lender as of the end of the business day.
Securities value	The market value of the transferred securities as of the end of the business day, inclusive of accrued interest.
Securities value at inception	The market value of the transferred securities at the inception of the transaction, inclusive of accrued interest.
Securities value currency	The currency used in the Securities value and Securities value at inception fields.
Haircut	The difference between the market value of the transferred securities and the purchase price paid at the inception of the transaction.
Special instructions, notes, or comments	The covered reporter may characterize any detail of the transaction with special instructions, notes, or comments.

(d) *Reporting process.* Covered reporters shall submit the required data for each business day by 11 a.m. Eastern Time on the following business day. The Office may either collect the data itself or designate a collection agent for that purpose.

(e) *Compliance date.* (1) Any financial company that meets the criteria set forth in paragraph (b)(2)(i) of this section as of the effective date of this section shall comply with the reporting requirements pursuant to this section 150 days after the effective date of this section. Any such covered reporter's first submission shall be submitted on the first business day after such compliance date.

(2) Any financial company that meets the criteria set forth in paragraph (b)(2)(ii) of this section as of the effective date of this section shall comply with the reporting requirements pursuant to this section 270 days after the effective date of this section. Any such covered reporter's first submission shall be submitted on the first business day after such compliance date.

(3) Any financial company not described in subparagraph (e)(1) or (2) of this section that meets the criteria set forth in paragraph (b)(2)(i) of this section after the effective date of this section shall comply with the reporting requirements pursuant to this section 150 days after the last day of the calendar quarter in which such financial company becomes a covered reporter.

(4) Any financial company not described in subparagraph (e)(1) or (2) of this section that meets the criteria set forth in paragraph (b)(2)(ii) of this section after the effective date of this section shall comply with the reporting requirements pursuant to this section 270 days after the last day of the calendar quarter in which such financial company becomes a covered reporter.

James D. Martin,

Acting Director.

[FR Doc. 2024–08999 Filed 5–3–24; 8:45 am]

BILLING CODE 4810–AK–P–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0036; Project Identifier MCAI–2023–00731–E; Amendment 39–22739; AD 2024–08–06]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model Trent 1000–A, Trent 1000–A2, Trent 1000–AE, Trent 1000–AE2, Trent 1000–C, Trent 1000–C2, Trent 1000–CE, Trent 1000–CE2, Trent 1000–D, Trent 1000–D2, Trent 1000–E, Trent 1000–E2, Trent 1000–G, Trent 1000–G2, Trent 1000–H, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 engines. This AD was prompted by reports of wear in the combining spill valve (CSV) assembly of certain hydro-mechanical units (HMUs). This AD requires removing certain HMUs from service and replacing with a serviceable part. This AD also prohibits the installation of certain HMUs unless the HMU is a serviceable part or the CSV assembly has been replaced, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 10, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 10, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–0036; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For EASA service information, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

• You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2024–0036.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all RRD Model Trent 1000–A, Trent 1000–A2, Trent 1000–AE, Trent 1000–AE2, Trent 1000–C, Trent 1000–C2, Trent 1000–CE, Trent 1000–CE2, Trent 1000–D, Trent 1000–D2, Trent 1000–E, Trent 1000–E2, Trent 1000–G, Trent 1000–G2, Trent 1000–H, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 engines. The NPRM published in the **Federal Register** on January 24, 2024 (89 FR 4582). The NPRM was prompted by EASA AD 2023–0113, dated June 1, 2023 (EASA AD 2023–0113) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that occurrences have been reported of finding wear in the CSV assembly of certain HMUs. This wear can reduce the fuel flow output when the engine is operated at high power conditions and lead to thrust reduction. To address this unsafe condition, the manufacturer published service information that specifies procedures to remove certain HMUs from service and replace with a serviceable part. The MCAI also specifies an implementation schedule, based on engine flight-hour (EFH) limits, for replacement of each affected part with a serviceable part and prohibits installation or reinstallation of affected HMUs that have exceeded the allowable EFH limit unless the HMU is a serviceable part or the CSV assembly has been replaced.

In the NPRM, the FAA proposed to require removing certain HMUs from service and replacing with a serviceable part. The NPRM also proposed to prohibit installation of certain HMUs unless the HMU is a serviceable part or the CSV assembly has been replaced. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–0036.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment from Boeing which supported the NPRM without change.

Conclusion

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2023–0113, which specifies procedures for removing certain part-numbered HMUs from service and replacing with a serviceable part. The MCAI also specifies prohibiting installation or reinstallation of an affected HMU on any engine unless the HMU is a serviceable part.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 28 engines installed on airplanes, of U.S. registry.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace the HMU	7 work-hours × $85 per hour = $595	$552,000	$552,595	$15,472,660

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–08–06 Rolls-Royce Deutschland Ltd & Co KG: Amendment 39–22739; Docket No. FAA–2024–0036; Project Identifier MCAI–2023–00731–E.

(a) Effective Date

This airworthiness directive (AD) is effective June 10, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG Model Trent 1000–A, Trent 1000–A2, Trent 1000–AE, Trent 1000–AE2, Trent 1000–C, Trent 1000–C2, Trent 1000–CE, Trent 1000–CE2, Trent 1000–D, Trent 1000–D2, Trent 1000–E, Trent 1000–E2, Trent 1000–G, Trent 1000–G2, Trent 1000–H, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7300, Engine Fuel and Control.

(e) Unsafe Condition

This AD was prompted by reports of wear in the combining spill valve (CSV) assembly of certain hydro-mechanical units (HMUs). The FAA is issuing this AD to prevent thrust reduction. The unsafe condition, if not addressed, could result in reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0113, dated June 1, 2023 (EASA AD 2023–0113).

(h) Exceptions to EASA AD 2023–0113

(1) Where EASA AD 2023–0113 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Table 1 of EASA AD 2023–0113 specifies ''15 June 2023'', replace that text with ''As of the effective date of this AD.''

(3) Where Table 1 of EASA AD 2023–0113 specifies ''01 January 2025'', replace that text with ''Within 4 months after the effective date of this AD or January 1, 2025, whichever occurs later.''

(4) Where the service information referenced in EASA AD 2023–0013 specifies to discard certain parts, this AD requires those parts to be removed from service.

(5) This AD does not adopt the Remarks paragraph of EASA AD 2023–0113.

(i) Definitions

For the purposes of this AD, the ''implementation date'' is defined as the date that the applicable engine flight hour limit takes effect.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0113, dated June 1, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0113, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locationsoremailfr.inspection@nara.gov.*

Issued on April 17, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09555 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0030; Project Identifier AD–2023–01066–E; Amendment 39–22722; AD 2024–07–02]

RIN 2120–AA64

Airworthiness Directives; CFM International, S.A. Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for CFM International, S.A. (CFM) Model LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A engines. This AD was prompted by detection of melt-related freckles in the billet, which may reduce the life of certain high-pressure turbine (HPT) rotor interstage seals. This AD requires removing the affected HPT rotor interstage seals from service and replacing with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 10, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 10, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–0030; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For service information identified, contact CFM International, S.A., GE Aviation Fleet Support, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45215; phone: (877) 432–3272; email: *aviation.fleetsupport@ge.com.*

• You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2024–0030.

FOR FURTHER INFORMATION CONTACT: Mehdi Lamnyi, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7743; email: *mehdi.lamnyi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to CFM Model LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A engines. The NPRM published in the **Federal Register** on January 11, 2024 (89 FR 1847). The NPRM was prompted by detection of melt-related freckles in the billet, which may reduce the life of certain HPT rotor interstage seals. In the NPRM, the FAA proposed to require removing the affected HPT rotor interstage seals from service and replacing with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed CFM Service Bulletin LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00, dated April 6, 2023, which provides the serial numbers of the affected HPT rotor interstage seals and specifies procedures for replacement of the HPT rotor interstage seal. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 1 engine installed on an airplane of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove HPT rotor interstage seal	225 work-hours × $85 per hour = $19,125	$168,000	$187,125	$187,125

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–07–02 CFM International, S.A.: Amendment 39–22722; Docket No. FAA–2024–0030; Project Identifier AD–2023–01066–E.

(a) Effective Date

This airworthiness directive (AD) is effective June 10, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFM International, S.A. (CFM) Model LEAP–1A23, LEAP–1A24, LEAP–1A24E1, LEAP–1A26, LEAP–1A26CJ, LEAP–1A26E1, LEAP–1A29, LEAP–1A29CJ, LEAP–1A30, LEAP–1A32, LEAP–1A33, LEAP–1A33B2, and LEAP–1A35A engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by detection of melt-related freckles in the billet, which may reduce the life of certain high-pressure

turbine (HPT) rotor interstage seals. The FAA is issuing this AD to prevent failure of the HPT rotor interstage seal. The unsafe condition, if not addressed, could result in release of uncontained debris, damage to the engine, and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

For engines with an affected HPT rotor interstage seal installed, before exceeding the applicable threshold specified in Table 1 of paragraph 3.E., Compliance, of CFM Service Bulletin (SB) LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00, dated April 6, 2023 (CFM SB LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00), or at the next HPT rotor module exposure, whichever occurs first after the effective date of this AD, remove the affected HPT rotor interstage seal from service and replace it with a part eligible for installation.

(h) Definitions

(1) For the purpose of this AD, an ''affected HPT rotor interstage seal'' is any HPT rotor interstage seal having part number 2466M68P02 and a serial number listed in Table 1 of paragraph 3.E., Compliance, of CFM SB LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00.

(2) For the purpose of this AD, a ''part eligible for installation'' is any HPT rotor interstage seal having a serial number that is not listed in Table 1 of paragraph 3.E., Compliance, of CFM SB LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00.

(3) For the purpose of this AD, an ''HPT rotor module exposure'' is an engine shop visit during which the HPT rotor assembly is fully removed from the engine core.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

For more information about this AD, contact Mehdi Lamnyi, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7743; email: *mehdi.lamnyi@faa.gov*.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) CFM International, S.A. Service Bulletin LEAP–1A–72–00–0492–01A–930A–D, Issue 001–00, dated April 6, 2023.

(ii) [Reserved]

(3) For service information, contact CFM International, S.A., GE Aviation Fleet Support, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45215; phone: (877) 432–3272; email: *aviation.fleetsupport@ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locationsoremailfr.inspection@nara.gov.*

Issued on March 27, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09564 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 490

National Highway Traffic Safety Administration

23 CFR Part 1300

RIN 2127–AM45

Uniform Procedures for State Highway Safety Grant Programs

AGENCY: National Highway Traffic Safety Administration (NHTSA), Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends the uniform procedures implementing the State Highway Safety Grant Program to waive, for Fiscal Year (FY) 2025, the requirement that targets for the common performance measures be identical to targets in the State Highway Safety Improvement Program. This final rule makes a corresponding change to a similar requirement in the FHWA's performance management regulation.

DATES: This final rule is effective May 6, 2024.

ADDRESSES: This document may be viewed online through the Federal eRulemaking portal at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's website at: *www.federalregister.gov* and the U.S. Government Publishing Office's website at: *www.GovInfo.gov.*

FOR FURTHER INFORMATION CONTACT:

For NHTSA: Program issues: Barbara Sauers, Associate Administrator, Regional Operations and Program Delivery, National Highway Traffic Safety Administration; Telephone number: (202) 366–0144; Email: *barbara.sauers@dot.gov.* Legal issues: Megan Brown, Attorney-Advisor, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; Telephone number: (202) 366–1834; Email: *megan.brown@dot.gov.*

For FHWA: Kelly Morton, Office of Safety, (202) 366–8090 or via email at *kelly.morton@dot.gov* or Dawn Horan, Office of the Chief Counsel, (202) 366–9615 or via email at *dawn.horan@dot.gov*. Office hours are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The NHTSA and the FHWA share three common performance measures in their highway safety programs—total fatalities, rate of fatalities, and total serious injuries—and have shared these common performance measure for many years. Both NHTSA and FHWA regulations require States to submit identical targets for the three common performance measures—in NHTSA's triennial Highway Safety Plan (HSP) and in FHWA's Highway Safety Improvement Program (HSIP) annual report. See 23 CFR 1300.11(b)(3)(ii)(C) and 490.209(a)(1), respectively.

On November 15, 2021, the President signed into law the ''Infrastructure Investment and Jobs Act'' (known also as the Bipartisan Infrastructure Law, or BIL), Public Law 117–58. The BIL provided additional grant funds to States and changed several requirements to support States in their efforts to

strengthen their highway safety programs. Among other things, the BIL required that all performance targets submitted to NHTSA in the triennial HSP demonstrate constant or improved performance. 23 U.S.C. 402(d)(4)(A)(ii).

The NHTSA published a final rule implementing the Highway Safety Grant Program under the BIL on February 6, 2023, at 88 FR 7780. The rule provides direction to States on procedures for meeting the statutory requirements governing their highway safety grant programs and applications. In addition to changing from performance targets submitted to NHTSA in an annual HSP to a triennial HSP, the rule requires States to submit constant or improved targets for the common performance measures and that these targets be identical to the targets that are reported by the State department of transportation (State DOT) in the HSIP annual report. See 23 CFR 1300.11(b)(3)(ii)(B).

On June 5, 2023, NHTSA and FHWA amended the uniform procedures implementing the State Highway Safety Grant Program to waive, for FY 2024, the requirement that targets for the common performance measures be identical to targets in the State Highway Safety Improvement Program. 88 FR 36472. The amendment was in response to questions from stakeholders about the interplay between NHTSA's and FHWA's current regulations.

On January 25, 2024, FHWA released a notice of proposed rulemaking concerning its performance measures that addresses and seeks comment on this issue. 89 FR 4857. Stakeholders continue to raise questions about the interplay between NHTSA's and FHWA's current regulations; however, the FHWA has not yet completed a new regulation implementing any changes to its performance measures since the passage of BIL.

II. Waiver of Identical Targets for Common Performance Measures

In this rulemaking, FHWA amends 23 CFR 490.209(a)(1) to waive, for FY 2025, the requirement that the State DOT targets shall be identical to the targets established by the State Highway Safety Office (HSO) for common performance measures reported in the State's HSP. The NHTSA amends 23 CFR 1300.12 to revise paragraph (b)(1)(ii) to provide that States may update the triennial HSP to amend common performance measures only if necessary, in order to submit identical performance targets to FHWA in the HSIP annual report. As a result of FHWA's waiver in this document, this amendment will mean that States may not amend the common performance targets submitted in the FY 24 triennial HSP in the FY 25 Annual Grant Application. With these changes, State HSOs will continue to use the non-identical targets submitted in the FY 24 triennial HSP and State DOTs have the flexibility to submit non-identical targets for the common performance measures for FY 2025 in the 2024 HSIP annual reports.

While NHTSA and FHWA are affording States flexibility to continue to use non-identical targets for FY 2025 highway safety programs, HSOs and State DOTs are nevertheless encouraged to continue to collaborate as they work together to implement a Safe System Approach and reduce deaths and serious injuries on our roadways.

III. Waiver of Notice and Comment

The NHTSA and FHWA find good cause to issue, without notice and comment, and to make effective immediately, this time-limited waiver of the requirement for identical targets, in accordance with 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(1). The Administrative Procedure Act provides that when an agency, for good cause, finds that notice and public comment are impractical, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment (5 U.S.C. 553(b)(B)). For the same reason, the rule can become effective immediately. See 5 U.S.C. 553(d)(1). The safety programs of NHTSA and FHWA are governed by different statutory provisions, and FHWA has not completed its notice and comment rulemaking on the National Performance Management Measures since the passage of BIL. The NHTSA and FHWA recognize the importance of allowing time for States to provide comments on the FHWA program, but also recognize that HSOs must meet the upcoming statutory August 1 deadline to submit their Annual Grant Applications, which includes amendments to their triennial HSPs for the NHTSA program and State DOTs must meet the August 31 deadline to submit their safety performance targets in their HSIP annual reports. States' efforts to develop their FY 2025 Annual Grant Applications are underway at this time, and it is critical that States be provided certainty about application criteria. With these considerations in mind, NHTSA finds it in the public interest to amend the regulation to clarify that, States may only amend common performance targets only if necessary to submit identical targets to FHWA in the HSIP, and to make this amendment effective immediately.

Likewise, FHWA finds it in the public interest to waive the regulatory requirement in 23 CFR 490.209(a)(1) that the State DOT targets shall be identical to the targets established by the State HSO for the common performance measures, for fiscal year 2025, and to make this waiver effective immediately.

IV. Regulatory Analyses and Notices

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563, and DOT Regulatory Policies and Procedures

The NHTSA and FHWA have considered the impact of this rulemaking action under E.O. 12866 (as amended by E.O. 14094), E.O. 13563, and the DOT's regulatory policies and procedures. This rulemaking document was not reviewed by the Office of Management and Budget (OMB) under E.O. 12866. This action is not expected to impose any costs because it makes limited revisions to the uniform procedures implementing State highway safety grant programs. This rulemaking has been determined to be not ''significant'' under the DOT's regulatory policies and procedures and the policies of OMB.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980 (5 U.S.C. 601 *et seq.*) requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations, and small governmental jurisdictions. Section 605 of the RFA allows an Agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities. The Small Business Regulatory Enforcement Fairness Act amended the RFA to require Federal agencies to provide a statement of the factual basis for certifying that an action would not have a significant economic impact on a substantial number of small entities.

This final rule makes limited revisions to the uniform procedures implementing State highway safety grant programs, which were previously determined to not have a significant impact on a substantial number of small entities. The grant programs impacted by this rule will affect only State governments, which are not considered to be small entities as that term is defined by the RFA. Therefore, the Agencies certify that this action will not have a significant impact on a substantial number of small entities and

find that the preparation of a Regulatory Flexibility Analysis is unnecessary.

C. Executive Order 13132 (Federalism)

Executive Order 13132 on ''Federalism'' requires NHTSA and FHWA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' 64 FR 43255 (August 10, 1999). ''Policies that have federalism implications'' are defined in the E.O. to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under E.O. 13132, an Agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local governments in the process of developing the proposed regulation. An Agency also may not issue a regulation with federalism implications that preempts a State law without consulting with State and local officials.

The Agencies have analyzed this rulemaking action in accordance with the principles and criteria set forth in E.O. 13132. The limited revisions made by this rulemaking provide flexibility to State applicants. The Agencies have therefore determined that this final rule would not have sufficient federalism implications as defined in the order to warrant formal consultation with State and local officials or the preparation of a federalism summary impact statement.

D. Executive Order 12988 (Civil Justice Reform)

Pursuant to E.O. 12988 (61 FR 4729 (February 7, 1996)), ''Civil Justice Reform,'' the Agencies have considered whether this rule would have any retroactive effect. The Agencies conclude that it would not have any retroactive or preemptive effect, and judicial review of it may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review. This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

E. Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal Agency unless the collection displays a valid OMB control number. This rulemaking does not establish any new information collection requirements.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires Agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in expenditures by State, local or Tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted annually for inflation with base year of 1995). This rulemaking would not meet the definition of a Federal mandate because any potential resulting annual State expenditures would not exceed the minimum threshold. The program is voluntary and States that choose to apply and qualify would receive grant funds.

G. National Environmental Policy Act

The NHTSA and FHWA have considered the impacts of this rulemaking action for the purposes of the National Environmental Policy Act. The Agencies have determined that this rulemaking would not have a significant impact on the quality of the human environment and qualifies for the categorical exclusion at 23 CFR 771.117(c)(20).

H. Executive Order 13211

Executive Order 13211 (66 FR 28355, May 18, 2001) applies to any rulemaking that: (1) is determined to be economically significant as defined under E.O. 12866, and is likely to have a significantly adverse effect on the supply of, distribution of, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This rulemaking is not likely to have a significantly adverse effect on the supply of, distribution of, or use of energy. This rulemaking has not been designated as a significant energy action. Accordingly, this rulemaking is not subject to E.O. 13211.

I. Executive Order 13175 (Consultation and Coordination With Indian Tribes)

The Agencies have analyzed this rulemaking under E.O. 13175 and have determined that this action would not have a substantial direct effect on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal law. Therefore, a Tribal summary impact statement is not required.

J. Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR19477) or you may visit *https://dms.dot.gov.*

List of Subjects

23 CFR Part 490

Bridges, Highway safety, Highways and roads, Reporting and recordkeeping requirements.

23 CFR Part 1300

Administrative practice and procedure, Alcohol abuse, Drug abuse, Grant programs-transportation, Highway safety, Intergovernmental relations, Motor vehicles-inmotorcycles, Reporting and recordkeeping requirements.

Issued in Washington, DC, under authority delegated in 49 CFR 1.81, 1.85, and 1.95 and 49 CFR 501.5.

Shailen P. Bhatt,

Administrator, FHWA.

Sophie Shulman,

Deputy Administrator, NHTSA.

In consideration of the foregoing, NHTSA and FHWA amend 23 CFR parts 490 and 1300 as follows:

PART 490—NATIONAL PERFORMANCE MANAGEMENT MEASURES

■ 1. The authority citation for part 490 continues to read as follows:

Authority: 23 U.S.C. 134, 135, 148(i), and 150; 49 CFR 1.85.

Subpart B—National Performance Management Measures for the Highway Safety Improvement Program

■ 2. Amend § 490.209 by revising the second sentence in paragraph (a)(1) to read as follows:

§ 490.209 Establishment of performance targets.

(a)

* * * * *

(1) * * * For Fiscal Year 2025 only, the performance targets submitted under

this paragraph are not required to be identical to the targets established by the State Highway Safety Office for the common performance measures.

* * * * *

PART 1300—UNIFORM PROCEDURES FOR STATE HIGHWAY SAFETY GRANT PROGRAMS

■ 3. The authority citation for part 1300 continues to read as follows:

Authority: 23 U.S.C. 402; 23 U.S.C. 405; Sec. 1906, Pub. L. 109–59, 119 Stat. 1468, asamended by Sec. 25024, Pub. L. 117–58, 135 Stat. 879; delegation or authority at 49 CFR 1.95.

Subpart B—Triennial Highway Safety Plan and Annual Grant Application

■ 4. Amend § 1300.12 by revising paragraph (b)(1)(ii) to read as follows:

* * * * *

(b) * * *

(1) * * *

(ii) The State may add performance measures based on updated traffic safety problem identification or as part of an application for a grant under section 405, but may not amend existing performance targets. Provided, however, that States may amend common performance targets developed under § 1300.11(b)(3)(iv) only if necessary to submit identical targets to FHWA in the HSIP annual reports.

* * * * *

[FR Doc. 2024–09732 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 26, 301, and 602

[TD 9996]

RIN 1545–BH63

Relief Provisions Respecting Timely Allocation of GST Exemption and Certain GST Elections

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations that provide guidance describing the circumstances and procedures under which an extension of time will be granted to make certain allocations and elections related to the generation-skipping transfer (GST) tax. The statutory provision underlying these rules was enacted as part of the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA). The guidance affects individuals (or their estates) who failed to make a timely allocation of GST exemption, a timely election out of the GST automatic allocation rules, or certain other timely GST elections.

DATES:

Effective date: These regulations are effective on May 6, 2024.

Applicability date: For dates of applicability, *see* §§ 26.2642–7(j), 301.9100–2(f)(2), and 301.9100–3(g)(2).

FOR FURTHER INFORMATION CONTACT: Mayer R. Samuels at (202) 317–6859 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations in 26 CFR parts 26, 301, and 602 that provide guidance on the application of section 2642(g)(1) of the Internal Revenue Code (Code), which describes the circumstances and procedures under which an extension of time will be granted to make certain allocations and elections related to the GST tax.

Congress added section 2642(g)(1) to the Code by enacting section 564 of the EGTRRA, Public Law 107–16, section 564, 115 Stat. 91 (2001). Section 2642(g)(1) directs the Secretary of the Treasury or her delegate (Secretary) to issue regulations prescribing the circumstances and procedures under which an extension of time will be granted to make an allocation of GST exemption, as described in section 2631 of the Code, to a transfer, and the following three elections under section 2632 of the Code: (1) an election under section 2632(b)(3) not to have the deemed (automatic) allocation of GST exemption apply to a direct skip (generally, a transfer subject to gift or estate tax made to a person more than one generation below the transferor); (2) an election under section 2632(c)(5)(A)(i) not to have the deemed (automatic) allocation of GST exemption apply to an indirect skip or to transfers made to a particular trust; and (3) an election under section 2632(c)(5)(A)(ii) to treat any trust as a GST trust for purposes of section 2632(c). In determining whether to grant relief, section 2642(g)(1) directs that all relevant circumstances be considered, including evidence of intent contained in the trust instrument or the instrument of transfer.

The legislative history accompanying section 2642(g)(1) indicates that Congress believed that, in appropriate circumstances, an individual should be granted an extension of time to allocate GST exemption regardless of whether any period of limitations had expired. Those circumstances include situations in which the taxpayer intended to allocate GST exemption and the failure to allocate the exemption was inadvertent. H.R. Conf. Rep. No. 107–84, 202 (2001).

After the enactment of section 2642(g)(1), the IRS issued Notice 2001–50 (2001–2 CB 189), which provided guidance for transferors seeking an extension of time to make an allocation of GST exemption or an election described in sections 2632(b)(3) or (c)(5). Notice 2001–50 provides, generally, that relief will be granted under § 301.9100–3 of the Procedure and Administration Regulations (regarding requests of extensions of time for certain regulatory elections) if the taxpayer satisfies the requirements of those regulations and establishes to the satisfaction of the Commissioner of Internal Revenue or his delegate (Commissioner) that the taxpayer acted reasonably and in good faith and that a grant of the requested relief will not prejudice the interests of the government. If relief is granted under § 301.9100–3 and the allocation is made, the amount of GST exemption allocated to the transfer is the Federal gift or estate tax value of the property as of the date of the transfer and the allocation is effective as of the date of the transfer. Notice 2001–50 will be made obsolete upon the publication of this Treasury decision in the **Federal Register**.

On August 2, 2004, the IRS issued Rev. Proc. 2004–46 (2004–2 CB 142), which provides a simplified alternate method to obtain an extension of time to allocate GST exemption in certain situations. Generally, this method is available only with respect to an inter vivos transfer to a trust from which a GST may be made and only if each of the following requirements is met: (1) The transfer qualified for the gift tax annual exclusion under section 2503(b) of the Code; (2) the sum of the amount of the transfer and all other gifts by the transferor to the donee in the same year did not exceed the applicable annual exclusion amount for that year; (3) no GST exemption was allocated to the transfer; (4) the taxpayer has unused GST exemption to allocate to the transfer as of the filing of the request for relief; and (5) no taxable distributions or taxable terminations have occurred as of the filing of the request for relief.

On August 9, 2004, the IRS issued Rev. Proc. 2004–47 (2004 CB 169), which provides alternative relief for taxpayers who failed to make a reverse qualified terminable interest property (QTIP) election on an estate tax return.

On April 17, 2008, proposed regulations (REG–147775–06) were published in the **Federal Register** (73 FR 20870). The proposed regulations provided guidance on the application of section 2642(g)(1) by identifying the standards that the IRS will apply in determining whether to grant a transferor or a transferor's estate an extension of time to make an allocation of GST exemption, as described in section 2631, to property transferred by the transferor and the following three elections under section 2632: (1) an election under section 2632(b)(3) not to have the automatic allocation of GST exemption apply to a direct skip; (2) an election under section 2632(c)(5)(A)(i) not to have the automatic allocation of GST exemption apply to an indirect skip or to transfers made to a particular trust; and (3) an election under section 2632(c)(5)(A)(ii) to treat any trust as a GST trust for purposes of section 2632(c). In addition to proposing these standards, the proposed regulations included procedural requirements for establishing eligibility for the requested relief, including identification of the various persons from whom affidavits would be required.

In order to evaluate the necessity for and determine the burden imposed by the requirement to produce affidavits under proposed § 26.2642–7(h), the proposed regulations requested comments specifically as to (1) whether the affidavits are necessary for the proper performance of the functions of the IRS, including whether the information provided by the affidavits will have practical utility, (2) the accuracy of the estimated burden associated with preparing the affidavits, (3) how the quality, utility, and clarity of the information to be provided by the affidavits may be enhanced, (4) how the burden of providing the affidavits may be minimized, including through the application of automated collection techniques or other forms of information technology, and (5) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the affidavits.

The proposed regulations also identified situations that do not satisfy the standards for granting relief, and thus when the IRS will not grant the requested relief.

The IRS received a total of five comments, three of which explicitly addressed the procedural requirements of proposed § 26.2642–7(h), redesignated in the final regulations as § 26.2642–7(i). After careful consideration of the comments received on the proposed regulations, this Treasury decision adopts the proposed regulations with clarifying changes and additional modifications in response to comments as described in the Summary of Comments and Explanation of Revisions. Relief provided under section 2642(g)(1) will be granted through the IRS private letter ruling program.

Section 301.9100–1 generally provides that the Commissioner has the discretion to grant a reasonable extension of time under the rules set forth in §§ 301.9100–2 and 301.9100–3 to make a regulatory election under all subtitles of the Code, except subtitles E, G, H, and I (section 9100 provisions). On and after the date of publication of these final regulations, relief under section 2642(g)(1) no longer will be granted under § 301.9100–3. In addition, because these final regulations provide a replacement for the automatic six-month extension under § 301.9100–2(b) without substantive difference, the extension under § 301.9100–2(b) no longer will be available to transferors or transferor's estates qualifying for relief under proposed § 26.2642–7(h)(1), redesignated in the final regulations as § 26.2642–7(i)(1), on and after the date of publication of these final regulations. Accordingly, the final regulations amend §§ 301.9100–2(b) and 301.9100–3 to provide that relief under section 2642(g)(1) cannot be obtained through the provisions of §§ 301.9100–2(b) and 301.9100–3. However, requests that are pending with the IRS on the date of publication of these final regulations will continue to be processed under the section 9100 provisions unless the taxpayer requesting relief opts to withdraw the request and instead seek relief under these final regulations. In that case, the taxpayer's user fee will be refunded and a new user fee will be required with the new request. Furthermore, the procedures contained in Revenue Procedure 2004–46 and Revenue Procedure 2004–47 will remain effective for transferors within the scope of those revenue procedures.

The Department of the Treasury (Treasury Department) and the IRS are mindful that the proposed regulations were issued 16 years ago on April 17, 2008. Insofar as there have been no intervening legislative or regulatory changes regarding allocations of GST exemption or GST elections and because the issues addressed by the commenters on the proposed regulations continue to remain relevant, the Treasury Department and the IRS have determined that a new notice of proposed rulemaking or a further opportunity for public comment would be unlikely to generate different comments and, moreover, would unnecessarily delay further this rulemaking to the continued detriment of taxpayers seeking relief. In addition, the IRS has a ruling position that, because of the provisions of the 2008 proposed regulations, relief cannot be granted in certain otherwise appropriate situations until the 2008 proposed regulations have been superseded by the issuance of these final regulations. For such situations, the issuance of a new notice of proposed rulemaking or a reopening of the comment period would further delay, and in some cases prevent, the grant of needed relief to taxpayers.

The Treasury Department and the IRS currently are developing a new rulemaking that will complement these final regulations. In contrast to these final regulations, which address the standards for granting relief under section 2642(g)(1) for a failure to make a timely allocation or election, the forthcoming proposed regulations would address the practical effect of a grant of relief and would clarify the interplay between affirmative allocations and automatic allocations. Paragraphs in these final regulations have been reserved to accommodate the forthcoming proposed regulations.

Summary of Comments and Explanation of Revisions

I. Scope of Authority To Issue Regulations

Section 2642(g)(1) gives the Secretary the authority to issue regulations setting forth the ''circumstances and procedures'' under which extensions of time will be granted to make certain allocations of GST exemption and elections, taking into consideration all relevant circumstances, including evidence of intent contained in the trust instrument or instrument of transfer and such other factors as the Secretary deems relevant. Section 2642(g)(1) makes the late allocations and elections referenced in that section eligible for consideration for relief. Because deadlines prescribed by statute are not eligible for relief under § 301.9100–3, section 2642(g)(1)(B) concludes with the sentence, for purposes of determining whether to grant relief under this paragraph, the time for making the allocation (or election) shall be treated as if not expressly prescribed by statute. Some commenters maintained that this sentence, creating eligibility for a grant of relief, limits the authority of the Treasury Department and the IRS to issue regulations that provide standards for relief that are more restrictive than those under § 301.9100–3. Neither the statute nor its legislative history suggests that the standards for relief

under section 2642(g)(1) are required to be equivalent or limited to the standards set forth in § 301.9100–3, nor is there any implication that the enactment of section 2642(g) prohibits or forecloses the possibility of any future change to the regulatory standards in § 301.9100–3. Nevertheless, the final regulations adopt burden reducing provisions as explained later in this preamble.

II. Proposed § 26.2642–7(d)(2)—Reasonableness and Good Faith

Proposed § 26.2642–7(d)(2) provides a nonexclusive list of circumstances (the underlying facts of which may be either helpful or harmful to the taxpayer's request for relief) that the IRS will consider in determining whether the transferor or the transferor's executor acted reasonably and in good faith.

Commenters requested that the Treasury Department and the IRS modify proposed § 26.2642–7(d)(2) to provide that the transferor or the executor of the transferor's estate will be deemed to have acted reasonably and in good faith if the taxpayer establishes the existence of any one of the various factors listed in § 26.2642–7(d)(2). Alternatively, commenters requested that § 26.2642–7(d)(2) be clarified to denote the sufficiency or relative importance of the factors listed.

Section 2642(g)(1) directs the Treasury Department and the IRS to issue regulations that ''prescribe such circumstances and procedures'' under which the IRS will grant relief. Since the enactment of section 2642(g) and through the IRS private letter ruling program, the IRS has applied a facts and circumstances methodology in considering requests for relief. Given the inherent complexity of the GST exemption rules, no single factor can be determinative. While § 301.9100–3(b)(1) deems the reasonableness and good faith requirements to have been met if the taxpayer establishes any one of the factors therein, that rule is expressly made subject to the requirement of the absence of the use of hindsight and the other factors described in § 301.9100–3(b)(3) and (c), and thus is not a one-factor test. Accordingly, proposed § 26.2642–7(d)(2) seeks to delineate the many factors implicit in such a facts and circumstances inquiry, and the final regulations adopt the same methodology.

The IRS's experience with requests for relief under section 2642(g)(1) indicates that no one factor has more importance in all cases than any other factor. Further, the satisfaction of one factor alone may or may not be sufficient, in the context of the facts and circumstances of that particular taxpayer, to persuade the IRS that relief under section 2642(g)(1) is warranted. Therefore, the recommendation to allow one factor to be determinative has not been adopted in the final regulations. Nevertheless, the final regulations clarify that not all of these factors may be relevant in a particular situation (and those that are not relevant would not need to be addressed in the request for relief). In addition, based on all the facts and circumstances, a single factor listed in § 26.2642–7(d)(2) may (or may not) be determinative.

Section 301.9100–3(b)(1)(i) provides that a taxpayer is deemed to have acted reasonably and in good faith if the taxpayer requests relief before the failure to make the regulatory election is discovered by the IRS. A commenter requested that this circumstance be added to the factors listed in this provision. Thus, a taxpayer would be considered to have acted reasonably and in good faith if the taxpayer's request for relief was filed before the failure to make the allocation or regulatory election is discovered by the IRS. For purposes of section 2642(g)(1), the Treasury Department and the IRS have determined that this circumstance is not material because, in the context of a request for relief under section 2642(g)(1), the Treasury Department and the IRS believe that the party that first discovers the failure to make the allocation or election (be it the IRS or the taxpayer) generally has no correlation with the taxpayer's good faith or reasonable action. Particularly because of the significant length of time that often elapses between the transfer and the discovery of a missed GST election or allocation, the discovery by the IRS does not necessarily signify a lack of good faith or reasonable action by the taxpayer. At the same time, the taxpayer's discovery generally does not guarantee the existence of good faith and reasonable action by the taxpayer. Therefore, this factor has not been added to the final regulations. However, a delay in requesting relief, after the need for relief is discovered, may have an adverse effect on the availability of relief. See, for example, the circumstances described in § 26.2642–7(d)(3)(ii) and (e)(3).

III. Proposed § 26.2642–7(d)(2)(iv)—Consistency

Proposed § 26.2642–7(d)(2)(iv) provides that one of the factors to be considered in determining whether the taxpayer has acted reasonably and in good faith is whether the transferor acted consistently with regard to the allocation of the transferor's GST exemption. Section 26.2642–7(d)(2)(iv) is designed to elicit information relevant to the intent of the transferor with regard to allocating exemption or making an election. For instance, a transferor's pattern of allocating GST exemption in an amount equal to the value of transfers to a trust in three or more years (whether or not consecutive) tends to support an assumption that the transferor intended to have that trust be exempt from GST tax and thus supports a presumed intent to allocate exemption to a transfer to that same trust taking place in a year in which an allocation in fact was not made.

A commenter requested that this provision be clarified to provide that the enactment of the statute itself be deemed to be a change in circumstance that could explain any post-enactment deviations from pre-enactment decisions regarding the allocation of GST exemption. In response to this comment, § 26.2642–7(d)(2)(iv) has been modified in the final regulations to confirm that relief under this provision will not be denied merely because a pattern does not exist or because the existing pattern changed at some point, whether in response to the enactment of a statute or to some other factor unrelated to either a lack of reasonableness or good faith or prejudice to the interests of the government.

IV. Proposed § 26.2642–7(d)(3)—Prejudice to the Interests of the Government

One commenter queried the placement of two of the factors under § 26.2642–7(d)(3) pertaining to whether a grant of relief would prejudice the interests of the government. These two factors are (i) the extent to which the requested relief is an attempt to benefit from hindsight, and (ii) the extent to which a delay in the filing of the request for relief was an attempt to deprive the IRS of sufficient time to challenge the claimed identity of the transferor of the transferred property that is the subject of the request for relief, the value of that transferred property for Federal gift or estate tax purposes, or any other aspect of the transfer that is relevant for Federal gift or estate tax purposes. The commenter recommended that these two factors, to the extent they deal with the transferor's subjective intentions, be moved from proposed § 26.2642–7(d)(3) to proposed § 26.2642–7(d)(2), which relates to reasonableness and good faith.

While these two factors may reflect unreasonableness or bad faith on the part of the transferor or the transferor's executor, each of these factors also represents an instance in which granting relief would prejudice the interests of

the government. Therefore, the Treasury Department and the IRS have not adopted this suggestion in the final regulations.

V. Proposed § 26.2642–7(d)(3)(i)—Hindsight

Proposed § 26.2642–7(d)(3)(i) provides, in part, that one of the relevant factors in determining whether the government's interests would be prejudiced is whether the grant of the requested relief would permit an economic advantage or other benefit that would not have been available if the allocation or election had been timely made. A commenter suggested that the definition of the term ''economic advantage'' is vague and may be overbroad, in that no request for relief is ever made unless the grant of relief will be advantageous to the taxpayer by producing an economic advantage in the form of a reduction of tax liability. This provision, however, is intended to limit the reference to economic advantage to an advantage that may not have been available through a timely allocation or election. One example of an economic advantage that would not have been available at the time of a timely allocation of GST exemption would be a request to allocate exemption to only one of two trusts (specifically, to the trust with the greater appreciation) if the two trusts were created on the same date with the same beneficiaries but with different assets. Therefore, the Treasury Department and the IRS have not adopted this suggestion in the final regulations.

VI. Proposed § 26.2642–7(d)(3)(ii)—Timing of the Request for Relief

Proposed § 26.2642–7(d)(3)(ii) provides, in part, that the expiration of any period of limitations on the assessment or collection of transfer taxes prior to the filing of a request for relief will not by itself prohibit a grant of relief. The proposed regulation further states that the combination of the expiration of a period of limitations with the fact that the asset or interest was valued with the use of a valuation discount will not by itself prohibit a grant of relief. A commenter indicated that the relevance of the use of valuation discounts and the period of limitations in determining whether to grant section 2642(g)(1) relief is not clear. The commenter stated that the use of valuation discounts that are consistent with established valuation methods neither prejudices the government nor constitutes an act of bad faith and therefore should not be considered, even in combination with other factors, in determining whether relief should be granted. The commenter also stated that any consideration given to the expiration of the period of limitations is contrary to the legislative history of section 2642(g), which clearly directs that the IRS is to disregard the expiration of any period of limitations in considering requests for relief. The commenter maintains that the IRS should not use hindsight to deny relief simply because the IRS failed to challenge the valuation of transferred property or any other aspect of the transaction reported on a return prior to the expiration of a limitations period.

The sentences of proposed § 26.2642–7(d)(3)(ii) that discuss the expiration of the period of limitations and the use of valuation discounts as factors that are considered for relief are removed from the final regulations. Section 26.2642–7(d)(3)(iv) is added to the final regulations to confirm that, subject to the considerations related to the timing of the request for relief described in § 26.2642–7(d)(3)(ii), the expiration of the period of limitations on the assessment or collection of transfer taxes prior to the filing of a request for relief generally is not relevant to the determination of whether the requirements for a grant of relief under section 2642(g)(1) have been met. Section 26.2642–7(d)(3)(iv) provides, however, that if the IRS concludes that the value of the transferred asset or assets as reported by the transferor or the executor of the transferor's estate on the Federal gift or estate tax return was so understated that it is likely to have satisfied the definition of a ''gross valuation misstatement'' as defined in section 6662(h)(2)(C) of the Code, the IRS will consider the purported transfer tax undervaluation in determining whether a grant of relief would prejudice the interests of the government. This provision is tied to the definition of a gross valuation misstatement to confirm that the perceived understatement in value would have to be exceptional in degree to raise the possibility of prejudice to the interests of the government. This provision is relevant only if the period of limitations on assessment or collection for transfer tax purposes expired before the filing of the request for relief.

VII. Proposed § 26.2642–7(d)(3)(iii)—Intervening Taxable Events

Proposed § 26.2642–7(d)(3)(iii) provides that the occurrence and effect of an intervening taxable termination or taxable distribution will be considered in determining whether the interests of the government would be prejudiced by granting relief. The proposed regulations further state that the interests of the government may be prejudiced if a taxable termination or taxable distribution occurred between the time for making a timely allocation of GST exemption or a timely election described in section 2632(b)(3) or (c)(5) and the time at which the request for relief under this section was filed. A commenter requested that this language be removed from the final regulations and replaced with a sentence or example indicating that the existence of a GST tax liability when relief is requested is not relevant in determining whether relief under section 2642(g)(1) will be granted. Alternatively, the commenter requested that the final regulations provide that these rules not apply if the period of limitations on the assessment of resulting GST tax has not expired when relief is requested. In addition, the commenter requested that the final regulations provide transferors with the option of paying the GST tax resulting from the taxable termination or taxable distribution occurring prior to submission of the request for relief, or of forfeiting any refund of GST tax to which the transferor otherwise would be entitled upon the grant of relief.

These recommendations have not been adopted in the final regulations. Although an intervening taxable distribution or taxable termination itself does not necessarily bar a grant of relief under section 2642(g)(1), it may be relevant in identifying the existence of hindsight or in ascertaining the intent of the transferor. In addition, the difficulty and complexity of making all of the related adjustments caused by a grant of relief (including, for example, the grantor's willingness to pay any GST tax liability and any transfer tax consequences of that payment), some of which might also impact other taxpayers, will be a factor to be considered in determining whether the government's interests would be prejudiced.

VIII. Proposed § 26.2642–7(e)(1)—Timely Allocations and Elections

Proposed § 26.2642–7(e)(1) provides that relief will not be granted to decrease or revoke a timely allocation of GST exemption as described in § 26.2632–1(b)(4)(ii)(A)(*1*), or to revoke an election under section 2632(b)(3) or (c)(5) made on a timely filed Federal gift or estate tax return. Section 2631(b) provides that an allocation of GST exemption under section 2631(a), once made, is irrevocable. No statute, however, provides that an election made under section 2632(b)(3) or (c)(5) is irrevocable.

Accordingly, proposed § 26.2642–7(e)(1), redesignated in the final regulations as § 26.2642–7(e)(2), does not include the statement that relief is not available to revoke an election under section 2632(b)(3) or (c)(5) made on a timely filed Federal gift or estate tax return. Such relief may be available provided that the requirements of § 26.2642–7 of these final regulations are satisfied. Further, as described below, the final regulations, as they pertain to timely allocations, include three narrow exceptions that allow for relief from affirmative allocations of GST exemption.

Proposed § 26.2642–7(e)(1), redesignated in the final regulations as § 26.2642–7(e)(2), has been further modified to clarify that the allocation and election referred to is an affirmative (not an automatic) allocation or election. The Treasury Department and the IRS will address the effect of a grant of relief on automatic allocations in future guidance to be issued under section 2642(g).

A commenter indicated that it is not clear whether proposed § 26.2642–7(e)(1) also applies to allocations of GST exemption with respect to transfers made at death. This rule has been clarified in the final regulations to encompass transfers made at death and confirms that relief will not be granted to decrease or revoke an affirmative allocation (as opposed to an automatic allocation) of GST exemption, regardless of whether the transfer or the allocation of exemption was made during a transferor's life or upon the transferor's death.

The commenter further requested that the provision be modified to provide that affirmative allocations (as opposed to automatic allocations) of exemption or elections made on a timely filed estate tax return of the estate of a decedent dying prior to 2001 be exempted from this provision because section 2642(g)(1) relief was not available before December 31, 2000. Although this recommendation has not been adopted in the final regulations for all such allocations of exemption, relief from the problem raised by this comment is provided by the third of the exceptions included in the final regulations, as described in the following paragraphs.

The final regulations have been modified to include three narrow exceptions that allow for relief from affirmative allocations and elections. The first exception is that an allocation of GST exemption to a transfer or a trust (other than a charitable lead annuity trust (CLAT) or a trust subject to an estate tax inclusion period (ETIP) before the termination of the lead interest or ETIP, respectively) is void to the extent that the amount allocated exceeds the amount necessary to obtain an inclusion ratio of zero. *See* § 26.2632–1(b)(4)(i). (The allocation of exemption to a CLAT upon its creation may turn out to be insufficient or excessive for the purpose of making the CLAT fully GST exempt, but the allocation will not be voided. The allocation of exemption to a trust subject to an ETIP does not become irrevocable until the termination of the ETIP.)

The second exception is that an allocation is void if the allocation is made with respect to a trust that, at the time of the allocation, has no GST potential with respect to the transferor making the allocation. For this purpose, a trust has GST potential even if the possibility of a GST is so remote as to be negligible. *See* § 26.2632–1(b)(4)(i).

The third exception is that a late allocation (as defined in section 2642(b)(3)) will be deemed to be void as part of the relief granted under section 2642(g) if the late allocation was made in an effort to mitigate the tax consequences of the missed allocation that is the subject of the grant of relief and that was not eligible for relief prior to the enactment of section 2642(g)(1). Specifically, such a late allocation is deemed to be void if (1) prior to December 31, 2000, a transfer was made to a trust with GST potential with respect to the transferor; (2) a timely allocation of GST exemption to the trust was not made; (3) prior to December 31, 2000, a late allocation of GST exemption was made to the trust; (4) the late allocation is disclosed as part of the request for relief or during the IRS's consideration of that request; and (5) relief under section 2642(g)(1) is granted to make a timely allocation to the transfer made prior to December 31, 2000.

Finally, the commenter questioned what effect a grant of relief under section 2642(g)(1) has on a timely allocation (whether affirmative or automatic) of the same transferor's GST exemption to a transfer made subsequent to the transfer for which relief is requested. The commenter suggested that, if relief is granted under section 2642(g)(1) to timely allocate GST exemption to an earlier transfer, the GST exemption timely allocated (whether affirmatively or automatically) to a later transfer could be reduced or eliminated. The commenter suggested that the grant of relief for the earlier transfer could be conditioned on payment of the GST tax that may be due if the inclusion ratio with respect to the subsequent transfer is increased by the grant of relief. The Treasury Department and the IRS believe that, because the response to this comment may go beyond the scope of the proposed regulations, this issue is among those they intend to address in subsequent guidance.

IX. Proposed § 26.2642–7(f)—Period of Limitations Under Section 6501

Proposed § 26.2642–7(f), redesignated in the final regulations as § 26.2642–7(g), provides that a request for relief does not reopen, suspend, or extend the period of limitations on assessment or collection of any estate, gift, or GST tax under section 6501 of the Code. Thus, the IRS may request that the transferor or the transferor's executor consent under section 6501(c)(4) to an extension of the period of limitations on assessment or collection of any or all gift and GST taxes.

A commenter requested that the references to gift tax be removed from this provision, apparently in an effort to eliminate the possibility that the grant of relief might be conditioned on the taxpayer's agreement to extend the gift tax period of limitations. The commenter's rationale for this request is that the request for relief relates only to the GST tax. The references to gift tax in this provision, however, complement § 26.2642–7(d)(3)(ii) of the final regulations, in effect, by allowing the taxpayer to avoid a finding of prejudice to the interests of the government by agreeing to an extension of the gift tax period of limitations. An agreement to extend the period of limitations is voluntary and declining to agree to an extension would not necessarily mean that relief would be denied, but it is a factor that may be taken into consideration. By retaining this reference to the gift tax, the government would be given adequate time to consider the reported identity of the transferor, the valuation of the transferred interest that will eventually determine the amount of GST exemption that may be allocated to the transfer, or any other aspect of the transfer that is relevant for Federal gift or estate tax purposes. Therefore, this reference has not been deleted from the final regulations.

A taxpayer who seeks relief under section 2642(g)(1) will not be regarded as having filed a claim for refund or credit merely by requesting such relief.

X. Proposed § 26.2642–7(h)(2) and (3)—Affidavits and Declarations

Commenters recommended against requiring affidavits that provide more information than is required under § 301.9100–3(e)(2) and (3). One

commenter characterized the proposed procedural requirements as more burdensome than the corresponding procedural requirements under the section 9100 provisions and stated that these ''more burdensome'' requirements for relief are inconsistent with the statutory mandate in section 2642(g). Since the enactment of section 2642(g), the IRS has issued a significant number of private letter rulings granting relief under section 2642(g)(1). After considering the circumstances in the requests, the IRS has concluded that certain information in addition to that specified in § 301.9100–3(e)(2) and (3) is necessary to determine whether relief should be granted. Accordingly, based on the IRS's experience in evaluating such requests for relief, the Treasury Department and the IRS have not adopted this recommendation in the final regulations.

Another commenter maintained that the affidavits required by proposed § 26.2642–7(h) are not necessary for the proper performance of the functions of the IRS and, therefore, the quality, utility, and clarity of the information to be provided by the affidavits cannot be enhanced. In support, the commenter argued that the affidavits demand more substantiation from taxpayers than is contemplated by section 2642(g)(1)(B). In addition, the commenter asserted that the IRS can grant relief under section 2642(g)(1) without requiring these affidavits if the IRS focuses on the government's interest and the transferor's intent as evidenced in the transfer documents and other supporting documents. Finally, the commenter stated that the IRS could determine from the documents previously filed with the IRS that the period of limitations had expired or that a taxable termination or distribution had occurred, both factors that may be indicative of prejudice to the government.

In the course of issuing private letter rulings under § 301.9100–3, the IRS has determined that, while transfer instruments and other relevant documents provided by the transferor or the transferor's executor provide useful information, these documents do not necessarily provide all of the information needed to evaluate properly a request for relief under section 2642(g)(1). Accordingly, the final regulations retain the requirement that requests for relief include detailed affidavits. However, after consideration of the comments and review of the proposed regulations, the Treasury Department and the IRS have modified the regulations by decreasing the amount of information required in affidavits in order to replicate more closely the requirements of § 301.9100–3(e)(2) and (3). As a result, the final regulations reduce the burden the proposed regulations would have imposed.

Commenters also requested a narrowing of the categories of individuals from whom affidavits will be required. In addition to individuals involved in the preparation of the tax return, proposed § 26.2642–7(h)(3) also includes in this group each tax professional who advised or was consulted on ''any aspect of the transfer'' or on the trust, and each agent or legal representative of the transferor who participated ''in the transaction.'' Commenters noted that this group may include advisors, agents, or legal representatives of the transferor who had nothing to do with preparing the return or with the decision or failure to allocate exemption or to make an election on that return.

In response to these comments, the Treasury Department and the IRS have modified the regulations by narrowing the categories of individuals required to submit affidavits under proposed § 26.2642–7(h)(3), redesignated in the final regulations as § 26.2642–7(i)(4). Specifically, the final regulations do not include in this group of required affiants any tax professional unless that professional participated in or provided advice with regard to the GST tax exemption allocation or election, or with regard to the preparation of the return. As a result, the final regulations reduce the burden the proposed regulations would have imposed.

The final regulations, however, also have been modified to confirm that the IRS, consistent with current procedures in the IRS private letter ruling program, may require affidavits and copies of writings from persons not included in the more narrow group described in § 26.2642–7(i)(4) in cases in which the IRS believes additional information is required or would be helpful in making the determination as to whether relief under section 2642(g)(1) will be granted.

XI. Proposed § 26.2642–7(h)(3)(iii)—Affidavits of Other Parties

Proposed § 26.2642–7(h)(3)(iii) provides that a party making an affidavit must attach to each affidavit copies of any writing (including, without limitation, notes and emails) and other contemporaneous documents within the possession of the affiant relevant to the transferor's intent with regard to the application of GST tax to the transaction. A commenter requested that this provision be modified to provide that a lawyer or accountant is not deemed to possess any documents that are in the possession of his or her law firm or accounting firm. In response to this comment, this provision of the final regulations, redesignated in the final regulations as § 26.2642–7(i)(4)(iii), clarifies that the writings to be submitted under these regulations are those that the affiant discovers by conducting, in good faith, a reasonably diligent search of records in the possession of or accessible to the affiant, or subject to the affiant's control. A reasonably diligent search generally would include, without limitation, a review of the records in the possession or control of the affiant or the firm with which the affiant is employed or associated relating to the transaction or tax return at issue.

XII. Proposed § 26.2642–7(h)(3)(v)—Death or Incapacity

Proposed § 26.2642–7(h)(3)(v) provides that, if a person who would be required to provide an affidavit under proposed § 26.2642–7(h)(3)(i) has died or is not competent, the transferor or the transferor's executor must include a statement to that effect in the affidavit of that transferor or executor.

A commenter suggested that this proposed provision would require the transferor or the transferor's executor to determine the competency of a person and that such a requirement would be inappropriate. Further, the commenter noted that, in addition to death and incompetence, serious physical illness or other physical impairment also could render a person unable to provide an affidavit. The commenter recommended that this provision be modified to provide that the transferor or the transferor's executor may satisfy the requirements of this provision with a statement that such transferor or executor, despite his or her best efforts in good faith, was unable to obtain the affidavit required under proposed § 26.2642–7(h)(3)(i) and an explanation of the basis for the transferor's or executor's conclusion, based on his or her best knowledge and reasonable belief that such affidavit was not obtainable.

The corresponding provision in the final regulations (§ 26.2642–7(i)(4)(vi)) has been modified to apply to persons who have died or who are unwilling or unable to provide the required affidavit at the time relief is requested. For purposes of this provision, the term *unwilling* refers to a person who does not (other than one who is unable to) provide the required affidavit, despite the best efforts of the transferor or the transferor's executor, made in good faith, to obtain the required affidavit.

The unwillingness of certain persons to provide an affidavit, however, may be considered by the IRS in determining whether or not to grant the requested relief. In addition, for purposes of this provision, the term *unable* refers to a permanent condition such as physical or mental incapacity that prevents a person from providing the required affidavit, but not a temporary condition such as a temporary physical or mental incapacity or a person's inability due to a leave of absence, travel, or a contractual requirement such as a confidentiality agreement.

XIII. User Fee and Estimated Burden

A commenter noted that taxpayers have to pay a user fee when seeking relief under section 2642(g)(1) through the IRS private letter ruling program. The commenter proposed that, given the complexity of the rules and the frequency of changes to the rules, relief under section 2642(g)(1) should be granted without charging a user fee. The commenter noted that, under other circumstances, the IRS has developed simplified procedures that do not necessitate a private letter ruling request and suggested that the compliance burden would be eased significantly if a simplified procedure to administer relief under section 2642(g)(1) were developed.

The Treasury Department and the IRS believe that the most efficient way to address these requests for relief continues to be through the IRS private letter ruling program. The user fee is imposed to recover the government's full cost for providing the service. The Treasury Department and the IRS agree that the compliance burden would be eased significantly if it was possible to develop a simplified procedure to administer relief under section 2642(g)(1). For instance, Rev. Proc. 2004–46 (2004–2 CB 142) and Rev. Proc. 2004–47 (2004–2 CB 169) identify situations in which the Treasury Department and the IRS believe that relief may be granted without adversely affecting the interests of the government. *See* § 601.601(d)(2)(ii)(*b*). The Treasury Department and the IRS are prepared to issue additional revenue procedures or other guidance when they identify situations for which simplified or automatic relief under section 2642(g)(1) would be appropriate and administrable. Until such guidance is issued, however, the IRS private letter ruling program will continue to allow the IRS to obtain and evaluate the information necessary to identify such situations. The user fee would follow the same schedule and amount as rulings under § 301.9100–1. See Appendix A of Rev. Proc. 2024–1, 2024–1 I.R.B. 1, 85.

The IRS had estimated in the proposed regulations that the annual burden to prepare the affidavits was two hours. Many commenters mentioned that the estimated burden was drastically underestimated due to the numerous requirements of the proposed regulations. In response to these comments, the IRS has reconsidered this estimate of the annual burden and has increased the estimated annual burden to 20 hours.

Effect on Other Documents

Notice 2001–50, 2001–2 CB 189, is obsolete as of May 6, 2024.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA), information collection requirements contained in these final regulations are in § 26.2642–7(i)(3) and (4). These provisions require transferors or the executors of transferors' estates to provide one or more affidavits when requesting relief under section 2642(g)(1) of the Internal Revenue Code. The IRS will use the information in the affidavits to determine whether to grant a transferor or a transferor's estate an extension of time to (1) allocate GST exemption as defined in section 2631, (2) elect under section 2632(b)(3) not to have the automatic allocation of GST exemption apply to a direct skip, (3) elect under section 2632(c)(5)(A)(i) not to have the automatic allocation of GST exemption apply to an indirect skip or to transfers made to a particular trust, and (4) elect under section 2632(c)(5)(A)(ii) to treat any trust as a GST trust for purposes of section 2632(c).

The reporting burden associated with the information collection in the final regulations are included in the aggregate burden estimates for OMB control number 1545–2116. The estimated number of respondents, who are mainly attorneys representing the taxpayers, for each year is estimated to be 50. The estimated burden for each respondent to prepare the private letter ruling request and the accompanying affidavits is 20 hours per respondent. Thus, the total annual burden is estimated to be 1000 hours. It should be noted that the burden is not an annual burden for each taxpayer, as taxpayers do not need to request a private letter ruling each year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

Books or records relating to a collection of information must be retained as long as their contents might become material in the administration of any Internal Revenue law. Generally, tax returns and tax information are confidential, as required by 26 U.S.C. 6103.

III. Regulatory Flexibility Act

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. The applicability of these regulations is limited to individuals (or their estates) and trusts, which are not small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Although it is anticipated that there may be a beneficial economic impact for some small entities, including entities that provide tax and legal services that assist individuals in the IRS private letter ruling program, any benefit to those entities would be indirect. Further, this indirect benefit will not affect a substantial number of these small entities because only a limited number of individuals (or their estates) and trusts would submit a private letter ruling request under this rule. Therefore, only a small fraction of tax and legal services entities would generate business or benefit from this rule. Accordingly, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business and no comments were received in response.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated

annually for inflation. This rule does not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications and do not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Drafting Information

The principal author of these regulations is Mayer R. Samuels, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 26

Estate taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR parts 26, 301, and 602 as follows:

PART 26—GENERATION-SKIPPING TRANSFER TAX REGULATIONS UNDER THE TAX REFORM ACT OF 1986

■ **Paragraph 1.** The authority citation for part 26 is amended by adding an entry for § 26.2642–7 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 26.2642–7 also issued under 26 U.S.C. 2642(g).

* * * * *

■ **Par. 2.** Section 26.2642–7 is added to read as follows:

§ 26.2642–7 Relief under section 2642(g)(1).

(a) *In general.* Under section 2642(g)(1)(A) of the Internal Revenue Code (Code), the Secretary of the Treasury or her delegate (Secretary) has the authority to issue regulations describing the circumstances in which a transferor, as defined in section 2652(a) of the Code, or the executor of a transferor's estate, as defined in section 2203 of the Code, will be granted an extension of time to allocate generation-skipping transfer (GST) exemption as described in section 2642(b)(1) and (2). The Secretary also has the authority to issue regulations describing the circumstances under which a transferor or the executor of a transferor's estate will be granted an extension of time to make the elections described in section 2632(b)(3) and (c)(5) of the Code. Section 2632(b)(3) provides that an election may be made by or on behalf of a transferor not to have the transferor's GST exemption automatically allocated under section 2632(b)(1) to a direct skip, as defined in section 2612(c), made by the transferor during life. Section 2632(c)(5)(A)(i) provides that an election may be made by or on behalf of a transferor not to have the transferor's GST exemption automatically allocated under section 2632(c)(1) to an indirect skip, as defined in section 2632(c)(3)(A), or to any or all transfers made by such transferor to a particular trust. Section 2632(c)(5)(A)(ii) provides that an election may be made by or on behalf of a transferor to treat any trust as a GST trust, as defined in section 2632(c)(3)(B), for purposes of section 2632(c) with respect to any or all transfers made by that transferor to the trust. This section generally describes the factors that the Internal Revenue Service (IRS) will consider when an extension of time is sought by or on behalf of a transferor to timely allocate GST exemption or to make an election under section 2632(b)(3) or (c)(5). If the time period for an automatic six-month extension under paragraph (i)(1) of this section has passed, relief provided under this section can be requested through the IRS private letter ruling program. See paragraph (i) of this section.

(b) *Effect of relief*—(1) *In general.* If an extension of time to allocate GST exemption is granted under this section, the allocation of GST exemption, once made, will be considered effective as of the date of the transfer. Further, the amount of the transferor's GST exemption required to be allocated in order to produce a zero inclusion ratio solely with regard to that transfer will be the value of the property transferred for purposes of chapter 11 or chapter 12 of the Code as of the date of the transfer. If an extension of time to elect out of the automatic allocation of GST exemption under section 2632(b)(3) or (c)(5)(A)(i) is granted under this section, the election, once made, will be considered effective as of the date of and immediately prior to the transfer. If an extension of time to elect to treat any trust as a GST trust under section 2632(c)(5)(A)(ii) is granted under this section, the election, once made, will be considered effective as of the date of and immediately prior to the first (or each) transfer covered by that election. See paragraph (h) of this section with regard to preserving a taxpayer's eligibility for a refund generated by a grant of relief, if applicable.

(2) [Reserved]

(3) *Effect on other transfers.* Except as otherwise provided in paragraph (e)(2)(ii) of this section, an allocation of exemption or an election made pursuant to a grant of relief under this section does not reduce or eliminate any affirmative allocation or void any election made with respect to any other transfer occurring contemporaneously with or subsequent to the transfer or transfers for which relief has been granted.

(c) *Limitation on relief.* The amount of GST exemption that may be allocated to a transfer as the result of relief granted under this section in no event may exceed the amount of the transferor's unused GST exemption under section 2631(c) of the Code as of the date of the transfer. Thus, if, by the time of the making of the allocation or election pursuant to relief granted under this section, the GST exemption amount under section 2631(c) has increased to an amount in excess of the amount in effect for the date of the transfer, no portion of the increased amount may be applied to that earlier transfer by reason of the relief granted under this section.

(d) *Basis for determination*—(1) *In general.* Requests for relief under this section will be granted when and to the extent that the transferor or the executor of the transferor's estate provides evidence (including the affidavits described in paragraph (i) of this section) establishing to the satisfaction of the IRS that the transferor or the executor of the transferor's estate acted reasonably and in good faith, and that the grant of relief will not prejudice the interests of the government. Paragraphs (d)(2) and (3) of this section set forth nonexclusive lists of factors the IRS will consider in determining whether this

standard of reasonableness, good faith, and lack of prejudice to the interests of the government has been met so that such relief will be granted. In making this determination, the IRS will consider those factors set forth in paragraphs (d)(2) and (3) of this section, as well as all other facts and circumstances not specifically set forth herein that are relevant to the particular situation. Paragraph (e) of this section sets forth some situations in which this standard is not met and, as a result, in which relief under this section will not be granted.

(2) *Reasonableness and good faith.* The following is a nonexclusive list of factors that will be considered in determining whether the transferor or the executor of the transferor's estate acted reasonably and in good faith for purposes of this section. Not all of these factors may be relevant in a particular situation (and those that are not relevant are not required to be addressed in the request for relief made in accordance with paragraph (i) of this section). Further, it is possible that the evidence relating to any one of these factors, in the context of all of the facts and circumstances of the particular situation, may be sufficient to persuade the IRS that the grant of relief under section 2642(g)(1) would be appropriate. However, as a general rule, no single factor (whether listed or not) will be determinative in all cases. The factors are as follows:

(i) *Intent.* The intent of the transferor to timely allocate GST exemption to a transfer or to timely make an election under section 2632(b)(3) or (c)(5), as evidenced in the trust instrument, the instrument of transfer, or other relevant documents contemporaneous with the transfer, such as Federal gift and estate tax returns and correspondence. This may include evidence of the intended GST tax status of the transfer or the trust (for example, exempt, non-exempt, or partially exempt), or more explicit evidence of intent with regard to the allocation of GST exemption or the election under section 2632(b)(3) or (c)(5).

(ii) *Intervening events.* Intervening events beyond the control of the transferor or of the executor of the transferor's estate that caused the failure to allocate GST exemption to a transfer or the failure to make an election under section 2632(b)(3) or (c)(5).

(iii) *Lack of awareness.* Lack of awareness, despite the exercise of reasonable diligence, by the transferor or the executor of the transferor's estate of the need to allocate GST exemption to the transfer, taking into account the experience of the transferor or the executor of the transferor's estate and the complexity of the GST tax issue, as the cause of the failure to allocate GST exemption to a transfer or to make an election under section 2632(b)(3) or (c)(5).

(iv) *Consistency.* Consistency by the transferor with regard to the allocation of the transferor's GST exemption to one or more trusts or skip persons. For example, the transferor's consistent pattern of allocation of GST exemption to transfers (whether or not made in consecutive years) to skip persons or to a particular trust, or the transferor's consistent pattern of electing not to have the automatic allocation of GST exemption apply to transfers (whether or not made in consecutive years), will be taken into consideration. Evidence of consistency may be less relevant if there has been a change of circumstances or a change of trust beneficiaries that otherwise would explain a deviation from prior GST exemption allocation decisions. Relief under this section will not be denied merely because a pattern of allocation or election does not exist or because the existing pattern changed at some point, whether in response to the enactment of section 2642(g) or to some other factor unrelated to either a lack of reasonableness or good faith or prejudice to the interests of the government.

(v) *Qualified tax professional.* Reasonable reliance by the transferor or the executor of the transferor's estate on the advice of a qualified tax professional retained or employed by one or both of them and either the failure of the tax professional, or, in reliance on or consistent with (or in the absence of) that tax professional's advice, the failure of the transferor or the executor, to allocate GST exemption to the transfer or to make an election described in section 2632(b)(3) or (c)(5). Reliance on a qualified tax professional will not be considered to have been reasonable if the transferor or the executor of the transferor's estate knew or should have known that the professional either—

(A) Was not competent to render advice on the GST exemption; or

(B) Was not aware of all relevant facts.

(3) *Prejudice to the interests of the government.* The following is a nonexclusive list of factors that will be considered to determine whether the interests of the government would be prejudiced for purposes of this section:

(i) *Hindsight.* An attempt to benefit from hindsight will be deemed to prejudice the interests of the government. A factor relevant to this determination is whether the grant of the requested relief would permit an economic advantage or other benefit that would not have been available if the allocation or election had been timely made. For example, there may be prejudice if a grant of the requested relief would permit an economic advantage or other benefit that results from the selection of one out of a number of alternatives (other than whether or not to make an allocation or election) that were available at the time the allocation or election could have been timely made, if hindsight makes the selected alternative more beneficial than the other alternatives. Prejudice also would exist if the transferor failed to make the allocation or election in order to wait to see (thus, with the benefit of hindsight) whether making an allocation of exemption or election would be more beneficial than not making the allocation or election. For instance, assume that a transferor funds several trusts with different property interests on the same date, and does not allocate GST exemption to any trust. Several years later, the transferor seeks relief to allocate GST exemption to the trust that enjoyed the greatest asset appreciation and thus constitutes the most effective use of the transferor's GST exemption. Relief will not be granted because the transferor attempted to benefit from hindsight and thereby acquire an economic advantage.

(ii) *Timing of the request for relief.* The timing of the request for relief will be considered in determining whether the interests of the government would be prejudiced by granting relief under this section. The interests of the government would be prejudiced if delay by the transferor or the executor of the transferor's estate in the filing of the request for relief was intended to deprive the IRS of a sufficient period of time in which to challenge any element of the transfer that is the subject of the request for relief, such as the value of the transferred property for Federal gift or estate tax purposes, the claimed identity of the transferor of the transferred property, or any other aspect of the transfer that is relevant for Federal gift or estate tax purposes. For this purpose, such intent will be presumed, but may be rebutted by evidence persuasive to the IRS of the existence of other reasons for or circumstances causing the delay.

(iii) *Intervening taxable events.* The occurrence and effect of an intervening taxable termination or taxable distribution will be considered in determining whether and to what extent the interests of the government would be prejudiced by a grant of relief under this section. The interests of the government may be prejudiced if a taxable termination or a taxable

distribution occurred between the time for making a timely allocation of GST exemption or a timely election described in section 2632(b)(3) or (c)(5) and the time at which the request for relief under this section was filed. The impact of a grant of relief on (and the difficulty of adjusting) the GST tax consequences of that intervening termination or distribution will be considered in determining whether the occurrence of a taxable termination or taxable distribution constitutes prejudice.

(iv) *Closed years.* Subject to the considerations described in paragraph (d)(3)(ii) of this section, the expiration of any period of limitations on the assessment or collection of transfer taxes prior to the filing of a request for relief under this section generally is not relevant to the determination of whether the requirements for a grant of relief under this section have been met. If that period has expired, however, and if the IRS concludes that the value of the transferred asset or assets as reported on a Federal gift or estate tax return by the transferor or the executor of the transferor's estate is likely to have satisfied the definition of a gross valuation misstatement as defined in section 6662(h)(2)(C) of the Code, the IRS will consider the purported undervaluation in determining whether a grant of relief will prejudice the interests of the government.

(e) *Situations in which the standard of reasonableness, good faith, and lack of prejudice to the interests of the government has not been met*—(1) *In general.* Relief under this section will not be granted if the IRS determines that the transferor or the executor of the transferor's estate has not acted reasonably and in good faith, or that the grant of relief would prejudice the interests of the government. The following situations illustrate some circumstances in which the standard of reasonableness, good faith, and lack of prejudice to the interests of the government has not been met, and as a result, in which relief under this section will not be granted.

(2) *Affirmative allocations*—(i) In general, relief will not be granted under this section to the extent that it would decrease or revoke an affirmative (but not automatic) allocation of GST exemption under section 2632(a) or 2642(b) that was made on a Federal gift or estate tax return, regardless of whether the transfer or the allocation of exemption was made during the transferor's life or upon the transferor's death.

(ii) There are three exceptions to this general rule, as follows. No request for relief is required for either of the first two exceptions:

(A) An allocation of GST exemption is void to the extent the amount allocated exceeds the amount necessary to obtain an inclusion ratio of zero with respect to the property transferred or to the trust. This provision does not apply to charitable lead annuity trusts, nor does it apply to an allocation made to a trust subject to an estate tax inclusion period before the termination of that period. *See* § 26.2632–1(b)(4)(i).

(B) An allocation is void if the allocation is made with respect to a trust that, at the time of the allocation, has no GST potential with respect to the transferor making the allocation. For this purpose, a trust has GST potential even if the possibility of a GST is so remote as to be negligible. *See* § 26.2632–1(b)(4)(i).

(C) A late allocation of GST exemption, as described in section 2642(b)(3), to a transfer or to a trust will be deemed void upon the grant of relief under this section if—

(*1*) Prior to December 31, 2000, a transfer is made that is subject to GST tax or to a trust that has GST potential with respect to the transferor;

(*2*) A timely allocation of GST exemption was not made to the transfer or the trust, and this missed allocation was not eligible for relief prior to the enactment of section 2642(g)(1);

(*3*) Prior to December 31, 2000, a late allocation of GST exemption was made to the transfer or the trust;

(*4*) The late allocation is disclosed as part of the request for relief or during the IRS's consideration of that request; and

(*5*) Relief under this section is granted to make a timely allocation to the transfer or the trust described in paragraph (e)(2)(ii)(C)(*1*) of this section.

(3) *Timing.* Relief will not be granted with regard to a transfer reported on the transferor's gift tax return in the situation in which the transferor filed the request for relief shortly after the expiration of the period during which an assessment of gift tax could be made with respect to that transfer, the IRS reasonably concludes that the transferor intentionally delayed that filing for the purpose of preventing an IRS examination of the reported value of the property subject to that transfer or the claimed identity of the transferor or other fact relevant for transfer tax purposes, and the transferor is unable to produce evidence sufficient to convince the IRS that the filing delay was attributable to some other reason or purpose.

(4) *Failure after being accurately informed.* Relief will not be granted under this section if the decision made by the transferor or the executor of the transferor's estate (who had been accurately informed in all material respects by a qualified tax professional retained or employed by either (or both) of them with regard to the allocation of GST exemption or an election described in section 2632(b)(3) or (c)(5)) was reflected or implemented by the action or inaction that is the subject of the request for relief.

(5) *Hindsight.* Relief under this section will not be granted if the IRS determines that the requested relief is an attempt to benefit from hindsight by waiting to see which of multiple transfers, made at substantially the same time but consisting of different property interests, enjoyed the greatest appreciation and thus would constitute the most effective use of the transferor's GST exemption.

(f) [Reserved]

(g) *Period of limitations under section 6501.* A request for relief under this section does not reopen, suspend, or extend the period of limitations on assessment or collection of any estate, gift, or GST tax under section 6501 of the Code. The IRS may request that the transferor or the transferor's executor consent, under section 6501(c)(4) and prior to the expiration of that period of limitations, to an extension of the period of limitations on assessment or collection of any or all gift and GST taxes for the transfer or transfers that are the subject of the requested relief. The transferor or the transferor's executor has the right to refuse to extend the period of limitations, or to limit any such extension to particular issues or to a particular period of time. *See* section 6501(c)(4)(B). Because a consent to an extension (whether or not limited) may eliminate prejudice to the interests of the government described in paragraphs (d)(3)(ii) and (e)(3) of this section, a refusal to consent to an extension is a factor that may adversely impact the availability of the requested relief.

(h) *Refunds.* The filing of a request for relief under section 2642(g)(1) with the IRS does not constitute a claim for refund or credit of an overpayment and no implied right to refund will arise from the filing of such a request for relief. Similarly, the filing of such a request for relief does not extend the period of limitations under section 6511 of the Code for filing a claim for refund or credit of an overpayment. If the grant of relief under section 2642(g)(1) results in the decrease of a trust's inclusion ratio or a reduction in the amount of a direct skip, and thus in a potential claim for refund or credit of an overpayment of tax, no such refund or credit will be

allowed to the taxpayer or to the taxpayer's estate if the period of limitations under section 6511 for filing a claim for a refund or credit of the Federal gift, estate, or GST tax that was reduced by the granted relief has expired, unless a claim for refund or credit was filed before the expiration of that period. The taxpayer or the taxpayer's estate is responsible for preserving any potential claim for refund or credit.

(i) *Procedural requirements*—(1) *Automatic 6-month extension.* An automatic extension of 6 months from the due date of the gift or estate tax return, or of the Form 8939, *Allocation of Increase in Basis for Property Acquired From a Decedent,* of a decedent dying in calendar year 2010, (in each case, excluding extensions) is granted to file a supplemental return or Form 8939 on which the transferor or the executor of the transferor's estate may allocate GST exemption or make an election under section 2632(b)(3) or (c)(5). This extension, however, is available only if the transferor (or the executor of a transferor's estate) both timely filed the gift or estate tax return or the Form 8939 on which the GST exemption should have been allocated or the election should have been made, and, within that 6-month extension period, files a supplemental return or other supplementary filing. On the supplemental return or other filing, the taxpayer must comply with all of the requirements for allocating GST exemption under section 2632 or for making the election under section 2632(b)(3) or (c)(5) for the year the allocation or election should have been made to make a valid allocation or election. Any supplemental return filed pursuant to this paragraph must say *FILED PURSUANT TO § 26.2642–7(i)(1)* on the front page of the return or the Form 8939, and must be sent to the same address that a timely return or Form 8939 on which the allocation or election should have been made would have been sent, subject to address changes in future forms or instructions or guidance published in the Internal Revenue Bulletin. *See* § 601.601(d)(2) of this chapter. No request for a private letter ruling is required and, as a result, no user fee is required to be paid.

(2) *Private letter ruling program.* Except for the automatic 6-month extension provided in paragraph (i)(1) of this section, the relief described in this section is provided through the IRS's private letter ruling program. Requests for relief may be submitted in accordance with the applicable procedures for requests for a private letter ruling.

(3) *Affidavit and declaration of transferor or the executor of the transferor's estate.* (i) The transferor or the executor of the transferor's estate must submit a detailed affidavit describing the events that led to the failure to timely allocate GST exemption to a transfer or the failure to timely elect under section 2632(b)(3) or (c)(5), and the events that led to the discovery of the failure. In situations described in paragraph (i)(4)(vi) of this section, this affidavit also must include the additional information and statements described in that paragraph. If the transferor or the executor of the transferor's estate relied on a tax professional for advice with respect to the allocation or election, the affidavit also must describe—

(A) The scope of the engagement;

(B) The responsibilities the transferor or the executor of the transferor's estate believed the professional had assumed; and

(C) The extent to which the transferor or the executor of the transferor's estate relied on the professional.

(ii) Attached to each affidavit must be copies of any writings (including, without limitation, notes and emails) and other contemporaneous documents within the possession or control of the affiant relevant to the determination of the transferor's intent with regard to the application of GST tax to the transaction for which relief under this section is requested.

(iii) The affidavit must be accompanied by a dated declaration, signed by the transferor or the executor of the transferor's estate, that states:

Under penalties of perjury, I declare that I have examined this affidavit, including any attachments thereto, and to the best of my knowledge and belief, this affidavit, including any attachments thereto, is true, correct, and complete. In addition, under penalties of perjury, I declare that I have examined all the documents included as part of this request for relief, and that, to the best of my knowledge and belief, these documents collectively contain all the relevant facts relating to the request for relief and such facts are true, correct, and complete.

(4) *Affidavits and declarations from other parties.* (i) The transferor or the executor of the transferor's estate must submit detailed affidavits from the individuals specified in paragraphs (i)(4)(i)(A) through (D) of this section and other individuals who have knowledge or information about the events that led to the failure to allocate GST exemption or to elect under section 2632(b)(3) or (c)(5), or to the discovery of the failure. These individuals may include individuals whose knowledge or information is not within the personal knowledge of the transferor or the executor of the transferor's estate. The individuals described in this paragraph must include—

(A) Each agent or legal representative of the transferor who participated in the consideration of, or the decision with regard to, the allocation of GST exemption or the election under section 2632(b)(3) or (c)(5), or the preparation of the return for which relief is being requested;

(B) The preparer of the relevant Federal estate or gift tax return or returns;

(C) Each individual (including an employee of the transferor or of the executor of the transferor's estate) who provided information or advice with regard to, or otherwise made a significant contribution to, the decision concerning the allocation of GST exemption, the election under section 2632(b)(3) or (c)(5), or the preparation of the relevant Federal estate and/or gift tax return or returns; and

(D) Each tax professional who advised or was consulted by the transferor or the executor of the transferor's estate with regard to the allocation of GST exemption, the election under section 2632(b)(3) or (c)(5), or the preparation of the relevant Federal estate or gift tax return or returns.

(ii) Each affidavit must describe the scope of the engagement and the responsibilities of the individual as well as the advice or service the individual provided to the transferor or the executor of the transferor's estate.

(iii) Attached to each affidavit must be a copy of each writing (including, without limitation, notes and emails) and other contemporaneous documents within the possession of the affiant relevant to the transferor's intent or the affiant's advice with regard to the application of GST tax to the transaction for which relief under this section is requested. The documents that the affiant discovers by conducting in good faith a reasonably diligent search of records in the possession of or accessible to the affiant, or subject to the affiant's control, will be sufficient to satisfy the requirements of this paragraph (i)(4)(iii). A reasonably diligent search generally would include, without limitation, a review of the records in the possession or control of the affiant or the firm at which the affiant is employed or associated relating to the transaction or tax return at issue.

(iv) The IRS may require additional affidavits from persons not set forth in paragraph (i)(4)(i) of this section as well

as additional documents when additional information or documents with respect to a transfer is believed by the IRS to be required or helpful in making its determination as to whether relief under this section should be granted.

(v) Each affidavit also must include the name and current address of the affiant, and must be accompanied by a dated declaration signed by the affiant that states:

Under penalties of perjury, I declare that I have personal knowledge of the information set forth in this affidavit, including any attachments thereto. In addition, under penalties of perjury, I declare that I have examined this affidavit, including any attachments thereto, and, to the best of my knowledge and belief, the affidavit contains all the relevant facts and the attachments include copies of all relevant writings or other documents resulting from a reasonably diligent search, conducted in good faith, of all records within my possession, accessible to me, or subject to my control, relating to the allocation of GST exemption, the election under section 2632(b)(3) or (c)(5), and the preparation of the tax return at issue in the request for relief filed by or on behalf of [*transferor or executor of transferor's estate*], and such facts and attached documents are true, correct, and complete.

(vi) If an individual who would be required to provide an affidavit under paragraph (i)(4)(i) of this section has died or is unwilling or otherwise unable to provide the required affidavit, the affidavit required under paragraph (i)(3) of this section must include a statement to that effect, as well as a statement describing the relationship between that individual and the transferor or the executor of the transferor's estate; the information or knowledge the transferor or the executor of the transferor's estate believes that individual had about the events that led to the failure to make the allocation or the election or to the discovery of that failure; and, in cases other than the death of the individual, a detailed description of the efforts made to obtain the affidavit from the individual. The unwillingness of certain affiants to provide an affidavit, however, may be considered by the IRS in determining whether to grant the requested relief. For purposes of this paragraph (i)(4)(vi), the term *unwilling* refers to a person who is apparently able but refuses or otherwise fails, despite the best efforts, made in good faith, of the transferor or the transferor's executor, to provide the required affidavit. In addition, for purposes of this paragraph, the term *unable* refers to a permanent or potentially long-term condition such as physical or mental incapacity that prevents the person from providing the required affidavit, but not a temporary condition such as a temporary physical or mental incapacity or a person's inability due to a leave of absence, travel, or a contractual requirement such as a confidentiality agreement.

(5) *Additional rules regarding relief.* For purposes of relief under paragraphs (i)(1) and (2) of this section, the grant of relief in the form of an extension of time is not a determination that the taxpayer is otherwise eligible to make the election. In addition, notwithstanding the provisions of this section, an extension of time will not be granted under this section if alternative relief is provided by a statute, a regulation published in the **Federal Register**, or a revenue ruling, revenue procedure, notice, or announcement published in the Internal Revenue Bulletin (see § 601.601(d)(2) of this chapter).

(j) *Applicability date.* This section applies to requests for relief to which section 2642(g)(1) applies that are filed on or after May 6, 2024, regardless of the date of the transfer.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 3.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 4.** Section 301.9100–2 is amended by adding paragraph (f) to read as follows:

§ 301.9100–2 Automatic extensions.

* * * * *

(f) *Automatic 6-month extension for certain generation-skipping transfer tax allocations and elections*—(1) *Availability.* Paragraph (b) of this section is not available to obtain an automatic 6-month extension to allocate generation-skipping transfer (GST) exemption to a transfer pursuant to section 2632 or to make an election under section 2632(b)(3) or (c)(5). An automatic 6-month extension to allocate GST exemption under section 2632 or to make an election under section 2632(b)(3) or (c)(5) is available to transferors or the executors of transferors' estates pursuant to § 26.2642–7(i)(1) of this chapter if the requirements of that provision are satisfied.

(2) *Applicability date.* Paragraph (f) of this section applies to any gift or estate tax return or Form 8939, *Allocation of Increase in Basis for Property Acquired from a Decedent,* for which the date prescribed for filing is on or after May 6, 2024 (excluding extensions), regardless of the date of the transfer.

■ **Par. 5.** Section 301.9100–3 is amended by adding paragraph (g) to read as follows:

§ 301.9100–3 Other extensions.

* * * * *

(g) *Relief under section 2642(g)(1)*—(1) *Procedures.* The procedures set forth in this section are not applicable for requests for relief under section 2642(g)(1). For requests for relief under section 2642(g)(1), *see* § 26.2642–7 of this chapter.

(2) *Applicability date.* This paragraph (g) applies to requests for relief to which section 2642(g)(1) applies that are filed on or after May 6, 2024, regardless of the date of the transfer.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 6.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 7.** In § 602.101, amend the table in paragraph (b) by adding an entry in numerical order for ''§ 26.2642–7(i)(3) and (4)'' to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
26.2642–7(i)(3) and (4)	1545–2116
* * * * *	

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: March 12, 2024.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–09644 Filed 5–3–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2024–OS–0047]

RIN 0790–AL77

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense, Department of Defense (DoD).

ACTION: Direct final rule with request for comments.

SUMMARY: The Department of Defense (DoD or Department) is giving concurrent notice of a new system of records titled ''All-domain Anomaly Resolution Office (AARO) Report System,'' AARO–0001, and this rulemaking, which exempts portions of this system of records from certain provisions of the Privacy Act of 1974, as amended, because of national security. This rule is being published as a direct final rule as the Department does not expect to receive any adverse comments. If such comments are received, this direct final rule will be withdrawn and a proposed rule for comments will be published.

DATES: The rule will be effective on July 15, 2024 unless comments are received that would result in a contrary determination. If significant adverse comments are received, the DoD will publish a timely withdrawal of the rule in the **Federal Register**. Comments will be accepted on or before July 5, 2024.

ADDRESSES: You may submit comments, identified by docket number, Regulation Identifier Number (RIN), and title, by any of the following methods.

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, *OSD.DPCLTD@mail.mil,* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, DoD is establishing a new system of records titled ''All-domain Anomaly Resolution Office (AARO) Report System,'' AARO–0001. This system of records describes the AARO's collection, use, and maintenance of correspondence and reports submitted from current or former U.S. government employees, service members, or contractors with direct knowledge of U.S. Government programs or activities related to Unidentified Anomalous Phenomenon (UAP) dating back to 1945. This system also includes correspondence and reports submitted from members of the general public and government-affiliated personnel on events related to UAP. The submitted information will be used to carry out AARO's mission, including to inform AARO's congressionally directed Historical Record Report.

II. Privacy Act Exemption

The Privacy Act permits Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including the provisions providing individuals with a right to request access to and amendment of their own records and accountings of disclosures of such records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process to provide public notice and an opportunity to comment on the exemption. The Office of the Secretary is amending 32 CFR part 310 to add a new Privacy Act exemption rule for this system of records. The DoD is claiming an exemption for this system of records because some of its records may contain classified national security information and providing notice, access, amendment, and disclosure of accounting of those records to an individual, as well as certain record-keeping requirements, may cause damage to national security and reveal sensitive sources and methods. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), authorizes agencies to claim an exemption for systems of records that contain information properly classified pursuant to executive order. DoD is claiming an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain record-keeping and notice requirements, to prevent disclosure of any information properly classified pursuant to executive order, as implemented by DoD Instruction 5200.01, ''DoD Information Security Program and Protection of Sensitive Compartmented Information (SCI)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/520001p.PDF?ver=cF1II-jcFGP6jfNrnTr8lQ%3d%3d*); DoD Manual 5200.01, Volume 1, ''DoD Information Security Program: Overview, Classification, and Declassification'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol1.pdf?ver=2020-08-04-092500-203;* and DoD Manual 5200.01, Volume 3, ''DoD Information Security Program: Protection of Classified Information'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol3.pdf?ver=MJfVD-nRd2HTyLSzDse9VQ%3d%3d*).

III. Direct Final Rulemaking

This rule is being published as a direct final rule as the Department does not expect to receive any significant adverse comments. If such comments are received, this direct final rule will be cancelled and a proposed rule for comments will be published. If no such comments are received, this direct final rule will become effective ten days after the comment period expires.

For purposes of this rulemaking, a significant adverse comment is one that explains (1) why the rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the rule will be ineffective or unacceptable without a change. In determining whether a significant adverse comment necessitates withdrawal of this direct final rule, the Department will consider whether the comment raises an issue serious enough to warrant a substantive response had it been submitted in a standard notice-and-comment process. A comment recommending an addition to the rule will not be considered significant and adverse unless the comment explains how this direct final rule would be ineffective without the addition.

This direct final rule adds to the DoD's Privacy Act exemptions for systems of records found in 32 CFR 310.29. Records in this system of records are only exempt from the Privacy Act to the extent the purposes underlying the exemption pertain to the record.

A notice of a new system of records for AARO–0001 is also published in this issue of the **Federal Register**.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review,'' as Amended by Executive Order 14094, ''Modernizing Regulatory Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 (as amended by Executive Order 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action under these Executive Orders.

Congressional Review Act (5 U.S.C. 804(2))

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DoD will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal Register**, whichever is later. This direct final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, in any one year of $100 million in 1995 dollars, updated annually for inflation. This rule will not mandate any requirements for State, local, or Tribal governments, nor will it affect private sector costs.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601 et seq.)

The Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency has certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule is concerned only with the administration of Privacy Act systems of records within the DoD. Therefore, the Regulatory Flexibility Act, as amended, does not require DoD to prepare a regulatory flexibility analysis.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 501 et seq.)

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and tribal governments; and other persons resulting from the collection of information by or for the Federal government. The Act requires agencies obtain approval from the Office of Management and Budget before using identical questions to collect information from ten or more persons. This rule does not impose reporting or recordkeeping requirements on the public.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that has federalism implications, imposes substantial direct requirement costs on State and local governments, and is not required by statute, or has federalism implications and preempts State law. This rule will not have a substantial effect on State and local governments.

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on one or more Indian Tribes, preempts tribal law, or affects the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rule will not have a substantial effect on Indian Tribal governments.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 310.29 by *adding paragraph (c)(29) to read as follows:*

§ 310.29 Office of the Secretary of Defense (OSD) exemptions.

* * * * *

(c) * * *

(29) *System identifier and name.* AARO–0001, All-domain Anomaly Resolution Office (AARO) Report System.

(i) *Exemptions.* This system of records is exempt from 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

(ii) *Authority.* 5 U.S.C. 552a(k)(1).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections of the Privacy Act of 1974, as amended, pursuant to exemption (k)(1) is justified for the following reasons:

(A) *Subsections (c)(3) and (d)(1) and (2).* Records in this system of records may contain information concerning individuals that is properly classified pursuant to executive order. Application of exemption (k)(1) for such records may be necessary because access to and amendment of the records, or release of the accounting of disclosures for such records, could reveal classified information. Disclosure of classified records to an individual may cause damage to national security and reveal sensitive sources and methods. Accordingly, application of exemption (k)(1) may be necessary.

(B) *Subsections (d)(3) and (4).* These subsections are inapplicable to the extent an exemption is claimed from (d)(2).

(C) *Subsection (e)(1).* Records within this system may be properly classified pursuant to executive order. In the collection of information for AARO reporting and analysis purposes, it may not always be possible to conclusively determine the relevance and necessity of particular information in the early stages of these types of activities. Additionally, disclosure of classified records to an individual may cause damage to national security and reveal sensitive sources and methods. Accordingly, application of exemption (k)(1) may be necessary.

(D) *Subsections (e)(4)(G) and (H) and subsection (f).* These subsections are inapplicable to the extent exemption is claimed from the access and amendment provisions of subsection (d). Because portions of this system are exempt from the individual access and amendment provisions of subsection (d) for the reasons noted in paragraphs (c)(29)(iii)(A) and (B) of this section, DoD is not required to establish requirements, rules, or procedures with respect to such access or amendment provisions. Providing notice to individuals with respect to the existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which

individuals may access, view, and seek to amend records pertaining to themselves in the system would potentially undermine national security and the confidentiality of classified information. Accordingly, application of exemption (k)(1) may be necessary.

(E) *Subsection (e)(4)(I).* To the extent that this provision is construed to require more detailed disclosure than the broad information currently published in the system notice concerning categories of sources of records in the system, an exemption from this provision is necessary to protect national security and the confidentiality of sources and methods, and other classified information.

(iv) *Exempt records from other systems.* In the course of carrying out the overall purpose for this system, exempt records from other systems of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09607 Filed 5–3–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0299]

Special Local Regulations; Montlake Cut, Lake Washington, Seattle, Washington

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Windermere Cup on May 4, 2024, from 8 a.m. to 12 p.m. to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Thirteenth Coast Guard District identifies the regulated area for this event on the Montlake Cut and Union Bay Reach between Portage Bay and Webster Point on Lake Washington in Seattle, WA. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.1311 will be enforced May 4, 2024, from 8 a.m. to 12 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or Lieutenant Junior Grade Kaylee K. Lord, Sector Puget Sound Waterways Management Division, Coast Guard; telephone 206–217–6045, email *SectorPugetSound@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.1311 for the Windermere Cup on May 4, 2024, from 8 a.m. to 12 p.m. This action is being taken to provide for the safety of life on navigable waterways during this one-day event. Our regulation for marine events within the Thirteenth Coast Guard District, § 100.1311(a), specifies the location of the regulated area for the Windermere Cup which encompasses waters from Montlake Cut and Union Bay Reach between Portage Bay and Webster Point on Lake Washington in Seattle, WA. During the enforcement period, as reflected in § 100.1311, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period and modifications, if any, via the Local Notice to Mariners and marine information broadcasts.

Dated: May 1, 2024.

Mark. A. McDonnell,

Captain, U.S. Coast Guard, Captain of the Port Sector Puget Sound.

[FR Doc. 2024–09815 Filed 5–3–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG–2024–0356]

RIN 1625–AA00

Safety Zone; Revolution Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0486, Offshore Rhode Island, Atlantic Ocean

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing 16 temporary safety zones around the construction of each facility during the development of the Revolution Wind Farm project area within Federal waters on the Outer Continental Shelf, specifically in the Bureau of Ocean Energy Management Renewable Energy Lease Area OCS–A 0486, approximately 15 nautical miles offshore southeast of Point Judith, Rhode Island. This action protects life, property, and the environment during construction of each facility from May 1, 2024, to May 31, 2024. When enforced, only attending vessels and vessels with authorization are permitted to enter or remain in the temporary safety zones.

DATES: This rule is effective without actual notice from May 6, 2024, through 11:59 p.m. on May 31, 2024. For the purposes of enforcement, actual notice will be used from May 1, 2024, until May 6, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0356 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Craig Lapiejko, Waterways Management, at Coast Guard First District, telephone 617–603–8592, email *craig.d.lapiejko@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BOEM Bureau of Ocean Energy Management
CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
NAD 83 North American Datum of 1983
NM Nautical Mile

RWF Revolution Wind Farm
§ Section
U.S.C. United States Code
WTG Wind Turbine Generator

II. Background, Purpose, and Legal Basis

On February 2, 2024, Orsted, an offshore wind farm developer, notified the Coast Guard that they plan to begin construction of the Revolution Wind facilities in the Revolution Wind Farm (RWF) project area within federal waters on the Outer Continental Shelf (OCS), specifically in the Bureau of Ocean Energy Management (BOEM) Renewable Energy Lease Area OCS–A 0486, approximately 15 nautical miles (NM) offshore southeast of Point Judith, Rhode Island, 32 NM southeast of the Connecticut coast and 12 NM southwest of Martha's Vineyard, Massachusetts. Hence, after determining that establishment of safety zones was necessary to provide for the safety of life, property, and the environment during the anticipated construction of the structures, on March 21, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zone; Revolution Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0486, Offshore Rhode Island, Atlantic Ocean'' (89 FR 20150) to begin construction on June 1st. There we explained the basis for the NPRM and invited comments on our proposed regulatory action related to the establishment of safety zones around the construction of 65 Wind Turbine Generators (WTG) and two Offshore Sub Stations (OSS) located in the RWF project area. 86 comments were received during the comment period that ended April 22, 2024, that are currently being considered before the safety zones are modified or extended.

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when, for good cause, the agency finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists to not complete notice and comment procedures in this case because it would be impracticable and contrary to the public interest of ensuring the safety of mariners transiting the area. After the aforementioned March 21, 2024 NPRM was published, the Coast Guard was informed that construction of RWF project area could begin as soon as May 1, 2024, leaving insufficient time to consider the received comments, and issue a final rule by this anticipated date of construction.

Under 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** considering the anticipated start of construction on May 1, 2024. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety risks associated with the extremely complex and unusually hazardous construction of these OCS facilities including hydraulic pile driving hammer operations, heavy lift operations, overhead cutting operations, potential falling debris, increased vessel traffic, and stationary barges in close proximity to the facilities and each other, occurring at times within 12 NM of shore.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority provided in 14 U.S.C. 544, 43 U.S.C. 1333, and Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3. As an implementing regulation of this authority, 33 CFR part 147 permits the establishment of safety zones for non-mineral energy resource permanent or temporary structures located on the OCS for the purpose of protecting life and property on the facilities, appurtenances and attending vessels, and on the adjacent waters within the safety zone (see 33 CFR 147.10). Accordingly, a safety zone established under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property, and the environment.

IV. Discussion of Rule

This rule establishes 16 temporary 500-meter safety zones around the construction of 16 WTGs on the OCS from May 1, 2024, through 11:59 p.m. on May 31, 2024.

The construction of these facilities is expected to repeatedly include the installation of the monopile type foundations followed by the installation of the upper structures for all 16 facilities. Major construction activity could take place at several locations simultaneously in the lease area for these 16 facilities. The Coast Guard will make notice of each enforcement period via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency or hazardous condition.

Additional information about the construction process of the RWF can be found at *https://www.boem.gov/renewable-energy/state-activities/revolution-wind.*

The 16 temporary 500-meter safety zones around the construction of the WTGs are in the RWF project area, specifically in the BOEM Renewable Energy Lease Area OCS–A 0486, approximately 15 nautical NM offshore southeast of Point Judith, Rhode Island, 32 NM southeast of the Connecticut coast and 12 NM southwest of Martha's Vineyard, Massachusetts.

The positions of each individual safety zone are referred to using a unique alpha-numeric naming convention outlined in the ''Rhode Island and Massachusetts Structure Labeling Plot (West) [1]''.

Aligning with authorities under 33 CFR 147.15, the temporary safety zones will include the area within 500-meters of the center point of the positions provided in the table below expressed in Degrees (°) Minutes (') (DM) based on North American Datum 1983 (NAD 83).

Name	Facility type	Latitude	Longitude
AE06	WTG	41°13.555′ N	71°10.367′ W
AE07	WTG	41°13.575′ N	71°09.050′ W
AE10	WTG	41°13.652′ N	71°05.081′ W
AE11	WTG	41°13.676′ N	71°03.763′ W
AF05	WTG	41°12.528′ N	71°11.647′ W
AG06	WTG	41°11.554′ N	71°10.302′ W
AJ02	WTG	41°09.452′ N	71°15.530′ W

[1] The Rhode Island and Massachusetts Structure Labeling Plot (West) is an attachment to the Conditions of Construction and Operations Plan Approval Lease Number OCS–A 0517 (boem.gov) and can be found at *https://www.boem.gov/sites/default/files/documents/renewable-energy/state-activities/SFWF-COP-Terms-and-Conditions.pdf.*

Name	Facility type	Latitude	Longitude
AK12	WTG	41°08.699′ N	71°02.260′ W
AL21	WTG	41°07.887′ N	70°50.387′ W
AM21	WTG	41°06.904′ N	70°50.325′ W
AN13	WTG	41°05.675′ N	71°00.836′ W
AN16	WTG	41°05.792′ N	70°56.911′ W
AP13	WTG	41°04.731′ N	71°00.873′ W
AP14	WTG	41°04.746′ N	70°59.423′ W
AP15	WTG	41°04.766′ N	70°58.180′ W
AP16	WTG	41°04.788′ N	70°56.858′ W

When enforced, no unauthorized vessel or person would be permitted to enter the safety zone without obtaining permission from the First Coast Guard District Commander or a designated representative. Requests for entry into the safety zone would be considered and reviewed on a case-by-case basis. Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–603–1560 (First Coast Guard District Command Center). If permission is granted, all persons and vessels shall comply with the instructions of the First Coast Guard District Commander or designated representative.

The Proposed Regulatory Text Appears at the End of This Document.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB).

Aligning with 33 CFR 147.15, the safety zones established would extend to a maximum distance of 500-meters around the OCS facility measured from its center point. Vessel traffic would be able to safely transit around the proposed safety zones, which would impact a small, designated area in the Atlantic Ocean, without significant impediment to their voyage. This safety zone would provide for the safety of life, property, and the environment during the construction of each structure, in accordance with Coast Guard maritime safety missions.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This rule may affect owners or operators of vessels intending to transit or anchor in the RWF, some of which might be small entities. However, these safety zones would not have a significant economic impact on a substantial number of these entities because they are temporarily enforced, allow for deviation requests, and do not impact vessel transit significantly. Regarding the enforcement period, although these safety zones would be in effect from May 1, 2024, through May 31, 2024, vessels would only be prohibited from the regulated zone during periods of actual construction activity in conjunction with the period of enforcement. We expect the enforcement period at each location to last for a short period. Additionally, vessel traffic could pass safely around each safety zone using an alternate route. Use of an alternate route likely will cause minimal delay for the vessel in reaching their destination depending on other traffic in the area and vessel speed. Vessels would also be able to request deviation from this rule to transit through a safety zone. Such requests would be considered on a case by-case basis and may be authorized by the First Coast Guard District Commander or a designated representative. For these reasons, the Coast Guard expects any impact of this rulemaking establishing a temporary safety zone around these OCS facilities to be minimal and have no significant economic impact on small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism

principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone around an OCS facility to protect life, property, and the marine environment. It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (waters).

For the reasons discussed in the preamble, the Coast Guard is amending 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 544; 43 U.S.C. 1333; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 147.T01–0356 to read as follows:

§ 147.T01–0356 Safety Zone; Revolution Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0486, Offshore Rhode Island, Atlantic Ocean.

(a) *Description.* The area within 500-meters of the center point of the positions provided in the table below is a safety zone:

Name	Facility type	Latitude	Longitude
AE06	WTG	41°13.555′ N	71°10.367′ W
AE07	WTG	41°13.575′ N	71°09.050′ W
AE10	WTG	41°13.652′ N	71°05.081′ W
AE11	WTG	41°13.676′ N	71°03.763′ W
AF05	WTG	41°12.528′ N	71°11.647′ W
AG06	WTG	41°11.554′ N	71°10.302′ W
AJ02	WTG	41°09.452′ N	71°15.530′ W
AK12	WTG	41°08.699′ N	71°02.260′ W
AL21	WTG	41°07.887′ N	70°50.387′ W
AM21	WTG	41°06.904′ N	70°50.325′ W
AN13	WTG	41°05.675′ N	71°00.836′ W
AN16	WTG	41°05.792′ N	70°56.911′ W
AP13	WTG	41°04.731′ N	71°00.873′ W
AP14	WTG	41°04.746′ N	70°59.423′ W
AP15	WTG	41°04.766′ N	70°58.180′ W
AP16	WTG	41°04.788′ N	70°56.858′ W

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the First Coast Guard District Commander in the enforcement of the safety zones.

(c) *Regulations.* No vessel may enter or remain in this safety zone except for the following:

(1) An attending vessel as defined in 33 CFR 147.20;

(2) A vessel authorized by the First Coast Guard District Commander or a designated representative.

(d) *Request for permission.* Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or a designated representative. If permission is granted, all persons and vessels must comply with lawful instructions of the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–603–1560 (First Coast Guard District Command Center).

(e) *Effective and enforcement periods.* This section will be effective from May 1, 2024, through 11:59 p.m. on May 31, 2024. But it will only be enforced during active construction or other instances which may cause a hazard to navigation deemed necessary by the First Coast Guard District Commander. The First Coast Guard District Commander will make notification of the exact dates and times in advance of each enforcement period for the locations in paragraph (a) of this section to the local maritime community through the Local Notice to Mariners and will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency. If the project is

completed before May 31, 2024, enforcement of the safety zones will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: April 30, 2024.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2024–09754 Filed 5–3–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0295]

RIN 1625–AA00

Safety Zone; Presque Isle Bay, Erie, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 210-foot radius of Bicentennial Tower at Dobbins Landing in Erie, PA. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display. During the enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of Port Eastern Great Lakes or a designated representative.

DATES: The rule is effective from 8:30 p.m. through 10:30 p.m. on June 23, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0295 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT William Kelley, Waterways Management at Sector Eastern Great Lakes, U.S. Coast Guard; telephone 716–843–9343, email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor did not submit notice of the fireworks display to the Coast Guard with sufficient time remaining before the event to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest by inhibiting the Coast Guard's ability to protect spectators and vessels from the hazards associated with this firework display.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30-day notice period to run would be impracticable and contrary to the public interest.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Eastern Great Lakes (COTP) has determined that fireworks over the water presents significant risks to public safety and property. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display is taking place.

IV. Discussion of the Rule

This rule establishes a safety zone from 8:30 p.m. through 10:30 p.m. on June 23, 2024. The safety zone will cover all navigable waters within a 210-foot radius of land launched fireworks over the Presque Isle Bay in Erie, PA at 42°08′19.87″ N 80°05′29.54″ W. The duration of the zone is intended to protect spectators, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration and time of day of the regulated area The safety zone will encompass a 210-foot radius of land launched fireworks in the Presque Isle Bay in Erie, PA lasting approximately two hours during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental

jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves safety zone lasting approximately two hours that will prohibit entry within a 210-foot radius in Presque Isle Bay in Erie, PA for a fireworks display. It is categorically excluded from further review under paragraph L[60a] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T09–0295 to read as follows:

§ 165.T09–0295 Safety Zone; Presque Isle Bay, Erie, PA.

(a) *Location.* The following area is a safety zone: All waters of Presque Isle Bay, from surface to bottom, encompassed by a 210-foot radius around 42°08′19.87″ N 80°05′29.54″ W.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Eastern Great Lakes (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated representative.

(2) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or their designated representative to obtain permission to do so. The COTP or their designated representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP, or their designated representative.

(d) *Enforcement period.* The regulated area described in paragraph (a) of this section is effective from 8:30 p.m. through 10:30 p.m. on June 23, 2024.

Dated: April 29, 2024

M.I. Kuperman,

Captain, U.S. Coast Guard, Captain of the Port Eastern Great Lakes.

[FR Doc. 2024–09753 Filed 5–3–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 219

RIN 0596–AD60

Planning

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: The United States Department of Agriculture (Department), Forest Service is making technical revisions to clarify regulations governing National Forest System Land Management Planning (planning). These purely technical changes to the names and definitions of terms used to describe information accrued by Tribes and Indigenous people align with guidance from the Executive Office of the President and are more consistent with language used in regulations of other Federal agencies.

DATES: This rule is effective May 6, 2024.

ADDRESSES: Information on this final rule may be obtained via written request addressed to the Director, Policy Office, at USDA Forest Service, 201 14th Street SW, Washington, DC 20250–1124 or by email to *nicholas.diprofio@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Nick DiProfio, Senior Land Management Planner, Ecosystem Management Coordination, at (202) 253–0640 or *nicholas.diprofio@usda.gov.* Individuals who use telecommunication devices for the hearing impaired may call the Federal Relay Service at (800) 877–8339 between 8:00 a.m. and 5:00 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: This final rule makes purely technical, clarifying revisions to the Forest Service's existing planning regulations at 36 CFR 219.4(a)(3) and at 36 CFR 219.19. These purely technical, clarifying revisions do not formulate standards, criteria, or guidelines applicable to Forest Service programs and therefore do not require public notice and opportunity to comment under section 14(a) of the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1612(a)).

36 CFR Part 219, Subpart A

The Department is revising text in § 219.4(a)(3) and § 219.19 to adhere to guidance set forth by the Office of Science and Technology Policy and the Council on Environmental Quality within the Executive Office of the President on November 30, 2022, titled *Guidance for Federal Departments and Agencies on Indigenous Knowledge* (*https://www.whitehouse.gov/wp-content/uploads/2022/12/OSTP-CEQ-IK-Guidance.pdf*). The Department is changing the term Native Knowledge to Indigenous Knowledge and updating the associated definition to conform precisely with this guidance. The revised definition is substantially similar in substance to the existing definition and will have no discernable impact on how this concept is applied in Forest Service operations.

Regulatory Certifications

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Consistent with Executive Order (E.O.) 12866, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will determine whether proposed, interim, and final rules that impose, eliminate, or modify requirements on non-Forest Service parties are significant and will review any proposed, interim, or final rules that OIRA has designated as significant. This final rule does not impose, eliminate, or modify requirements on non-Forest Service parties and therefore does not require a significance determination by OIRA. E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Department has developed this final rule consistent with E.O. 13563.

Congressional Review Act

Because this final rule does not impose, eliminate, or modify requirements on non-Forest Service parties, it is not a major rule as defined by the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act, 5 U.S.C. 804(2)).

National Environmental Policy Act

This final rule will make only technical, clarifying revisions to existing Forest Service regulations at 36 CFR part 219, subpart A. Forest Service regulations at 36 CFR 220.6(d)(2) (73 FR 43093) exclude from documentation in an environmental assessment or environmental impact statement ''rules, regulations, or policies to establish service-wide administrative procedures, program processes, or instructions.'' The Department has concluded that this final rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Regulatory Flexibility Act Analysis

The Department has considered this final rule under the requirements of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). This final rule will not have any direct effect on small entities as defined by the Regulatory Flexibility Act. The final rule will not impose recordkeeping requirements on small entities; will not affect their competitive position in relation to large entities; and will not affect their cash flow, liquidity, or ability to remain in the market. Therefore, the Department has determined that this final rule will not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

Federalism

The Department has considered this final rule under the requirements of E.O. 13132, *Federalism.* The Department has determined that the final rule conforms with the federalism principles set out in this E.O.; will not impose any compliance costs on the states; and will not have substantial direct effects on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Department has concluded that the final rule does not have federalism implications.

Consultation With Tribal Governments

The Department has reviewed this final rule in accordance with the requirements of E.O. 13175, *Consultation and Coordination with Indian Tribal Governments.* The Department has determined that national Tribal consultation is not necessary for the final rule. The final rule, which will make only technical, clarifying revisions to existing Forest Service regulations in 36 CFR part 219, subpart A, does not impose, eliminate, or modify requirements on non-Forest Service parties and therefore does not have any direct effects on Tribes.

Environmental Justice

The Department has considered the final rule under the requirements of E.O. 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.* The final rule, which will make only technical, clarifying revisions to existing Forest Service regulations in 36 CFR part 219, subpart A, does not impose, eliminate, or modify requirements on non-Forest Service parties and therefore will not result in disproportionately high and adverse impacts on minority or low-income populations or the exclusion of minority and low-income populations from meaningful involvement in decision making.

No Takings Implications

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12630, *Governmental Actions and Interference With Constitutionally Protected Property Rights.* The Department has determined that the final rule will not pose the risk of a taking of private property.

Energy Effects

The Department has reviewed the final rule under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Department has determined that the final rule will

not constitute a significant energy action as defined in E.O. 13211, and OIRA has not otherwise designated the final rule as a significant energy action.

Civil Justice Reform

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12988, *Civil Justice Reform.* Upon issuance of the final rule, (1) all state and local laws and regulations that conflict with the final rule or that impede its full implementation will be preempted, (2) no retroactive effect will be given to this final rule, and (3) it will not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the Department has assessed the effects of the final rule on state, local, and Tribal governments, and the private sector. The final rule will not compel the expenditure of $100 million or more by any state, local, or Tribal government or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Controlling Paperwork Burdens on the Public

The final rule does not contain information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

List of Subjects in 36 CFR Part 219

Administrative practice and procedure, Environmental impact statements, Indians, Intergovernmental relations, National forests, Reporting and recordkeeping requirements, Science and technology.

Therefore, for the reasons set forth in the preamble, the Department is amending chapter II of title 36 of the Code of Federal Regulations as follows:

PART 219—PLANNING

■ 1. The authority citation for part 219 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 1604, 1613.

■ 2. Amend § 219.4 by revising paragraph (a)(3) to read as follows:

§ 219.4 Requirements for public participation.

(a) * * *

(3) *Indigenous knowledge and land ethics.* As part of tribal participation and consultation as set forth in paragraphs (a)(1)(v) and (a)(2) of this section, the responsible official shall request information about Indigenous Knowledge, land ethics, cultural issues, and sacred and culturally significant sites.

* * * * *

■ 3. Amend § 219.19 by removing the definition ''Native knowledge'' and adding the definition ''Indigenous knowledge'' in alphabetical order to read as follows:

§ 219.19 Definitions.

* * * * *

Indigenous knowledge. A body of observations, oral and written knowledge, innovations, practices, and beliefs developed by Tribes and Indigenous Peoples through interaction and experience with the environment. It is applied to phenomena across biological, physical, social, cultural, and spiritual systems. Indigenous Knowledge can be developed over millennia, continues to develop, and includes understanding based on evidence acquired through direct contact with the environment and long-term experiences, as well as extensive observations, lessons, and skills passed from generation to generation. Indigenous Knowledge is developed by Indigenous Peoples including, but not limited to, Tribal Nations, Native Americans, Alaska Natives, and Native Hawaiians. Each Tribe or Indigenous community has its own place-based body of knowledge that may overlap with that of other Tribes. Indigenous Knowledge is based in ethical foundations often grounded in social, spiritual, cultural, and natural systems that are frequently intertwined and inseparable, offering a holistic perspective. Indigenous Knowledge is inherently heterogeneous due to the cultural, geographic, and socioeconomic differences from which it is derived, and is shaped by the Indigenous Peoples' understanding of their history and the surrounding environment. Indigenous Knowledge is unique to each group of Indigenous Peoples and each may elect to utilize different terminology or express it in different ways. Indigenous Knowledge is deeply connected to the Indigenous Peoples holding that knowledge.

* * * * *

Homer Wilkes,

Under Secretary, Natural Resources and Environment.

[FR Doc. 2024–09624 Filed 5–3–24; 8:45 am]

BILLING CODE 3411–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0494; FRL–9931–02–R9]

Air Plan Approval; Nevada; Clark County Department of Environment and Sustainability; Nonattainment New Source Review; 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a state implementation plan (SIP) revision submitted by the State of Nevada addressing the nonattainment new source review (NNSR) requirements for the 2015 ozone National Ambient Air Quality Standards (NAAQS). This SIP revision addresses the Clark County Department of Environment and Sustainability (''Department'') portion of the Nevada SIP. This action is being taken pursuant to the Clean Air Act (CAA or ''Act'') and its implementing regulations.

DATES: This rule is effective on June 5, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2022–0494. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please

contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Amita Muralidharan, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4140 or by email at *muralidharan.amita@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On February 2, 2024 (89 FR 7318), the EPA proposed to approve the SIP revision listed in table 1 of this document, addressing the NNSR requirements for the 2015 ozone NAAQS for the Department.

TABLE 1—SUBMITTED CERTIFICATION LETTER

Air pollution control agency	Adoption date	Submittal date [1]
Clark County Department of Environment and Sustainability	7/20/2021	8/5/2021

[1] The submitted certification letter was dated August 3, 2021. The electronic submittal was received by EPA on August 5, 2021.

We proposed approval of the submitted SIP revision because we determined that the 2015 ozone certification submitted by the Department fulfills the 40 CFR 51.1314 revision requirement and meets the requirements of CAA sections 110, 172(c)(5), 173, 182(a)(2)(c), 193, and the minimum SIP requirements of 40 CFR 51.165. Our proposed action contains more information on the SIP revision and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment in support of this action. The comment outlines the air quality improvements that will result from finalizing this action. The EPA has considered this comment in its final decision to approve the Department's SIP revision.

III. EPA Action

One favorable comment was received during the 30-day public comment period. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving this certification into the Nevada SIP as proposed.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on Tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 5, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for

the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2))

List of Subjects in 40 CFR part 52

Environmental protection, Air pollution control, Incorporation by Reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: April 22, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart DD–Nevada

■ 2. Amend § 52.1470, in paragraph (e), by adding an entry to the table for ''Revision to the Nevada State Implementation Plan for the 2015 Ozone NAAQS: Nonattainment Major NSR Requirements: Las Vegas Valley Nonattainment Area'' after the entry for ''Revision to Nevada 2015 Eight-Hour Ozone Plan, Emissions Inventory Requirement for the Las Vegas Valley Nonattainment Area, Clark County, NV (October 15, 2020)'' to read as follows:

§ 52.1470 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEVADA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
Air Quality Implementation Plan for the State of Nevada [1]				
* * *	*	*	*	*
Revision to the Nevada State Implementation Plan for the 2015 Ozone NAAQS: Nonattainment Major NSR Requirements: Las Vegas Valley Nonattainment Area.	Las Vegas Valley, Clark County.	8/5/2021	[INSERT **FEDERAL REGISTER** CITATION], 5/6/2024.	This is an approval of Clark County's certification that the existing Nonattainment New Source Review program is at least as stringent as the requirements of 40 CFR 51.165 for the 2015 ozone NAAQS.
* * *	*	*	*	*

[1] The organization of this table generally follows from the organization of the State of Nevada's original 1972 SIP, which was divided into 12 sections. Nonattainment and maintenance plans, among other types of plans, are listed under Section 5 (Control Strategy). Lead SIPs and Small Business Stationary Source Technical and Environmental Compliance Assistance SIPs are listed after Section 12 followed by nonregulatory or quasi-regulatory statutory provisions approved into the SIP. Regulatory statutory provisions are listed in 40 CFR 52.1470(c).

* * * * *

[FR Doc. 2024–09308 Filed 5–3–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220919–0193; RTID 0648–XD926]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; Closure of the Angling Category Southern New England Area Trophy Fishery for 2024

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the Angling category southern area fishery for large medium and giant (''trophy'' (*i.e.,* measuring 73 inches (185 centimeters (cm)) curved fork length or greater)) Atlantic bluefin tuna (BFT). The southern New England area trophy fishery is defined as south of 42° N lat. and north of 39°18′ N lat. This action applies to Highly Migratory Species (HMS) Angling and HMS Charter/Headboat permitted vessels when fishing recreationally.

DATES: Effective 11:30 p.m., local time, May 2, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., *larry.redd@noaa.gov,* or Ann Williamson, *ann.williamson@noaa.gov,* 301–427–8503.

SUPPLEMENTARY INFORMATION: BFT fisheries are managed under the 2006 Consolidated HMS Fishery Management Plan (FMP) and its amendments, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota, established by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act at 16 U.S.C. 1854(g)(1)(D) to provide U.S. fishing vessels with a reasonable

opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

Under § 635.28(a)(1), NMFS files a closure notice with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. Retaining, possessing, or landing BFT under that quota category is prohibited on and after the effective date and time of a closure notice for that category, for the remainder of the fishing year, until the opening of the subsequent quota period or until such date as specified.

The 2024 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2024. The Angling category season opened January 1, 2024, and continues through December 31, 2024. As described in § 635.27(a), the current baseline U.S. BFT quota is 1,316.14 metric tons (mt) (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area per § 635.27(a)(3)). The Angling category baseline quota is 297.4 mt, of which 9.2 mt (3.1 percent of the annual Angling category quota) is sub-allocated for the harvest of large medium and giant (trophy) BFT by vessels fishing under the Angling category quota, with 2.3 mt (25 percent of the annual large medium and giant BFT Angling category quota) allocated for each of the following areas: North of 42° N lat. (the Gulf of Maine area); south of 42° N lat. and north of 39°18′ N lat. (the southern New England area); south of 39°18′ N lat., and outside of the Gulf of Mexico (the southern area); and the Gulf of Mexico region. Trophy BFT measure 73 inches (185 cm) curved fork length or greater. This closure action applies to the southern New England area.

Angling Category Large Medium and Giant Southern New England ''Trophy'' Fishery Closure

Based on landings data from the NMFS Automated Catch Reporting System, as well as average catch rates and anticipated fishing conditions, the Angling category southern New England area trophy BFT subquota of 2.3 mt has been reached and exceeded. Therefore, retaining, possessing, or landing large medium or giant (*i.e.,* measuring 73 inches (185 cm) curved fork length or greater) BFT south of 42° N lat. and north of 39°18′ N lat. by persons aboard HMS Angling and HMS Charter/Headboat permitted vessels (when fishing recreationally) must cease at 11:30 p.m. local time on May 2, 2024. This closure will remain effective through December 31, 2024. This action applies to HMS Angling and HMS Charter/Headboat permitted vessels when fishing recreationally for BFT, and is taken consistent with the regulations at § 635.28(a)(1). This action is intended to prevent further overharvest of the Angling category southern New England area trophy BFT subquota.

If needed to ensure available quotas or subquotas are not exceeded or to enhance fishing opportunities, subsequent Angling category adjustments or closures will be published in the **Federal Register** per §§ 635.27(a)(7) and 635.28(a)(1). Information regarding the Angling category fishery for Atlantic tunas, including daily retention limits for BFT measuring 27 inches (68.5 cm) to less than 73 inches (185 cm), and any further Angling category adjustments, is available at *https://www.hmspermits.noaa.gov.* During a closure, fishermen aboard HMS Angling and HMS Charter/Headboat permitted vessels when fishing recreationally may continue to catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/.*

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Per § 635.5(c)(1), HMS Angling and HMS Charter/Headboat permitted vessel owners are required to report the catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing *https://www.hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)) and regulations at 50 CFR part 635, and this action is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons. Specifically, the regulations implementing the 2006 Consolidated HMS FMP and its amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing for prior notice and opportunity to comment is impracticable and contrary to the public interest as this fishery is currently underway and, based on landings information, the Angling category southern New England area fishery subquota has been reached and exceeded. Delaying this action could result in further excessive trophy BFT landings that may result in future potential quota reductions for the Angling category, depending on the magnitude of a potential Angling category overharvest. NMFS must close the southern New England area trophy BFT fishery before additional landings of these sizes of BFT occur. Taking this action does not raise conservation and management concerns, and would support effective management of the BFT fishery. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria.

For all of the above reasons, the AA also finds that pursuant to 5 U.S.C. 553(d), there is good cause to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: May 1, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09782 Filed 5–1–24; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 88
Monday, May 6, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 26

[Docket No. CISA–2022–0010]

RIN 1670–AA04

Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA) Reporting Requirements; Extension of Comment Period

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On April 4, 2024, the Cybersecurity and Infrastructure Security Agency (CISA) published a proposed rule in the **Federal Register**, the Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA), which proposes regulations implementing the statute's covered cyber incident and ransom payment reporting requirements for covered entities. CISA is extending the public comment period for the proposed rulemaking for an additional 30 days through July 3, 2024, in response to comments received from the public requesting additional time.

DATES: The comment period for the proposed rulemaking published on April 4, 2024, at 89 FR 23644 is extended an additional 30 days. Comments and related material must be submitted on or before July 3, 2024.

ADDRESSES: You may send comments, identified by docket number CISA–2022–0010, through the Federal eRulemaking Portal available at *http://www.regulations.gov.*

Instructions: All comments received must include the docket number for this rulemaking. All comments received will be posted to *https://www.regulations.gov,* including any personal information provided. If you cannot submit your comment using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions. For detailed instructions on sending comments and additional information on the types of comments that are of particular interest to CISA for this proposed rulemaking, see the **SUPPLEMENTARY INFORMATION** section of the proposed rulemaking document.

Docket: For access to the docket and to read background documents mentioned in this proposed rule and comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Todd Klessman, CIRCIA Rulemaking Team Lead, Cybersecurity and Infrastructure Security Agency, *circia@cisa.dhs.gov,* 202–964–6869.

SUPPLEMENTARY INFORMATION:

Background and Discussion

On April 4, 2024, CISA published a notice of proposed rulemaking, ''Cyber Incident Reporting for Critical Infrastructure Act Reporting Requirements'' (89 FR 23644), which proposes a rulemaking required by the Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA). See 6 U.S.C. 681–681g; Public Law 117–103, as amended by Public Law 117–263 (Dec. 23, 2022). The proposed rule provided for a 60-day comment period which was scheduled to close on June 3, 2024.

CISA received comments requesting that the agency consider extending the comment period for an additional 30 days. Requesters cited the complexity inherent in addressing cybersecurity within critical infrastructure sectors, the potential impact of this rulemaking on each critical infrastructure sector, and the need for additional time to sufficiently review and comment. In response to these requests, CISA has decided to extend the public comment period by 30 days. The comment period is now open through July 3, 2024.

Public Participation and Requests for Comments

CISA is including in the docket a draft privacy and civil liberties guidance document that would apply to CISA's retention, use, and dissemination of personal information contained in a CIRCIA Report and guide other Federal departments and agencies with which CISA will share CIRCIA Reports. CISA encourages interested readers to review this draft guidance and to submit comments on it. Commenters should clearly identify which specific comment(s) concern the draft guidance document.

CISA will accept comments no later than the date provided in the **DATES** section of this document. Interested parties may submit data, comments, and other information using any of the methods described in the **ADDRESSES** section of this document. To ensure appropriate consideration of your comment, indicate the specific section of this proposed rule and, if applicable, the specific comment request number associated with the topic to which each comment applies; explain a reason for any suggestion or recommendation; and include data, information, or authority that supports the recommended course of action. Comments submitted in a manner other than those described above, including emails or letters sent to Department of Homeland Security or CISA officials, will not be considered comments on the proposed rule and may not receive a response from CISA.

Instructions to Submit Comments. If you submit a comment, you must submit it to the docket associated with CISA Docket Number CISA–2022–0010. All submissions may be posted, without change, to the Federal eRulemaking Portal at *www.regulations.gov* and will include any personal information that you provide. You may choose to submit your comment anonymously. Additionally, you may upload or include attachments with your comments. Do not upload any material in your comments that you consider confidential or inappropriate for public disclosure. Do not submit comments that include trade secrets, confidential commercial or financial information, Protected Critical Infrastructure Information, Sensitive Security Information, or any other protected information to the public regulatory docket. Please submit comments containing protected information separately from other comments by contacting the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below for instructions on how to submit comments that include protected information. CISA will not place comments containing protected information in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. CISA will hold such

comments in a separate file to which the public does not have access and place a note in the public docket documenting receipt. If CISA receives a request for a copy of any comments submitted containing protected information, CISA will process such a request consistent with the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department's FOIA regulation found in part 5 of title 6 of the Code of Federal Regulations (CFR).

To submit a comment, go to *www.regulations.gov,* type CISA–2022–0010 in the search box and click ''Search.'' Next, look for the CIRCIA **Federal Register** notice of proposed rulemaking in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your comment by using *https://www.regulations.gov,* call or email the point of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. For access to the docket and to view documents mentioned in the CIRCIA NPRM as being available in the docket, go to *https://www.regulations.gov,* search for the docket number provided in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in the docket and can be viewed by following instructions on the Frequently Asked Questions web page *https://www.regulations.gov/faq.* The Frequently Asked Questions page also explains how to subscribe for email alerts that will notify you when comments are posted or if another **Federal Register** document is published. CISA will review all comments received. CISA may choose to withhold information provided in comments from public viewing or to not post comments that CISA determines are off-topic or inappropriate.

Jennie M. Easterly,

Director, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2024–09505 Filed 5–3–24; 8:45 am]

BILLING CODE 9110—P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1288; Project Identifier MCAI–2024–00063–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A330–243, –302, –343, and –941 airplanes. This proposed AD was prompted by a determination that a certain aft bulkhead cover panel may have been made with a non-conforming material. This proposed AD would require replacing the aft bulkhead cover panel and prohibit the installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 20, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1288; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2024–1288.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3229; email: *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–1288; Project Identifier MCAI–2024–00063–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this

NPRM. Submissions containing CBI should be sent to Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3229; email: *vladimir.ulyanov@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0023, dated January 23, 2024 (EASA AD 2024–0023) (also referred to as the MCAI), to correct an unsafe condition on certain Airbus SAS Model A330–243, –302, –343, and –941 airplanes. The MCAI states that a certain aft bulkhead cover panel may have been made with a non-conforming material. This panel is installed in galley G4 and does not meet the heat release requirements. This condition, if not corrected, represents a non-compliance with certification requirements that could result in injury to occupants and reduced evacuation capacity from the airplane in case of an emergency.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1288.

Related Service Information Under 1 CFR Part 51

EASA AD 2024–0023 specifies procedures for replacing the aft bulkhead cover panel installed in galley G4 and prohibits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0023 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0023 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0023 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0023 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0023. Service information required by EASA AD 2024–0023 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–1288 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 25 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3.5 work-hours × $85 per hour = $298	Up to $123,000	Up to $123,298	Up to $3,082,450.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus SAS: Docket No. FAA–2024–1288; Project Identifier MCAI–2024–00063–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 20, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A330–243, –302, –343, and –941 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0023, dated January 23, 2024 (EASA AD 2024–0023).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a determination that a certain aft bulkhead cover panel may have been made with a non-conforming material. The FAA is issuing this AD to address the non-conforming aft bulkhead cover panel. The unsafe condition, if not addressed, could result in injury to occupants, and reduced evacuation capacity from the airplane in case of an emergency.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0023.

(h) Exceptions to EASA AD 2024–0023

(1) Where EASA AD 2024–0023 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0023.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3229; email: *vladimir.ulyanov@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0023, dated January 23, 2024.

(ii) [Reserved]

(3) For EASA AD 2024–0023, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 26, 2024.

James D. Foltz,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09508 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1289; Project Identifier MCAI–2023–01049–T]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This proposed AD was prompted by a report that at various lavatory and galley locations within the airplane, incorrect terminal lugs were installed which are not compatible with the associated wire gauge. This proposed AD would require removing and replacing existing lug terminals at various lavatory and galley locations, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 20, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1289; or in person at

Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Transport Canada material, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–1289; Project Identifier MCAI–2023–01049–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2023–67, dated October 4, 2023 (Transport Canada AD CF–2023–67) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The MCAI states that at lavatory and galley locations within the airplane, incorrect terminal lugs have been installed which are not compatible with the associated wire gauge.

The FAA is proposing this AD to address incorrect terminal lugs that may become loose causing a loss of electromagnetic interference protection, which could result in false alarms of the lavatory smoke detectors, false alarms of low crew oxygen pressure, loss of automatic control of automatic cabin temperature control, and loss of lavatory flush. The unsafe condition, if not corrected, could result in an increase in crew workload, including diversions and descent to below 10,000 feet or the lowest safe altitude.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1289.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–67 specifies procedures for removing existing terminal lugs and installing new terminal lugs at lavatories A, C1, C2, C3, D2, D4, and E, and galleys G2A, G2G, and G4, including replacing the ground wires for new terminal lugs if the ground wire length is not sufficient; and installing the service bulletin incorporation placards.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2023–67 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2023–67 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–67 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by Transport Canada AD CF–2023–67 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–1289 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 66 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 81 work-hours × $85 per hour = Up to $6,885	(*)	Up to $6,885	Up to $454,410.

*The FAA has received no definitive data on which to base the cost estimates for the parts specified in this proposed AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Docket No. FAA–2024–1289; Project Identifier MCAI–2023–01049–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 20, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (type certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–67, dated October 4, 2023 (Transport Canada AD CF–2023–67).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report that at lavatory and galley locations within the airplane, incorrect terminal lugs have been installed which are not compatible with the associated wire gauge. The FAA is issuing this AD to address incorrect terminal lugs that may become loose causing a loss of electromagnetic interference protection, which could result in false alarms of the lavatory smoke detectors, false alarms of low crew oxygen pressure, loss of automatic control of automatic cabin temperature control, and loss of lavatory flush. The unsafe condition, if not corrected, could result in an increase in crew workload, including diversions and descent to below 10,000 feet or the lowest safe altitude.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–67.

(h) Exception to Transport Canada AD CF–2023–67

(1) Where Transport Canada AD CF–2023–67 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2023–67 refers to hours air time, this AD requires using flight hours.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-NYACO-COS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Airbus Canada Limited Partnership's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Transport Canada AD CF–2023–67, dated October 4, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–67, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this Transport Canada AD on the Transport Canada website at *tc.canada.ca/en/aviation.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 26, 2024.

James D. Foltz,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09506 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2 and 38

[Docket No. RM05–5–031]

Standards for Business Practices and Communication Protocols for Public Utilities

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission proposes to amend its regulations to incorporate by reference, with certain exceptions, the latest version (Version 004) of the Standards for Business Practices and Communication Protocols for Public Utilities adopted by the Wholesale Electric Quadrant of the North American Energy Standards Board.

DATES: Comments are due July 5, 2024.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways. Electronic filing through *http://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (Including Courier) Delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

The Comment Procedures Section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

John O. Sillin (technical issues), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 502–6548

Veronica Norman (legal issues), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8751

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Overview

1. The Federal Energy Regulatory (Commission) proposes to amend its regulations at 18 CFR 38.1(b) to incorporate by reference, with certain enumerated exceptions,[1] the latest

[1] In addition to the standards discussed below that are not proposed for incorporation by reference, the Commission is not proposing to incorporate by reference the following: (1) the WEQ–009 Standards of Conduct for Electric Transmission Providers, which NAESB has eliminated as they duplicate the Commission's regulations; and (2) the WEQ–014 WEQ/WGQ eTariff Related Business Practice Standards, which provide an implementation guide describing the various mechanisms, data tables, code values/

Continued

version (Version 004) of the Standards for Business Practices and Communication Protocols for Public Utilities adopted by the Wholesale Electric Quadrant (WEQ) of the North American Energy Standards Board (NAESB) (WEQ Version 004 Standards) applicable to the wholesale electric industry. NAESB is an American National Standards Institute-accredited, non-profit standards development organization formed for the purpose of developing voluntary standards and model business practices that promote more competitive and efficient natural gas and electric markets. On July 31, 2023, NAESB filed a notice that it had approved and published the WEQ Version 004 Standards to replace the currently incorporated version (Version 003.3) of those business practice standards (Informational Report).[2] The revisions made by NAESB in the WEQ Version 004 Standards are designed to aid public utilities with the consistent and uniform implementation of requirements promulgated by the Commission as part of the *pro forma* Open Access Transmission Tariff.

II. Background

2. Since 2006, the Commission has adopted in its regulations NAESB's business practice standards and communication protocols for public utilities, promulgated in the Order No. 697 series of orders,[3] wherein the Commission incorporated by reference the standards for public utilities developed by NAESB's WEQ. Upon incorporation by reference, this version of the standard will replace the currently incorporated version (Version 003.3) of those business practice standards.

3. On July 31, 2023, NAESB filed a report informing the Commission that it had approved and published the WEQ Version 004 Standards. NAESB states that the WEQ Version 004 Standards include newly created standards, as well as modifications to existing standards, developed through the NAESB standards development process. WEQ Version 004 Standards build upon WEQ Version 003.3 Standards and include standards developed in response to the directives from Order Nos. 676–I and 676–J,[4] business practice standards developed to support cybersecurity for the wholesale electric industry, modifications to complement the NERC Reliability Standards, the new NAESB Base Contract for Sale and Purchase of Voluntary Renewable Energy Certificates (NAESB REC Contract), and standards to identify definitions for common grid services to support distributed energy resource interactions in response to a request submitted by the Department of Energy (DOE), Lawrence Berkeley National Laboratory (Berkeley Lab), and Pacific Northwest National Laboratory (PNNL). Additionally, WEQ Version 004 Standards include modifications applied to Open Access Same-Time Information Systems (OASIS) Business Practice Standards, the Coordinate Interchange Business Practice Standards, and the Abbreviations, Acronyms, and Defined Terms.

4. The Informational Report includes an overview of all standard additions, modifications, and reservations applied to Version 004 of the WEQ Business Practice Standards and summarizes the deliberations that led to the changes. It also identifies changes to the existing standards that were considered but not adopted.[5]

III. Discussion

5. In this notice of proposed rulemaking (NOPR), we propose to incorporate by reference into the Commission's regulations at 18 CFR 38.1(b) the WEQ Version 004 Standards as developed by NAESB, with certain exceptions.[6] In the subsections that follow, we provide the summary required by the Office of **Federal Register** regulations. As an initial matter, we note that the WEQ Version 004 Standards include modifications, reservations, and additions to the following set of existing WEQ Standards, *i.e.,* the Version 003.3 Business Practice Standards.

Standard No.	Business practice standards
WEQ–000	Abbreviations, Acronyms, and Definition of Terms.
WEQ–001	OASIS.
WEQ–002	OASIS Standards and Communication Protocol (S&CP).
WEQ–003	OASIS Data Dictionary.
WEQ–004	Coordinate Interchange.
WEQ–005	Area Control Error Equation Special Cases.
WEQ–006	Manual Time Error Correction.
WEQ–008	Transmission Loading Relief (TLR)—Eastern Interconnection.
WEQ–010	Contracts Related Business Practice Standards.
WEQ–012	Public Key Infrastructure (PKI).
WEQ–013	OASIS Implementation Guide.
WEQ–015	Measurement and Verification of Wholesale Electricity Demand Response.
WEQ–021	Measurement and Verification of Energy Efficiency Products.
WEQ–022	Electric Industry Registry.
WEQ–023	Modeling.

6. Additionally, the WEQ Version 004 Business Practice Standards include two new sets of standards:

reference tables, and technical specifications used in the submission of electronic tariff filings to the Commission, which the Commission has not incorporated as these submittals are governed by the Commission's eTariff regulations.

[2] *See* NAESB WEQ Business Practice Standards Version 004 Report, Docket No. RM05–5–31, (filed July 31, 2023).

[3] This series of orders began with the Commission's issuance of *Standards for Bus. Practices & Commc'n Protocols for Pub. Utils.,* Order No. 676, 71 FR 26,199 (May 4, 2006), 115 FERC ¶ 61,102 (2006).

[4] *See Standards for Bus. Practices & Commc'n Protocols for Pub. Utils.,* Order No. 676–I, 85 FR 10571 (Feb. 25, 2020), 170 FERC ¶ 61,062 (2020); *Standards for Bus. Practices & Commc'n Protocols for Pub. Utils.,* No. 676–J, 86 FR 29,491 (Jun. 2, 2021), 175 FERC ¶ 61,139 (2021).

[5] Since the publication of WEQ Version 003.3, sixteen standards development efforts have resulted in recommendations from WEQ subcommittees for no action.

[6] In the discussion below, we identify the NAESB WEQ Version 004 Standards that we propose *not* to incorporate by reference.

WEQ–024	Cybersecurity.
WEQ–025	Grid Services Supporting Wholesale Electric Interactions.

7. As the Commission found in Order No. 676, adoption of consensus standards is appropriate because the consensus process helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of all segments of the industry. Moreover, since the industry itself conducts business under these standards, the Commission's regulations should reflect those standards that have the widest possible support. In section 12(d) of the National Technology Transfer and Advancement Act of 1995, Congress affirmatively requires Federal Agencies to use technical standards developed by voluntary consensus standards organizations, such as NAESB, as a means of carrying out policy objectives or activities unless use of such standards would be inconsistent with applicable law or otherwise impractical.[7]

8. We discuss below some specific aspects of NAESB's informational report. The following paragraphs describe NAESB's proposed modifications, reservations, and additions to its existing standards, which collectively produce NAESB's proposed WEQ Version 004 Standards. The paragraphs also describe relevant background information and impetuses for the changes.

A. Modifications to Previous Version of Standards

1. Modifications in Response to Commission Order Nos. 676–I and 676–J

9. WEQ Version 004 contains modifications made in response to directives contained in Order Nos. 676–I and 676–J and related industry-submitted standards requests under three separate standards development efforts related to standards for redirection of transmission, time error correction, and contract path management. As part of these efforts, NAESB modified the WEQ–000 Abbreviations, Acronyms, and Definition of Terms, WEQ–001 OASIS Business Practice Standards, WEQ–003 OASIS Data Dictionary Business Practice Standards, WEQ–006 Manual Time Error Correction Business Practice Standards, WEQ–013 OASIS Implementation Guide Business Practice Standards, and WEQ–023 Modeling Business Practice Standards.

a. Standards for Redirection of Transmission Service

10. In response to Order No. 676–I,[8] NAESB revised the WEQ–001, WEQ–003, and WEQ–013 standards to provide greater specificity regarding the transmission service reservation process that applies to redirection of transmission service (redirects) on a firm and non-firm basis, consistent with the Commission's *Dynegy*[9] policy addressing a customer's right to keep its contractual rights to point-to-point firm transmission service on the original path it has reserved while the customer's request for a redirect is pending.[10] In *Dynegy Power Marketing, Inc.* v. *Southwest Power Pool, Inc.,* the Commission held that a transmission customer receiving firm transmission service does not lose its rights to its original path until the redirect request satisfies all of the following criteria: (1) it is accepted by the transmission provider; (2) it is confirmed by the transmission customer; and (3) it passes the conditional reservation deadline under section 13.2 of the transmission provider's OATT.

11. In Order No. 676–I, the Commission incorporated by reference the NAESB standards, except for the preambles in WEQ–001–9 and WEQ 001–10. The Commission declined to incorporate by reference the two preambles because they appeared to permit transmission providers the option to implement their own entity-specific procedures, which would not have ensured consistency across the bulk power system.[11] The Commission also specified which firm parent reservations would be afforded the protection of the *Dynegy* policy and limited the *Dynegy* policy to redirects from unconditional firm service.[12]

12. In response to Order No. 676–I, NAESB conducted a full review of both the WEQ–001–9 and WEQ–001–10 NAESB Standards to identify any shortcomings and modifications needed to comply with the Commission's conclusions and with *Dynegy.* The proposed standards provide additional details regarding the treatment of redirects from unconditional and conditional parent transmission service reservations, require redirects of non-firm transmission service to be from unconditional parent transmission service reservations, and require resales of transmission service to be from unconditional parent transmission service reservations. Further, the modified standards establish a mechanism to allow capacity to be returned from a redirect of firm transmission service to the parent transmission service reservation.

b. Time Error Correction

13. In Order No. 676–I, the Commission found that NAESB had not provided sufficient justification for retiring the Time Error Correction standard (WEQ–006), as it had proposed. The Commission instead left in place the incorporation by reference of the time error correction standard in the prior version of the standards (WEQ Version 003.1).[13] The Commission requested that public utilities work through the NAESB business practices development process to revisit the rationale for removing the Time Error Correction standards to determine whether they should be retained or revised.

14. In response to the Commission in Order No. 676–I, NAESB revised WEQ–006 Manual Time Error Correction Business Practice Standards to address commercial requirements for entities calling for manual time error corrections in accordance with the NERC Time Monitoring Reference Document Version 5.[14] Under the revised standards, Interconnection Time Monitors are required to monitor Time Error and make a reasonable effort to initiate or terminate corrective action orders according to the table in the standards when the time is slow or fast. The standards further require that, when any balancing authority has been separated from the Interconnection, after reconnection, it is required to adjust its Time Error devices to coincide with the Time Error of the Interconnection Time Monitor. These requirements do not apply to balancing authorities and Interconnection Time

[7] Public Law 104–113, 12(d), 110 Stat. 775 (1996), 15 U.S.C. 272 note (1997).

[8] Order No. 676–I, 170 FERC ¶ 61,062 at PP 35–39.

[9] 99 FERC ¶ 61,054, at P 9 (2002) (*Dynegy*). This policy was retained and clarified in *Entergy Services, Inc.,* 143 FERC ¶ 61,143, at PP 30–33 (2013) (*Entergy*).

[10] Order No. 676–I, 170 FERC ¶ 61,062 at P 3.

[11] Order No. 676–I, 170 FERC ¶ 61,062 at PP 37–38.

[12] *Id.* P 36.

[13] Order 676–I, 170 FERC ¶ 61,062 at P 46.

[14] North American Electric Reliability Corporation, *Time Monitoring Reference Document, Version 5* (2019).

Monitors that use automatic Time Error Correction procedures.

c. Contract Path Management

15. In Order No. 676–J, the Commission incorporated by reference all the WEQ–023 Modeling Business Practice Standards as included in WEQ Version 003.3 Standards, which had two new standards—WEQ–023–1.4 and –1.4.1—related to contract path management not previously included in the NERC MOD A Reliability Standards. Those standards limited the amount of firm transmission service granted on an Available Transfer Capability (ATC) Path and limited the interchange schedule (both firm and non-firm) between balancing authority areas to the contract path limit for that given path, respectively. Bonneville Power Administration (BPA) and the ISO/RTO Council objected to these standards, contending that the standards interfere with the way service providers schedule their systems and that the standards may result in less efficient use of ATC. Notwithstanding these objections, the Commission incorporated these standards by reference, finding that declining to adopt these standards could loosen the requirements for non-discriminatory calculation of ATC. However, the Commission urged NAESB to consider the issues raised as to whether revisions to the standards would be warranted.[15]

16. In response, NAESB modified the WEQ–023 Modeling Business Practice Standards to allow the contract path limit to be exceeded for a certain period of time prior to the start of flow.[16] Specifically, the revisions to WEQ–023–1.4 and WEQ–023–1.4.1 were modified to better accommodate individual transmission provider business practices that may, for scheduling efficiency purposes, allow a contract path limit to be exceeded for a certain period prior to the implementation of the interchange schedule.[17] The modification to WEQ–023–1.4.1 stipulates that when a transmission provider is determining whether to approve a request for firm transmission service, the transmission provider will consider the methodology used by other transmission providers and determine whether there is agreement between the methodologies.

17. The modifications to WEQ–023–1.4.1 provide clarity by establishing a cutoff time by which transmission providers must ensure that the net interchange schedule does not exceed the contract path limit. The revisions also include changes to ensure consistency with WEQ–023–1.4, as well as changes to clarify that entities using conditional firm transmission service may exceed the firm limit transfers in accordance with WEQ–001.21.

18. The revised standards proposed for incorporation by reference provide increased flexibility for transmission providers to maximize the use of the transmission system while still preventing the allocation of firm transmission service that exceeds transfer capability.

2. Modifications To Support Cybersecurity for the Wholesale Electric Industry

19. In addition to the addition of a new set of standards, WEQ–024 Cybersecurity Business Practice Standards (*see* section III.B.1 below), NAESB made modifications to WEQ–012 to support the issuance of server-side or transport layer security certificates by NAESB Authorized Certification Authorities (ACA).

20. The modifications to WEQ–012 standards incorporate best industry practices regarding the issuance of server-side or transport layer security server certificates by a certificate authority and allow a NAESB ACA to issue code-signing certificates that can be used to verify software and other executables in support of the NERC CIP–010 Security—Configuration Change Management and Vulnerability Assessments Reliability Standard. As part of these modifications, any digital certificate issued by a NAESB ACA must clearly and uniquely identify the organizational affiliation of the certificate holder. Identification is done through the inclusion of the company's Entity Code, an alphanumeric code that uniquely identifies an entity registered in the NAESB Electric Industry Registry (EIR), in the Organization Unit field of the certificate. Recent changes to industry practices facilitated through the Certification Authority Browser Forum have halted use of the Organization Unit field in server-side/transport layer security certificates issued by any certificate authority.

21. Additional modifications were made to the NAESB Accreditation Requirements for ACAs. The modifications will allow NAESB ACAs to issue code signing certificates that can be used by industry to authenticate software and other executable computer files from third parties. The modifications are supportive of Reliability Standard CIP–010 Cyber Security—Configuration Change Management and Vulnerability Assessments Reliability Standards require verification of the identity of a software source.

3. Modifications To Complement NERC Reliability Standards

22. WEQ Version 004 Standards include revisions to complement the NERC Reliability Standards, including modifications to be consistent with the NERC Glossary. The revisions modified WEQ–005–1.2.1 and WEQ–005–1.2.2 and created four new standards—WEQ–005–1.2.1.1, WEQ–005–1.2.1.2, WEQ–005–1.2.2.1, and WEQ–005–1.2.2.2. The changes were made to provide further clarity on the incorporation of jointly owned units into the ACE equation and to ensure consistency in the use of terminology between the WEQ Business Practice Standards and the NERC Dynamic Transfer Reference Document, which provides reliability guidance on the use of pseudo-ties and dynamic schedules in a balancing authority's ACE equations.[18] Changes ensuring consistency in terminology were also made to WEQ–000.

23. NAESB also modified the definition for System Operating Limit in WEQ–000 to ensure consistency with the proposed changes to the definition in the NERC Glossary. As the term appears in WEQ–001, WEQ–004, WEQ–008, and WEQ–023, the review of the modified definition was coordinated with four WEQ subcommittees.

4. Modifications to the WEQ OASIS Business Practice Standards

24. In addition to the OASIS modifications referenced previously, NAESB completed nine final actions modifying the OASIS suite of Business Practice Standards.

a. Eligibility and Treatment of Rollover Rights

25. NAESB developed modifications to the WEQ OASIS suite of Business Practice Standards to address the eligibility and treatment of rollover rights[19] as part of the standards

[15] Order No. 676–J, 175 FERC ¶ 61,139 at P 30.

[16] Informational Report at 8.

[17] *Id.*

[18] North American Electric Reliability Corporation, *Dynamic Transfer Reference Document, Version 4* (2019).

[19] A Rollover Right is the option held by an existing firm transmission service customer to continue to take transmission service after a contract term expires. The contract ''rolls over'' or is, in effect, renewed. *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Servs. by Pub. Utils.; Recovery of Stranded Costs by Pub. Utils. & Transmitting Utils.,* Order No. 888, 61 FR 21540 at 21604 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996) (cross-referenced at 75 FERC ¶ 61,080), *order on reh'g,* Order No. 888–A, 62 FR 12274 (Mar. 14, 1997), FERC Stats. & Regs. ¶ 31,048 (cross-referenced at 78 FERC ¶ 61,220), *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order*

supporting Network Integration Transmission Service (NITS).[20] The recommendation includes new and revised standards that define if and when rollover rights are assigned, update posting requirements and establish supporting template structures, and create dynamic notifications within OASIS for rollover rights. In developing the recommendation, one area of major discussion within the subcommittee was the impact of a termination of transmission service on rollover rights. The subcommittee reached consensus that indefinite termination of transmission service will result in an automatic termination of rollover rights associated with that service. The resulting standards revisions, including template structures, were applied to WEQ–001, WEQ–002, WEQ–003, and WEQ–013.

b. Submission of Variables Associated With NITS

26. Several modifications were made to WEQ–002 and WEQ–003 to allow users the ability to submit specific lists of variables associated with NITS as part of the query/response functionality in OASIS templates. The revisions include changes to standards language in WEQ–002 and the addition of five new data elements to WEQ–003. No new NITS query variables were developed as part of these revisions.

c. Provide Consistency Between Standards Language

27. NAESB developed modifications to WEQ–001 to provide greater consistency between the standards language included in WEQ–001–9.2 and WEQ–001–9.4.3 and WEQ–001–B Appendix B—Redirect Business Practice Standards Examples. Specifically, the changes revise several of the illustrative examples included as part of the appendix to clarify that transmission service? requests submitted before the capacity is committed, or outside the time frame of the parent reservation, should be denied, consistent with WEQ–001–9.2 and WEQ–001–9.3. The changes also ensure consistency between the reservation processes that apply to redirects on firm and non-firm bases.

d. Improvements for OASIS Node Users

28. NAESB revised WEQ–002, WEQ–003, and WEQ–013 to establish a mechanism that enables OASIS node users to identify—in a single location—all service modifications made to an original transmission service request reservation. Specifically, the revisions include modifications to WEQ–002–4.3.4.3, the addition of nine new data elements in WEQ–003, and revisions to illustrative examples included in WEQ–013 Example 8.

e. Better Support Posting Requirements

29. NAESB developed modifications to WEQ–001 to better support posting requirements, included as part of 18 CFR 37.6, by adding specificity regarding the treatment of consolidations of transmission service requests. Consolidations of transmission service requests allow customers to combine capacity from like transmission service requests into a single request to promote efficient scheduling activities. When transmission service requests are consolidated, the consolidated request inherits attributes from the parent reservation, including the product code. The revisions to the standards ensure parity between consolidated and non-consolidated transmission service requests. The modifications are intended to eliminate the potential for a service increment to be created through consolidation that would otherwise be unavailable under a transmission provider's existing tariff processes, such as requests that have been consolidated into a daily transmission service request but inherited a monthly product code from one of the original parent reservations. The changes modify WEQ–001–24.2.4 and include two new standards, WEQ–001–24.2.4.1 and WEQ–001–24.2.4.2.

f. Provide Greater Clarity Regarding Priorities Between a Firm Transmission Service Request and a Previously Queued Non-Firm Request

30. NAESB modified WEQ–001 by modifying Table 25–3, Priorities for Competing Reservations or Requests, to better describe how a competition is conducted between a firm transmission service request and a previously queued non-firm request or reservation.

g. Response Timing Standards

31. The WEQ OASIS Subcommittee recommended certain modifications to extend response times for some functions to account for human performance.[21] As a result, the proposed revisions include revisions modifying the timing tables included in WEQ–001–4.13, WEQ–001–25.1.8, and WEQ–001–105.1.5 to extend specific timing criteria for instances in which systems are not fully automated. These changes will be utilized by transmission providers and operators who do not have automated systems for responding to transmission service requests. The benefits include extending timing requirements that are deemed unreasonably strict for non-automated implementations. Subjects covered include point-to-point transmission service, right of first refusal response processing, and Network Integration Transmission Service requests.

h. Provide Greater Clarity for Transmission Customers

32. NAESB also modified the WEQ OASIS suite of Business Practice Standards to provide greater clarity for transmission customers on which redirect requests would qualify for the conveyance of rollover rights. As part of the revisions, transmission customers are required to explicitly indicate their intent to convey rollover rights to the redirect path by expressly opting-in or opting-out of the conveyance, eliminating the possibility that rollover rights could be unintentionally redirected. Prior to ratification of these standards, the default option was to grant the conveyance automatically. The standards revisions include modifications to WEQ–001–9.7.3.1 and WEQ–002–4.3.6.2, as well as the creation of three new standards—WEQ–001–9.7.3.3, WEQ–001–9.7.3.4, and WEQ–001–9.7.3.3—and consistency changes to WEQ–003 and WEQ–013.

i. Improve Efficiencies by Creating a Tracking and Audit Mechanism for Transmission Service Reservations

33. Finally, NAESB revised the WEQ OASIS suite of Business Practice Standards to improve efficiencies by creating a tracking and audit mechanism for transmission service reservations that allows transmission providers and customers to easily assess changes that occur as a result of the preemption and right-of-first-refusal process. The standards revisions modify WEQ–001–25.4.6.5.3, WEQ–002–4.3.6.2, WEQ–002–4.3.6.3, and WEQ–013–6.3, and add two new data elements to WEQ–003.

5. Modifications To Coordinate Interchange Standards

34. NAESB revised the WEQ–004 Coordinate Interchange Business Practice Standards to promote efficiency by streamlining the procedures entities should follow in the event of a system failure of the primary communication

on reh'g, Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Pol'y Study Grp.* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

[20] The standards addressing rollover rights for point-to-point transmission service were included in the WEQ Version 003.2 Standards publication and were incorporated by reference through Order No. 676–I.

[21] Informational Report at 15.

method used to manage interchange transactions—electronic tags (e-Tags). The revised WEQ–004, specifically WEQ–004–2.1 and WEQ–004–A, clarify the existing back-up procedures for e-Tagging and remove the requirements supporting outdated communication methods.

35. NAESB also modified the WEQ–000 and WEQ–004 standards. The revisions add a new appendix to WEQ–004 to provide guidance and best practices to entities in the Eastern Interconnection that automate the net scheduled interchange checkout process. The standards are intended to support and complement the NERC Reliability Standard INT–009–3 Implementation of Interchange, which requires balancing authorities to communicate net interchange information on a periodic basis with adjacent balancing authorities. The WEQ Coordinate Interchange Scheduling Subcommittee discussed the development of a data specification that would include all data required to automate the net scheduled interchange checkout process. The subcommittee's participants drafted standards to provide guidance for the implementation of such automation. In the recommendation containing the standards revisions, the subcommittee noted that the Western Interconnection's use of the Western Electricity Coordinating Council Interchange Tool would not be impacted by the automation efforts for the Eastern Interconnection.

6. Modifications to Abbreviations, Acronyms, and Defined Terms

36. In addition to the consistency changes described above regarding WEQ–000, the WEQ Version 004 Standards publication includes a new cross-reference column displaying the abbreviations, acronyms, and definition of terms with their corresponding NAESB WEQ Standards. Additional changes to ensure consistency in the use of abbreviations, acronyms, and defined terms were made to the WEQ OASIS Suite of Standards, WEQ–004 Coordinate Interchange Business Practice Standards, WEQ–008 TLR—Eastern Interconnection Business Practice Standards, WEQ–012 PKI Business Practice Standards, WEQ–022 EIR Business Practice Standards, and WEQ–023 Modeling Business Practice Standards.

7. Voluntary Renewable Energy Certificates Contract

37. The Informational Report also includes a newly developed NAESB REC Contract, an accompanying *Frequently Asked Questions* document, and associated technical implementation standards containing data dictionaries and code values. These documents and standards are included in WEQ–010 Contracts Business Practice Standards to support the use of the NAESB REC Contract with digital technologies, such as blockchain, in the retail and wholesale markets.

8. Minor Corrections

38. Since the publication of WEQ Version 003.3 standards, NAESB processed ten minor corrections applicable to the WEQ Business Practice Standards through its Minor Correction Process, and incorporated them into the WEQ Version 004 Standards.[22]

B. New Sets of Standards

1. WEQ–024 Cybersecurity

39. In the WEQ Version 004 Standards, NAESB established a new set of Cybersecurity-related business practice standards in WEQ–024. This new set of standards reorganizes existing NAESB cybersecurity business practice standards into a new suite of NAESB standards. NAESB explained that it responded to an informal recommendation from DOE and Sandia National Laboratories (Sandia Labs) that arose from the 2019 Surety Assessment of cybersecurity elements contained in the NAESB Business Practice Standards. This consolidation should make the NAESB and Commission processes for revising NAESB cybersecurity business practice standards easier and faster to help match the fast pace of changes in cybersecurity practices. NAESB considered this consolidation a minor correction process; no new standards development efforts arose from this consolidation.

2. WEQ–025 Grid Services Supporting Wholesale Electric Interactions

40. In the WEQ Version 004 Standards, NAESB also established as a new suite of standards, WEQ–025 Grid Services Supporting Wholesale Electric Interactions Business Practice Standards, to promote greater consistency in wholesale market interactions and communication exchanges by flexible, ''grid-edge'' resources such as distributed energy resources and batteries. NAESB developed the standards in response to DOE, Berkeley Lab, and PNNL, which proposed that NAESB define a common list of grid services for electric market interactions in support of the DOE's Grid Modernization Laboratory Consortium efforts to modernize the nation's electric grid.

41. The WEQ–025 standards identify six categories of operations-based grid services used within the wholesale electric markets: (1) Energy Grid Service; (2) Reserve Grid Service; (3) Regulation Grid Service; (4) Frequency Response Grid Service; (5) Voltage Management Grid Service; and (6) Blackstart Grid Service. The standards also describe the types of attributes, such as location, timing, and performance determinations, that may be used by System Operators to define the unique requirements for services within their wholesale electricity markets. Due to regional variation and different markets, System Operators have varying names for operational objectives for the same or similar grid services. The new standards establish a technology-neutral framework that describes the operational objective of common types of market services and identifies the different physical capabilities to consume and/or inject electricity on the grid that a resource must be technically capable of providing.

42. According to the Informational Report, the framework introduced by these standards can enable regulators to easily compare market information regarding the use of transmission grid services across multiple jurisdictions. The changes are also designed to help market participants identify types of market services their resources may be able to provide and to create greater consistency in communications between resource owners participating in multiple markets and working with several System Operators to improve commercial transaction efficiencies.[23]

C. Standards the Commission Proposes Not To Incorporate by Reference

1. WEQ–010 Contracts Related Business Practice Standards

43. We propose to not to incorporate by reference WEQ–010, which includes the NAESB REC Contract, the accompanying Frequently Asked Questions document, and the associated technical implementation standards containing data dictionaries and code values contained in WEQ–010. This approach is consistent with our past practice[24] of not incorporating by reference into our regulations any

[22] As noted above, NAESB also used its minor correction process to compile the existing WEQ Cybersecurity Standards into a new book, WEQ–024 Cybersecurity Business Practice Standards.

[23] Informational Report at 12.

[24] *See, e.g., Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Notice of Proposed Rulemaking, 86 FR 12879 (Mar. 5, 2021), 174 FERC ¶ 61,103, at P 19 (2021) (*Version 3.2 NOPR*).

optional model contracts and related documents because we do not require the use of these contracts.[25]

2. WEQ–025 Grid Services Supporting Wholesale Electric Interactions

44. Although we support NAESB's standards development for grid services, we do not believe that it is necessary for the Commission to incorporate the WEQ–025 standards and the related changes to the WEQ–000 standards by reference. We note that the proposed NAESB standards use terms similar to but different from terms in the *pro forma* OATT that could introduce confusion if the Commission were to incorporate these standards by reference. Under the *pro forma* OATT, a transmission provider must provide a set of ancillary services, including reactive supply and voltage control (Schedule 2), regulation and frequency response (Schedule 3), and spinning and supplemental reserves (Schedules 5 & 6). The grid services set forth in the WEQ–025 set of standards address similar services; they include voltage, regulation, frequency response, and reserves. Also, the WEQ–025 standards are discretionary for system operators; thus, consistent with past practice,[26] we will not incorporate these standards by reference into our regulations.

D. Proposed Implementation Procedures

45. The Commission proposes that transmission providers whose tariffs do not automatically incorporate by reference all new NAESB standards submit compliance filings on the proposed NAESB standards nine months after publication of a final rule in the **Federal Register**. Those compliance filings must reflect the requirements of the final rule, any new waiver requests to comply with a part of the final rule, and any request to preserve any existing waivers.

46. The Commission proposes separate implementation schedules for the NAESB cybersecurity business practice standards and for all the remaining WEQ Version 004 Standards. Transmission providers will be required to implement the NAESB cybersecurity business practice standards within 12 months from the date of publication in the **Federal Register** of any final rule.[27] Transmission providers will be required to implement all other WEQ Version 004 Standards adopted in a final rule within 18 months from the date of publication in the **Federal Register** of any final rule. The Commission proposes implementation of the NAESB cybersecurity business practice standards on an expedited basis consistent with the Commission's implementation schedule previously adopted for the WEQ Version 003.3 Standards.[28] In that order, the Commission noted DOE's request that cybersecurity standards in that version be enacted on an expedited basis and that the stand-alone nature of the standards permitted expedited implementation.

47. This 18-month implementation timeline for the other WEQ Version 004 standards is consistent with Business Practice Standards WEQ 002–6, which states that transmission providers shall have 18 months from publication of a final rule in the **Federal Register** to implement all changes required to support the Business Practice Standards for OASIS version 004. Business Practice Standards WEQ 002–6 also state that: (a) OASIS Node changes required to support the version 004 OASIS template format must be made available to transmission customers no later than nine months after publication in the **Federal Register** and (b) OASIS Nodes shall maintain support for version 003.3 format queries and uploads for the full 18-month implementation period.

IV. Notice of Use of Voluntary Consensus Standards

48. Office of Management and Budget Circular A 119 (section 11) (February 10, 1998) provides that federal agencies should publish a request for comment in a NOPR when the agency is seeking to issue or revise a regulation proposing to adopt a voluntary consensus standard or a government-unique standard. In this NOPR, the Commission is proposing to incorporate by reference the WEQ Version 004 Standards, with the exception of WEQ–010 Contracts Related to Business Practice Standards, which includes the NAESB REC Contract, and WEQ–025 Grid Services Supporting Wholesale Electric Interactions. The WEQ Version 004 Standards were adopted by NAESB under NAESB's consensus procedures.[29]

V. Incorporation by Reference

49. The Office of the Federal Register requires agencies proposing to incorporate material by reference to discuss the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials.[30] The regulations also require agencies to summarize, in the preamble of the final rule, the materials that it incorporates by reference. The Commission proposes to incorporate by reference standards that consist of suites of NAESB WEQ business practice standards that address a variety of topics and are designed to aid public utilities with the consistent and uniform implementation of requirements promulgated by the Commission as part of the *pro forma* Open Access Transmission Tariff. We summarize these standards below.

50. The WEQ–000 Abbreviations, Acronyms, and Definition of Terms Business Practice Standards provide a single location for all abbreviations, acronyms, and defined terms referenced in the WEQ Business Practice Standards. These standards provide common nomenclature for terms within the wholesale electric industry, thereby reducing confusion and opportunities for misinterpretation or misunderstandings among industry participants.

51. The OASIS suite of business practice standards (WEQ–001 Open Access Same-Time Information Systems (OASIS), WEQ–002 OASIS Standards and Communication Protocols, WEQ–003 OASIS Data Dictionary, and WEQ–013 OASIS Implementation Guide) support the FERC posting and reporting requirements that provide information about each transmission provider's performance of the requirements of its *pro forma* OATT. The OASIS system is used for scheduling transmission on the bulk power system, comprises the computer systems and associated communications facilities that public utilities are required to provide for the purpose of making available to all transmission users comparable interactions, and provides transmission service information and any back-end supporting systems or user procedures that collectively perform the transaction processing functions for handling requests on OASIS. These standards establish business practices and communication protocols that provide

[25] *Id.; Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Order No. 587–V, 77 FR 43711 (Jul. 26, 2012), 140 FERC ¶ 61,036, at P 11 n.11 (2012).

[26] *See, e.g.,* Version 3.2 NOPR 174 FERC ¶ 61,103 at P 19.

[27] A complete list of the specific cybersecurity business practice standards is included at Appendix I.

[28] Order No. 676–J, 175 FERC ¶ 61,139 at P 11.

[29] Under this process, to be approved a standard must receive a super-majority vote of 67% of the members of the WEQ's Executive Committee with support from at least 40% from each of the five industry segments—transmission, generation, marketer/brokers, distribution/load serving entities, and end users. For final approval, 67% of the WEQ's general membership must ratify the standards.

[30] 1 CFR 51.5 (2022). *See* Incorporation by Reference, 79 FR 66267 (Nov. 7, 2014).

for consistent implementation across OASIS sites as well as consistent methods for posting to OASIS.

52. The WEQ–001 OASIS Business Practice Standards define the general and specific transaction processing requirements and related business processes required for OASIS. The standards detail requirements related to standard terminology for transmission and ancillary services, attribute values defining transmission service class and type, ancillary and other services definitions, OASIS registration procedures, procurement of ancillary and other services, path naming, next hour market service, identical transmission service requests, redirects, resales, transfers, OASIS postings, procedures for addressing ATC or AFC methodology questions, rollover rights, conditional curtailment option reservations, auditing usage of Capacity Benefit Margin, coordination of requests for service across multiple transmission systems, consolidation, preemption and right-of-first refusal process, and NITS requests.

53. The WEQ–002 OASIS Standards and Communication Protocols Business Practice Standards define the technical standards for OASIS. These standards detail network architecture requirements, information access requirements, OASIS and point-to-point interface requirements, implementation, and NITS interface requirements.

54. The WEQ–003 OASIS Data Dictionary Business Practice Standards define the data element specifications for OASIS.

55. The WEQ–004 Coordinate Interchange Business Practice Standards define the commercial processes necessary to facilitate interchange transactions via Request for Interchange (RFI) and specify the arrangements and data to be communicated by the entity responsible for authorizing the implementation of such transactions (the entities responsible for balancing load and generation).

56. The WEQ–005 Area Control Error (ACE) Equation Special Cases Business Practice Standards define commercial-based requirements regarding the obligations of a balancing authority to manage the difference between scheduled and actual electrical generation within its control area. Each balancing authority manages its ACE in accordance with the NERC Reliability Standards. These standards detail requirements for jointly owned utilities, supplemental regulation service, and load or generation transfer by telemetry.

57. The WEQ–006 Manual Time Error Correction Business Practice Standards define the commercial based procedures to be used for reducing time error to within acceptable limits of true time consistent with the guidance in Version 5 of NERC Time Monitoring Reference Document.

58. The WEQ–007 Inadvertent Interchange Payback Business Practice Standards define the methods in which inadvertent energy is paid back, mitigating the potential for financial gain through the misuse of paybacks for inadvertent interchange. Inadvertent interchange is interchange that occurs when a balancing authority cannot fully balance generation and load within its area. The standards allow for the repayment of any imbalances through bilateral in-kind payback, unilateral in-kind payback, or other methods as agreed to.

59. The WEQ–008 Transmission Loading Relief—Eastern Interconnection Business Practice Standards define the business practices for cutting transmission service during a Transmission Loading Relief (TLR) event. These standards detail requirements for the use of interconnection-wide TLR procedures, interchange transaction priorities for use with interconnection-wide TLR procedures, and the Eastern Interconnection procedure for physical curtailment of interchange transactions.

60. The WEQ–011 Gas/Electric Coordination Business Practice Standards define communication protocols intended to improve coordination between the gas and electric industries in daily operational communications between transportation service providers and gas-fired power plants. The standards include requirements for communicating anticipated power generation fuel for the upcoming day as well as any operating problems that might hinder gas-fired power plants from receiving contractual gas quantities.

61. The WEQ–012 Public Key Infrastructure (PKI) Business Practice Standards establish the cybersecurity framework for parties partaking in transactions via a transmission provider's OASIS or e-Tagging system. The NAESB PKI framework secures wholesale electric market electronic commercial communications via encryption of data and the electronic authentication of parties to a transaction using a digital certificate issued by a NAESB certified certificate authority. The standards define the requirements for parties utilizing the digital certificates issued by the NAESB certificate authorities.

62. The WEQ–013 OASIS Implementation Guide Business Practice Standards detail the implementation of the OASIS Business Practice Standards. The standards detail requirements related to point-to-point OASIS transaction processing, OASIS template implementation, preemption and right-of-first-refusal processing, NITS application and modification of service processing, and secondary network transmission service.

63. The WEQ–015 Measurement and Verification of Wholesale Electricity Demand Response Business Practice Standards define a common framework for transparency, consistency, and accountability applicable to the measurement and verification of wholesale electric market demand response practices. The standards describe performance evaluation methodology and criteria for the use of equipment, technology, and procedures to quantify the demand reduction value—the measurement of reduced electrical usage by a demand resource.

64. The WEQ–021 Measurement and Verification of Energy Efficiency Products Business Practice Standards define a common framework for transparency, consistency, and accountability applicable to the measurement and verification of wholesale electric market energy efficiency practices. The standards establish energy efficiency measurement and verification criteria and define requirements for energy efficiency resource providers for the measurement and verification of energy efficiency products and services offered in the wholesale electric markets.

65. The WEQ–022 EIR Business Practice Standards define the business requirements for entities utilizing the NAESB managed EIR, a wholesale electric industry tool that serves as the central repository for information needed in the scheduling of transmission through electronic transactions. The standards describe the roles within EIR, registration requirements, and cybersecurity.

66. The WEQ–023 Modeling Business Practice Standards provide technical details concerning the calculation of ATC for wholesale electric transmission services. The WEQ–023 standards are intended to address the aspects of certain of the NERC MOD A Reliability Standards relating to modeling, data, and analysis that are included in NERC's proposed retirement of its MOD A Reliability Standards.

67. The WEQ–024 Cybersecurity Business Practice Standards is a new suite to include and maintain all cybersecurity related requirements not included within the PKI business standards to be incorporated within this

single suite to better facilitate the incorporation by reference process.[31]

68. The following standards are listed for informational purposes as non-mandatory guidance:

69. WEQ–016, Specifications for Common Electricity Product and Pricing Definition standards address the business objectives and context for capturing the attributes associated with electricity price and product signals as part of the Smart Grid implementation, which is called for by NIST standards.

70. WEQ–017, Specifications for Common Schedule Communication Mechanism standards contain a set of specifications relating to the use of date and time based data elements that are commonly used in transactions for Demand Response programs.

71. WEQ–018, Specifications for Wholesale Standard Demand Response Signals standards address the business objectives and context for standardizing signals for demand response and distributed energy resources as part of the Smart Grid implementation, which is called for by NIST standards.

72. WEQ–019, Customer Energy Usage Information Communication standards establish the Business Practice Standards for end-use energy usage information communication.

73. WEQ–020, Smart Grid Standards Data Element Table standards contain the list of data elements used in Business Practice Standards WEQ–016 and WEQ–018.

74. Commission regulations provide that copies of the standards incorporated by reference may be obtained through purchase or otherwise from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002, Phone: (713) 356–0060, website: *http://www.naesb.org/.* The standards can also be reviewed without purchasing them.

75. The procedures used by NAESB make its standards reasonably available to those affected by Commission regulations, which generally is comprised of entities that have the means to acquire the information they need to effectively participate in Commission proceedings. Participants can join NAESB, for an annual membership cost of $8,000, which entitles them to full participation in NAESB and enables them to obtain these standards at no additional cost. Non-members may obtain any of the individual WEQ standards manuals for $250 per manual. Non-members also may obtain the complete set of Standards Manuals for $2,000.

76. NAESB provides ample opportunities for non-members, including agents, subsidiaries, and affiliates of NAESB members, to obtain access to the copyrighted standards through a no-cost limited copyright waiver. The limited copyright waivers are issued by the NAESB office and are granted to non-members on a case-by-case basis for the purpose of evaluating standards prior to purchase and/or reviewing the standards to prepare comments to a regulatory agency. Following the granting of a limited copyright waiver, the non-member is provided with read-only access to the standards through the end of the comment period or some other set period of time via Locklizard Safeguard Secure Viewer.[32] NAESB will grant one limited copyright wavier per company for each set of standards or final actions. Any entity seeking a limited copyright waiver should contact the NAESB office.

VI. Information Collection Statement

77. The following collection of information contained in this proposed rule is subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d).[33] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[34] Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

78. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

79. The following burden estimate is based on the projected costs for the industry to implement the new and revised business practice standards adopted by NAESB and proposed to be incorporated by reference in this NOPR.[35] The NERC Compliance Registry, as of December 2023, identifies approximately 216 entities in the United States that are subject to this proposed rulemaking.

DOCKET NOS. RM05–5–031

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden (hrs.) & cost ($) per response	Total annual burden hrs. & total annual cost ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
FERC–516E	216	1	216	6 hrs.; $600	1,296 hrs.; $129,600.
FERC–717	216	1	216	30 hrs.; $3,000	6,480 hrs.; $648,000.
Total				$3,600	7,776 hrs.; $777,600.

Costs To Comply With Paperwork Requirements

The estimated annual costs are as follows:

FERC–516E: 216 entities × 1 response/entity × (6 hours/response × $100.00/hour) = $129,600

FERC–717: 216 entities × 1 response/entity × (30 hours/response × $100.00/hour) = $648,000

Titles: FERC–516E, Electric Rate Schedule and Tariff Filings and FERC–717, Standards for Business Practices and Communication Protocols for Public Utilities.

[31] Informational Report at 21.

[32] For more information on Locklizard, please refer to the company's website: *https://www.locklizard.com.*

[33] 44 U.S.C. 3507(d).

[34] 5 CFR 1320.11.

[35] Commission staff estimates that industry is similarly situated in terms of hourly cost (wages plus benefits). Based on the Commission average cost (wages plus benefits) for 2024, $100.00/hour is used.

Action: Proposed amendment to regulations pertaining to the existing collections of information FERC–516E and FERC–717.

OMB Control Nos: 1902–0290 (FERC–516E) and 1902–0173 (FERC–717).

Respondents: Business or other for-profit, and not-for-profit institutions.

Frequency of Responses: On occasion.

Necessity of the Information: This proposed rule, if implemented, will amend the Commission's regulations to incorporate by reference, with certain enumerated exceptions, the NAESB WEQ Version 004 Standards. The standards include those that were developed in accordance with recommendations of the DOE-sponsored cybersecurity surety assessment of the NAESB Business Practice Standards that was conducted in 2019. Additional standards were developed in response to the directives from Order Nos. 676–I and 676–J. NAESB undertook two standards development efforts to update the WEQ–004 Coordinate Interchange Standards in the WEQ Version 004 Standards publication. The first set of modifications clarify existing back-up procedures for e-Tagging, improve efficiencies by removing requirements that supported outdated methods of communication, and streamline the processes following system communication failures. Through the second effort, NAESB modified WEQ–004 to provide guidance to balancing authorities in the Eastern Interconnection seeking to automate their net scheduled interchange checkout process. The revisions made by NAESB in the WEQ Version 004 Standards are designed to aid public utilities with the consistent and uniform implementation of requirements promulgated by the Commission as part of the *pro forma* Open Access Transmission Tariff.

Internal review: The Commission has reviewed NAESB's proposal and has made a preliminary determination that the Version 004 standards the Commission proposes to adopt by reference are both necessary and useful. In addition, the Commission has determined through internal review that there is specific, objective support for the burden estimates associated with the information requirements.

80. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE, Washington, DC 20426 [Attention: Kayla Williams, email: *DataClearance@ferc.gov,* phone: (202) 502–8663].

81. Comments concerning the information collections proposed in this NOPR and the associated burden estimates should be sent to the Commission at this docket and be emailed to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: *oira_submission@omb.eop.gov.* Please refer to the appropriate docket number of this notice of proposed rulemaking, Docket No. RM05–5–031, and OMB Control Nos. 1902–0290 (FERC–516E) and 1902–0173 (FERC–717), in your submission.

VII. Environmental Analysis

82. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[36] The actions proposed here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for sales, exchange, and transportation of electric power that requires no construction of facilities.[37] Therefore, an Environmental Assessment is unnecessary and has not been prepared for this NOPR.

VIII. Regulatory Flexibility Act

83. The Regulatory Flexibility Act of 1980 (RFA) [38] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect.

84. The Small Business Administration (SBA) revised its size standards (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: electric bulk power transmission and control, at least 500 employees.[39] The Commission estimates that 24 of the 216 respondents, or 11% of the respondents affected by this NOPR, are small businesses under SBA standards.

85. The Commission estimates that the impact on these entities is consistent with the paperwork burden of $3,600 per entity used above.[40] The Commission does not consider $3,600 to be a significant economic impact. Based on the above, the Commission certifies that implementation of the proposed Business Practice Standards will not have a significant impact on a substantial number of small entities. Moreover, these requirements are designed to benefit all customers, including small businesses that must comply with them. Further, as noted above, adoption of consensus standards helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of industry participants representing all segments of the industry. Because of that representation and the fact that industry conducts business under these standards, the Commission's regulations should reflect those standards that have the widest possible support.

86. Accordingly, pursuant to section 605(b) of the RFA,[41] the regulations proposed herein should not have a significant economic impact on a substantial number of small entities.

IX. Comment Procedures

87. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due July 5, 2024. Comments must refer to Docket No. RM05–5–031, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

88. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *https://www.ferc.gov.* The

[36] *Reguls Implementing the Nat'l Envt'l Pol'y Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[37] *See* 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), 380.4(a)(27) (2022).

[38] 5 U.S.C. 601–612.

[39] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control).

[40] 36 hours at $100.00/hour = $3,600.

[41] 5 U.S.C. 605(b).

Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

89. Commenters that are not able to file comments electronically may file an original of their comment by USPS mail or by courier or other delivery services. For submission sent via USPS only, filings should be mailed to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426. Submission of filings other than by USPS should be delivered to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

X. Document Availability

90. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*).

91. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

92. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects

18 CFR Part 2

Electric utilities, Natural gas, Pipelines, Reporting and recordkeeping requirements.

18 CFR Part 38

Conflicts of interest, Electric power plants, Electric utilities, Incorporation by reference, reporting and recordkeeping requirements.

By direction of the Commission.

(S E A L)

Issued: April 25, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

In consideration of the foregoing, the Commission proposes to amends part 2 and part 38, chapter I, title 18, Code of Federal Regulations, as follows:

PART 2—GENERAL POLICY AND INTERPRETATIONS

■ 1. The authority citation for Part 2 continues to read as follows:

Authority: 5 U.S.C. 601; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 792–828c, 2601–2645; 42 U.S.C. 4321–4370h, 7101–7352.

■ 2. Revise and republish § 2.27 to read as follows:

§ 2.27 Availability of North American Energy Standards Board (NAESB) Smart Grid Standards as non-mandatory guidance.

The Commission informationally lists the following NAESB Business Practices Standards as non-mandatory guidance:

(a) WEQ–016, Specifications for Common Electricity Product and Pricing Definition, (WEQ Version 004, July 31, 2023);

(b) WEQ–017, Specifications for Common Schedule Communication Mechanism for Energy Transactions (WEQ Version 004, July 31, 2023;

(c) WEQ–018, Specifications for Wholesale Standard Demand Response Signals (WEQ Version 004, July 31, 2023;

(d) WEQ–019, Customer Energy Usage Information Communication (WEQ Version 004, July 31, 2023); and

(e) WEQ–020, Smart Grid Standards Data Element Table (WEQ Version 004, July 31, 2023).

(f) Copies of these standards may be obtained from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002, Phone: (713) 356–0060; *https://www.naesb.org/.* Copies may also be obtained from the Federal Energy Regulatory Commission's website, *https://www.ferc.gov.*

PART 38—STANDARDS FOR PUBLIC UTILITY BUSINESS OPERATIONS AND COMMUNICATIONS

■ 3. The authority citation for Part 38 continues to read as follows:

Authority: 16 U.S.C. 791–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 4. Amend § 38.1 by revising paragraphs (b)(1) through (17) to read as follows:

§ 38.1 Incorporation by reference of North American Energy Standards Board Wholesale Electric Quadrant standards.

* * * * *

(b) * * *

(1) WEQ–000, Abbreviations, Acronyms, and Definition of Terms (Version 004, July 31, 2023);

(2) WEQ–001, Open Access Same-Time Information Systems (OASIS) (WEQ Version 004, July 31, 2023);

(3) WEQ–002, Open Access Same-Time Information Systems (OASIS) Business Practice Standards and Communication Protocol (S&CP) (WEQ Version 004, July 31, 2023);

(4) WEQ–003, Open Access Same-Time Information Systems (OASIS) Data Dictionary (WEQ Version 004, July 31, 2023);

(5) WEQ–004, Coordinate Interchange (WEQ Version 004, July 31, 2023);

(6) WEQ–005, Area Control Error (ACE) Equation Special Cases (WEQ Version 004, July 31, 2023);

(7) WEQ–006, Manual Time Error Correction (WEQ Version 004, July 31, 2023);

(8) WEQ–007 Inadvertent Interchange Payback (WEQ Version 004, July 31, 2023);

(9) WEQ–008, Transmission Loading Relief (TLR)—Eastern Interconnection (WEQ Version 004, July 31, 2023);

(10) WEQ–011, Gas/Electric Coordination (WEQ Version 004, July 31, 2023);

(11) WEQ–012, Public Key Infrastructure (PKI) (WEQ Version 004, July 31, 2023);

(12) WEQ–013, Open Access Same-Time Information Systems (OASIS) Implementation Guide (WEQ Version 004, July 31, 2023);

(13) WEQ–015, Measurement and Verification of Wholesale Electricity Demand Response (WEQ Version 004, July 31, 2023);

(14) WEQ–021, Measurement and Verification of Energy Efficiency Products (WEQ Version 004, July 31, 2023);

(15) WEQ–022, Electric Industry Registry (EIR) (WEQ Version 004, July 31, 2023);

(16) WEQ–023, Modeling (WEQ Version 004, July 31, 2023);

(17) WEQ–024, Cybersecurity (Version 004, July 31, 2023).

[FR Doc. 2024–09438 Filed 5–3–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2024–D–0083]

Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration Under Section 564; Draft Guidance for Laboratory Manufacturers and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' In the context of emergent situations involving chemical, biological, radiological, or nuclear (CBRN) threats, there may be a public health need for certain in vitro diagnostic devices (IVDs) to be available for immediate response purposes. When finalized, this guidance will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of a declaration applicable to IVDs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–0083 for ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

When finalized, this guidance will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of a declaration applicable to IVDs under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (hereafter referred to as an ''applicable 564 declaration'').[1] In the context of

[1] The Office of the Federal Register has published this document under the category ''Proposed Rule''

emergent situations involving CBRN threats, there may be a public health need for certain IVDs to be available for immediate response purposes. An emergent situation is, for purposes of this guidance, the period of time between detection of the exposure or outbreak and, either, resolution of the exposure or outbreak or issuance of an applicable 564 declaration. In the past, during this period of time, laboratory manufacturers offered laboratory developed tests (LDTs) for which FDA has had a general enforcement discretion approach. However, as discussed in the preamble to the final rule amending FDA regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory (LDT Final Rule),[2] FDA is phasing out this general enforcement discretion approach for LDTs. Accordingly, FDA is issuing this guidance with our enforcement policy for ''immediate response'' tests.

This guidance, when finalized, will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of an applicable 564 declaration. FDA does not intend to object to the offering of ''immediate response'' tests, as defined in the guidance, when the test is manufactured and offered by certain laboratory manufacturers, the test has been appropriately validated, FDA is notified, appropriate transparency is provided, the test is labeled for prescription use only, and there is no applicable 564 declaration, as described in the guidance. Prior to an emergent situation and after an emergent situation has been resolved, when there might not be a critical need for a coordinated and immediate public health response and where the implications of false results may not have as serious implications for public health decision-making, such tests may fall within the enforcement discretion policies described in section V.B of the preamble to the LDT Final Rule.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007032 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
803	Medical Device Reporting	0910–0437
810	Recalls	0910–0432

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08934 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

[2] ''Medical Devices: Laboratory Developed Tests'' is issued elsewhere in this **Federal Register**.

Notices

Federal Register
Vol. 89, No. 88
Monday, May 6, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–AMS–24–0016]

2024/2025 Rates Charged for AMS Services

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing the 2024/2025 rates it will charge for voluntary grading, inspection, certification, auditing, and laboratory services for a variety of agricultural commodities including meat and poultry, fruits and vegetables, eggs, dairy products, rice, and cotton and tobacco. The 2024/2025 regular, overtime, holiday, and laboratory services rates will be applied at the beginning of the crop year, fiscal year or as required by law depending on the commodity. Other starting dates are added to this notice based on cotton industry practices. This action establishes the rates for user-funded programs based on costs incurred by AMS. This year, cost-based analyses indicated the need to increase user fee rates when current rates are insufficient to cover the costs of providing the service. While cost-saving measures have and will continue to be implemented, user fee rate increases are necessary to offset rising operational costs. In cases where current rates are sufficient to cover the costs of providing the service, user fee rates remain unchanged.

DATES: May 7, 2024.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Associate Administrator, AMS, USDA, Room 2036–S, 1400 Independence Ave. SW, Washington, DC 20250; Telephone (202) 205–9356, or Email *melissa.bailey@usda.gov.*

SUPPLEMENTARY INFORMATION: The Agricultural Marketing Act of 1946, as amended (AMA) (7 U.S.C. 1621–1627), provides for the collection of fees to cover costs of various inspection, grading, certification, or auditing services covering many agricultural commodities and products. The AMA also provides for the recovery of costs incurred in providing laboratory services. The Cotton Statistics and Estimates Act (7 U.S.C. 471–476) and the U.S. Cotton Standards Act (7 U.S.C. 51–65) provide for classification of cotton and development of cotton standards materials necessary for cotton classification. The Cotton Futures Act (7 U.S.C. 15b) provides for futures certification services, and the Tobacco Inspection Act (7 U.S.C. 511–511s) provides for tobacco inspection and grading. These Acts also provide for the recovery of costs associated with these services.

On November 13, 2014, the U.S. Department of Agriculture (Department) published in the **Federal Register** a final rule that established standardized formulas for calculating the fees charged by AMS user-funded programs (79 FR 67313). On the basis of rates calculated using these formulas, AMS is to determine the fee rates necessary to sustain program services. Every year since then, the Department has published in the **Federal Register** a notice announcing the rates for its user-funded programs.

This notice announces the 2024/2025 fee rates for voluntary grading, inspection, certification, auditing, and laboratory services for a variety of agricultural commodities including meat and poultry, fruits and vegetables, eggs, dairy products, rice, and cotton and tobacco on a per-hour rate and, in some instances, the equivalent per-unit cost. The per-unit cost is provided to facilitate understanding of the costs associated with the service to the industries that historically used unit-cost basis for payment. Fee rates will be effective at the beginning of the fiscal year, crop year, or as required by specific laws.

Rates reflect direct and indirect costs of providing services. Direct costs include the cost of salaries, employee benefits, and, if applicable, travel and some operating costs. Indirect or overhead costs include the cost of Program and Agency activities supporting the services provided to the industry. The formula used to calculate these rates also includes operating reserve, which may add to or draw upon the existing operating reserves.

These services include the grading, inspection, or certification of quality factors in accordance with established U.S. Grade Standards or other specifications; audits or accreditation according to International Organization for Standardization (ISO) standards and/or Hazard Analysis and Critical Control Point (HACCP) principles; and other marketing claims. The quality grades serve as a basis for market prices and reflect the value of agricultural commodities to both producers and consumers. AMS' grading and certification, audit and accreditation, plant process and equipment verification, and laboratory approval services are voluntary tools paid for by the users on a fee-for-service basis. The agriculture industry can use these tools to promote and communicate the quality of agricultural commodities to consumers. Laboratory services are provided for analytic testing, including but not limited to chemical, microbiological, biomolecular, and physical analyses. AMS is required by statute to recover the costs associated with these services.

As required by the Cotton Statistics and Estimates Act (7 U.S.C. 471–476), consultations regarding the establishment of the fee for cotton classification with U.S. cotton industry representatives are held in the beginning of the year when most industry stakeholder meetings take place. Representatives of all segments of the cotton industry, including producers, ginners, bale storage facility operators, merchants, cooperatives, and textile manufacturers were informed of the fees during various industry-sponsored forums.

Rates Calculations

AMS calculated the rate for services, per hour per program employee, using the following formulas (a per-unit base is included for programs that charge for services on a per-unit basis):

(1) *Regular rate.* The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours for the previous year, which is then multiplied by the next year's percentage of cost of living increase, plus the benefits rate, plus the operating rate, plus the allowance for

bad debt rate. If applicable, travel expenses may also be added to the cost of providing the service.

(2) *Overtime rate.* The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 1.5, plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

(3) *Holiday rate.* The total AMS grading, inspection, certification, classification, audit, or laboratory service program personnel direct pay divided by direct hours, which is then multiplied by the next year's percentage of cost of living increase and then multiplied by 2, plus the benefits rate, plus the operating rate, plus an allowance for bad debt. If applicable, travel expenses may also be added to the cost of providing the service.

All rates are per-hour except when a per-unit cost is noted. The specific amounts in each rate calculation are available upon request from the specific AMS program.

2024/2025 RATES

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Cotton Fees					
7 CFR Part 27—Cotton Classification Under Cotton Futures Legislation Subpart A—Requirements; §§ 27.80–27.90 Costs of Classification and Micronaire					
Cotton Standardization:					
Certification for Futures Contract (Grading services for samples submitted by CCC-licensed samplers).	$4.75/bale			X	August 1, 2024.
Transfer of Certification Data to New Owner or Certified Warehouse (Electronic transfer performed).	$0.20/bale or $5.00 per page minimum			X	August 1, 2024.
7 CFR Part 28—Cotton Classing, Testing, and Standards Subpart A—Regulations Under the United States Cotton Standards Act; §§ 28.115–28.126 Fees and Costs Subpart D—Cotton Classification and Market News Service for Producers; § 28.909 Costs; § 28.910 Classification of Samples and Issuance of Classification Data; § 28.911 Review Classification.					
Cotton Grading:					
Form 1: Grading Services for Producers (submitted by licensed sampler).	$3.00/bale			X	July 1, 2024.
Form 1 Review (new sample submitted by licensed sampler).	$3.00/bale			X	July 1, 2024.
Form A Determinations (sample submitted by licensed warehouse).	$3.00/bale			X	July 1, 2024.
Form C Determinations (sample submitted by non-licensed entity; bale sampled under USDA supervision).	$3.00/bale			.....	July 1, 2024.
Form D Determination (sample submitted by owner or agent; classification represents sample only).	$3.00/bale			X	July 1, 2024.
Foreign Growth Classification (sample of foreign growth cotton submitted by owner or agent; classification represents sample only).	$6.00/sample			X	August 1, 2024.
Arbitration (comparison of a sample to the official standards or a sample type).	$6.00/sample			X	August 1, 2024.
Practical Cotton Classing Exam (for non-USDA employees).	Exam: $150/applicant; Reexamination: $130/applicant			X	July 1, 2024.
Special Sample Handling (return of samples per request)	$0.50/sample			X	July 1, 2024.
Electronic Copy of Classification Record	$0.05/bale ($5.00/month minimum with any records received)			X	July 1, 2024.
Form A Rewrite (reissuance of Form 1, Form A, or Futures Certification data or combination).	$0.15/bale or $5.00/page minimum			X	August 1, 2024.
Form R (reissuance of Form 1 classification only)	$0.15/bale or $5.00/page minimum			X	July 1, 2024.
International Instrument Level Assessment	$4.00/sample			X	July 1, 2024.

2024/2025 RATES—Continued

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Dairy Fees					
7 CFR Part 58—Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products; §§ 58.38—58.46 Fees and Charges					
Continuous Resident Grading Service	$95.00	$116.00	$137.00	X	Oct 1, 2024.
Continuous Resident Grading Service 6 p.m.–6 a.m.	$105.00	$128.00	$151.00	X	Oct 1, 2024.
Non-resident and Intermittent Grading Service; State Graders	$120.00	$155.00	$190.00	X	Oct 1, 2024.
Non-resident Services 6 p.m.–6 a.m. (10 percent night differential).	$132.00	$171.00	$190.00	X	Oct 1, 2024.
Export Certificate Services	$104.00/certificate			.....	Oct 1, 2024.
Equipment Review [1]	$135.00	$192.00	$249.00	.....	Oct 1, 2024.
Equipment Review 6 p.m.–6 a.m.[1]	$148.00	$211.00	$249.00	.....	Oct 1, 2024.
Audit Services	$135.00			X	Oct 1, 2024.
Special Handling	$52.00/certificate			.....	Oct 1, 2024.
Uncertified Copy of Certificate	$12.00/copy			.....	Oct 1, 2024.
Derogation Application	$125.00/application			.....	Oct 1, 2024.
Specialty Crops Fees					
7 CFR Part 51—Fresh Fruits, Vegetables and Other Products (Inspection, Certification, and Standards) Subpart A—Requirements; §§ 51.37–51.44 Schedule of Fees and Charges at Destination Markets; § 51.45 Schedule of Fees and Charges at Shipping Point Areas					
Quality and Condition Inspections for Whole Lots	$254.00 per lot			.....	Oct 1, 2024.
Quality and Condition Half Lot or Condition-Only Inspections for Whole Lots.	$210.00 per lot			.....	Oct 1, 2024.
Condition—Half Lot	$194.00 per lot			.....	Oct 1, 2024.
Quality and Condition or Condition-Only Inspections for Additional Lots of the Same Product.	$116.00 per lot			.....	Oct 1, 2024.
Dockside Inspections—Each package weighing <30 lbs	$0.044 per pkg.			.....	Oct 1, 2024.
Dockside Inspections—Each package weighing >30 lbs	$0.068/pkg.			.....	Oct 1, 2024.
Charge per Individual Product for Dockside Inspection	$252.00/lot			.....	Oct 1, 2024.
Charge per Each Additional Lot of the Same Product	$116.00/lot			.....	Oct 1, 2024.
Inspections for All Hourly Work	$123.00	$163.00	$203.00	.....	Oct 1, 2024.
Audit Services—Federal	$163.00			.....	Oct 1, 2024.
Audit Services—State	$163.00			.....	Oct 1, 2024.
GFSI Certification Fee [2]	$250.00/audit			.....	Oct 1, 2024.
7 CFR Part 52—Processed Fruits and Vegetables, Processed Products Thereof, and Other Processed Food Products Subpart A—Requirements Governing Inspection and Certification; §§ 52.41—52.51 Fees and Charges					
Lot Inspections	$95.00	$123.00	$151.00	.....	Oct 1, 2024.
In-plant Inspections Under Annual Contract (year-round)	$100.00	$126.00	$152.00	.....	Oct 1, 2024.
Additional Graders (in-plant) or Less Than Year-Round	$100.00	$130.00	$160.00	.....	Oct 1, 2024.
Audit Services—Federal	$163.00			.....	Oct 1, 2024.
Audit Services—State	$163.00			.....	Oct 1, 2024.
GFSI Certification Fee [2]	$250.00/audit			.....	Oct 1, 2024.

2024/2025 RATES—Continued

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Meat Fees					
7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) Subpart A—Grading of Meats, Prepared Meats, and Meat Products; §§ 54.27–54.28 Charges for Service					
Scheduled Grading	$92.00	$115.00	$139.00	X	Oct 1, 2024.
Unscheduled Grading	$123.00	$142.00	$166.00	.....	Oct 1, 2024.
Scheduled Night Differential (6 p.m.–6 a.m.)	$102.00	$127.00	$139.00	X	Oct 1, 2024.
7 CFR Part 62—Agricultural Marketing Service Audit Verification and Accreditation Programs (AVAAP) Subpart E—Fees; § 62.300 Fees and Other Costs of Service					
Auditing Activities	$175.00	$244.00	$268.00	.....	Oct 1, 2024.
Poultry Fees					
7 CFR Part 56—Voluntary Grading of Shell Eggs Subpart A—Grading of Shell Eggs; §§ 56.45–56.54 Fees and Charges **7 CFR Part 70—Voluntary Grading of Poultry and Rabbit Products** Subpart A—Grading of Poultry and Rabbit Products; §§ 70.70–70.78 Fees and Charges					
Scheduled Grading	$74.00	$96.00	$116.00	X	Oct 1, 2024.
Scheduled, Night Differential (6 p.m.–6 a.m.)	$82.00	$107.00	$116.00	X	Oct 1, 2024.
Scheduled, Sunday Differential	$95.00	$122.00	N/A	X	Oct 1, 2024.
Scheduled, Sunday and Night Differential	$106.00	$135.00	N/A	X	Oct 1, 2024.
Unscheduled Grading	$108.00	$133.00	$160.00	.....	Oct 1, 2024.
Science and Technology Fees					
7 CFR Part 91—Services and General Information Subpart I—Fees and Charges; §§ 91.37–91.45					
Laboratory Testing Services	$118.00	$137.00	$155.00	.....	Oct 1, 2024.
Laboratory Approval Services [1]	$188.00	$218.00	$249.00	X	Jan 1, 2025.
7 CFR Part 75—Provisions for Inspection and Certification of Quality of Agricultural and Vegetable Seeds § 75.41 General					
Laboratory Testing	$75.00	$95.00	$119.00	.....	Oct 1, 2024.
Administrative Fee	$17.00/certificate			.....	Oct 1, 2024.
Auditing Services	$149.00	$173.00	$198.00	.....	Oct 1, 2024.
Organization for Economic Cooperation and Development Seed Schemes for Corn Seeds.	$0.42/100 pounds			.....	July 1, 2024.
Organization for Economic Cooperation and Development Seed Schemes for Cotton, Soybeans, Sunflower, and Cereal Seeds.	$0.34/100 pounds			.....	July 1, 2024.
Organization for Economic Cooperation and Development Seed Schemes for Other Seeds.	$0.32/100 pounds			.....	July 1, 2024.
Tobacco Fees					
7 CFR Part 29—Tobacco Inspection Subpart A—Policy Statement and Regulations Governing the Extension of Tobacco Inspection and Price Support Services to New Markets and to Additional Sales on Designated Markets; Subpart B—Requirements; §§ 29.123—29.129 Fees and Charges; § 29.500 Fees and charges for inspection and acceptance of imported tobacco Subpart F—Policy Statement and Provisions Governing the Identification and Certification of Non-quota Tobacco Produced and Marketed in Quota Area; § 29.9251 Fees and Charges					
Domestic Permissive Inspection and Certification (re-grading of domestic tobacco for processing plants, retesting of imported tobacco, and grading tobacco for research stations.).	$55.00	$64.00	$72.00	.....	July 1, 2024.

2024/2025 RATES—Continued

	Regular	Overtime	Holiday	Includes travel costs in rate	Start date
Export Permissive Inspection and Certification (grading of domestic tobacco for manufacturers and dealers for duty drawback consideration).	$0.0025/pound			X	July 1, 2024.
Grading for Risk Management Agency (for Tobacco Crop Insurance Quality Adjustment determinations).	$0.015/pound			X	July 1, 2024.
Pesticide Test Sampling (collection of certified tobacco sample and shipment to AMS National Science Laboratory for testing).	$0.0065/kg or $0.0029/pound			X	July 1, 2024.
Pesticide Retest Sampling (collection of certified tobacco sample from a previously sampled lot for re-testing at the AMS National Science Laboratory; fee includes shipping).	$115.00/sample and $55.00/hour			X	July 1, 2024.
Standards Course (training by USDA-certified instructor on tobacco grading procedures).	$1,250.00/person			.....	July 1, 2024.
Import Inspection and Certification (grading of imported tobacco for manufacturers and dealers).	$0.0170/kg or $0.0080/pound			X	July 1, 2024.
Rice Fees					
7 CFR Part 868—General Regulations and Standards for Certain Agricultural Commodities Subpart A—Regulations; §§ 868.90–868.92 Fees					
Contract (per hour per Service representative) [3]	$79.30	$119.00	$158.60	.....	Oct 1, 2024.
Noncontract (per hour per Service representative) [3]	$99.10	$148.70	$198.30	.....	Oct 1, 2024.
Export Port Services [4]	$0.047/cwt			.....	Oct 1, 2024.
Inspection for quality (per lot, sublot, or sample inspection):					
Rough rice	$69.20			.....	Oct 1, 2024.
Brown rice for processing	$65.00			.....	Oct 1, 2024.
Milled rice	$57.70			.....	Oct 1, 2024.
Factor analysis for any single factor (per sample):					
Milling yield (Rough or Brown rice)	$54.00			.....	Oct 1, 2024.
All other factors (all rice)	$41.90/factor			.....	Oct 1, 2024.
Total oil and free fatty acid	$62.30			.....	Oct 1, 2024.
Faxed and extra copies of certificates	$1.90/copy			.....	Oct 1, 2024.
Stowage examination (service-on-request):					
Ship	$49.40 (per stowage space, minimum 5 spaces per ship)			.....	Oct 1, 2024.
Subsequent ship examinations	$49.40 (per stowage space, minimum 3 spaces per ship)			.....	Oct 1, 2024.
Barge	$51.60/examination			.....	Oct 1, 2024.
All other carriers	$18.40/examination			.....	Oct 1, 2024.
Aflatoxin (Rapid Test Kit)	$47.90/test			.....	Oct 1, 2024.
All Other Mycotoxins (Rapid Test Kit)	$54.00/test			.....	Oct 1, 2024

Authority: 7 U.S.C. 15b; 7 U.S.C. 473a–b; 7 U.S.C. 55 and 61; 7 U.S.C. 51–65; 7 U.S.C. 471–476; 7 U.S.C. 511–511s; and 7 U.S.C. 1621–1627.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–09773 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

White River National Forest; Colorado; Sweetwater Lake Recreation Management and Development Project

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service, U.S. Department of Agriculture, is preparing an environmental impact statement to evaluate the potential environmental impacts associated with the Sweetwater Lake Recreation Management and Development Project. This project encompasses 832 acres, including 488 acres acquired by the Forest Service in 2021, located on the White River National Forest on lands surrounding Sweetwater Lake in northeastern Garfield County, Colorado. The Forest Service proposes to improve recreation access and facilities and authorize a long-term special use permit to the Colorado Parks and Wildlife to manage the area. This project may require an amendment to the White River National Forest Land and Resource Management Plan (forest plan).

DATES: Comments concerning the scope of the analysis must be received by August 5, 2024. The draft environmental impact statement is expected February 2025, and the final environmental impact statement is expected February 2026.

ADDRESSES: Send written comments to Scott Fitzwilliams, White River National Forest Supervisor, c/o Leanne Veldhuis, District Ranger Eagle-Holy Cross Ranger District, White River National Forest, P.O. Box 190, Minturn, CO 81645. Comments may also be submitted electronically at *https://cara.fs2c.usda.gov/Public//CommentInput?Project=64047* or submitted via facsimile to 970–827–9343.

FOR FURTHER INFORMATION CONTACT: Additional information related to the project can be obtained from the project web page at *https://www.fs.usda.gov/project/whiteriver/?project=64047* or by contacting Leanne Veldhuis, District Ranger, Eagle-Holy Cross Ranger District, 24747 U.S. Hwy. 24, P.O. Box 190, Minturn, CO 81645. Ms. Veldhuis can be reached by phone at 970–827–5715 or by email at *leanne.veldhuis@usda.gov.* Individuals who use telecommunications devices for the hearing impaired may call 711 to reach the Telecommunications Relay Service, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: A successful grassroots effort within the local community, which included donations from Eagle County and the Town of Gypsum, was able to protect the area around Sweetwater Lake from private development with a purchase by The Conservation Fund. The Forest Service purchased the 488 acres surrounding Sweetwater Lake from The Conservation Fund to facilitate public access and maintain the natural resource-based recreational opportunities at the site.

Purpose and Need for Action

The purpose of the proposed action is to provide the public a natural resource-based recreational and educational experience at Sweetwater Lake that is reflective of the culture and history of the area while managing visitation at the appropriate scale for the long-term viability of the 832 acres surrounding the lake and its resources.

The actions proposed in the Sweetwater Lake Recreation Management and Development Project are needed to:

- Enhance and provide sustainable management of the public lands around Sweetwater Lake.
- Provide updated and sustainable nature-based recreational services to the public that are appropriate to the environment and are responsive to the recreational needs of the public.
- Improve the site's existing recreation infrastructure while providing updated facilities in alignment with applicable laws, policies, and known best practices.
- Develop and implement management strategies to reduce or mitigate potential impacts on the site's natural and cultural resources from public visitation.
- Provide for year-round on-site management, including oversight and management for all the site's resources and facilities.
- Provide public recreational, interpretative, and educational opportunities.

Proposed Action

The White River National Forest is proposing multiple actions to meet the purpose and need of the project, as described below.

Authorize a 20-year special use permit to Colorado Parks and Wildlife, under the Granger-Thye Act, to implement and maintain improvements described below and manage the area consistent with the purpose and need.

Redesign the current site to promote recreational opportunities at a scale that is compatible with the capacity of the project area, its resources, and the surrounding area. The proposed site design would minimize impacts to wildlife and natural resources by utilizing those areas and lands that have been previously disturbed and would include the following actions.

- Evaluate existing structures for retention with an emphasis on those buildings that provide the best opportunity to interpret the rich history at Sweetwater. If feasible, some structures may be restored to the historic character of their 1920-to-1940 construction and used as part of the cultural interpretative program for the site. Existing structures that are in a state of severe deferred maintenance and out of compliance with various laws, regulations, and policies may be removed.
- Develop a new campground area to provide 15 to 20 campsites in a historically disturbed area that currently contains little native vegetation (''lower pasture'').
- Construct 8 to 12 new cabins to provide an overnight recreation opportunity similar to that which historically existed in the vicinity. These cabins would be constructed with materials and architecture designed to provide a ''rustic'' western character similar to the styles of other cabins and lodges in the Flat Tops area of Colorado.
- Construct equestrian facilities in the ''middle pasture.'' Proposed facilities would include barn and stable operation, 4 to 7 overnight equestrian camping sites, and extra day-use parking for equestrian users. This area could also provide overnight parking and access to the surrounding Flat Tops Wilderness Area. This location is previously disturbed and is proposed

[1] Travel costs outside the United States will be added to the fee, if applicable.

[2] Global Food Safety Initiative (GFSI) Certification Fee—$250 per GFSI audit to recoup the costs associated with attaining technical equivalency to the GFSI benchmarking requirements.

[3] Original and appeal inspection services include Sampling, grading, weighing, and other services requested by the applicant when performed at the applicant's facility.

[4] Services performed at export locations on lots at rest.

for equestrian facilities to minimize the impact to the natural resources, while separating use between equestrians and other visitors.

- Develop additional lake access points. Any new access will include minimal disturbance to the lakeshore and lakeside willows by utilizing perpendicular-only paths through the willows to fishing docks or watercraft launching docks to minimize any disturbance on the lake edge.
- Convert the existing Forest Service campground and parking to day-use individual or group picnic sites and maintain the existing day-use trailhead and lake-access parking in this area.
- Construct a new lodge with administrative, educational, and interpretive spaces to enhance the visitor experience through site amenities and services. This new lodge building may offer small-scale food service capabilities such as a small coffee and pie shop or limited prepackaged food offerings that would align with Forest Service policies for providing food service on National Forest System lands while not necessitating an increase in wastewater accommodation. The construction of a group picnic site with a possible food truck or mobile kitchen parking will also be explored in this area for small events or day-to-day operations.
- Evaluate establishing day-use hiking and equestrian trails on the northeast side of the lake. These trails would provide loop trails and connections between the existing Ute Trail, to the new equestrian area, and the Keep Ditch Trail. These trails could provide an additional access to the Flat Tops Wilderness Area other than the existing Hilltop trailhead north of the project area. Evaluate establishing trails to a new overlook on the southwest side of the lake to provide an additional scenic overlook of the lake. Evaluate additional trails within the project area to highlight the historical significance of the site and its buildings as part of an interpretive trail system or provide other recreational opportunities.
- Construct appropriate maintenance facilities, equipment storage, and personnel housing necessary for management and maintenance.
- For the cave within the project area, develop a cave management plan in consultation with the tribes to ensure the vital cultural history is preserved and incorporate the plan into the proposed special use permit.

A map of the proposed project boundary and draft proposed action conceptional diagram are available on the project web page at *https://www.fs.usda.gov/project/whiteriver/?project=64047.*

The Forest Service would close the wetlands and the historic pasture north of the lake to human entry to preserve delicate ecologic resources. In addition, the proposed action will evaluate the need for ecosystem restoration in this area and authorize restoration actions, if needed.

The proposed action may require amending the forest plan. The project areas currently bounding the newly purchased property includes Management Area 5.41—Deer and Elk Winter Range to the north and Management Area 5.4—Forested Flora and Fauna Habitats to the south. Land acquisitions to the National Forest System generally adopt the adjacent management area prescription. The proposed action will be evaluated for forest plan consistency to determine the need for a plan amendment which could require modifications to some plan components or other plan content.

Lead and Cooperating Agencies

The lead agency for this project proposal is the Forest Service. Cooperating agencies include Garfield County, Eagle County, the Town of Gypsum, and Colorado Parks and Wildlife.

Responsible Official

The responsible official is Mr. Scott Fitzwilliams, White River National Forest Supervisor, White River National Forest, 900 Grand Ave., P.O. Box 948, Glenwood Springs, CO 81601.

Scoping Comments and the Objection Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. In this process the Forest Service is requesting comments on potential alternatives and impacts, and identification of any relevant information, including comments on aspects of the White River National Forest Land and Resource Management Plan (2002) that may guide or constrain activities described in the proposed action, or other studies or analyses concerning impacts affecting the quality of the human environment.

Multiple public engagement opportunities were held to inform the public and help shape this proposal. Online comment forms were available on the Eagle Valley Land Trust website from October 2021 to May 2023 and an online public survey was conducted in March 2023. Multiple public meetings in different locations were held in January and February 2022. A virtual ''NEPA 101'' training was provided in November 2022 and a virtual public meeting was held in November 2022. Forest Service and Colorado Parks and Wildlife leaders also met with twelve community members in a bi-weekly working group format (13 meetings) from October 2022 to May 2023 to bring community interest and ideas to the project as well as report back to the broader community. Forest Service and Colorado Parks and Wildlife leaders also conducted interviews with multiple stakeholders in the area and met regularly with the outfitter and guide who operated on the site under multiple private owners for almost 40 years. From July 2023 to January 2024, the Forest Service and the cooperating agencies have met approximately once a month for a total of seven (7) meetings to work through the project issues and address known public concerns in preparation for the scoping process. The scoping process will include three (3) public meetings in addition to the electronic or written comments to the Forest Service. Dates, times, and locations of the public meetings will be announced on the project web page at *https://www.fs.usda.gov/project/whiteriver/?project=64047.*

It is important that reviewers provide their comments at such times and in such manner that they are useful to the Agency's preparation of the final environmental impact statement; therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. Commenting during scoping and any other designated opportunity to comment provided by the responsible official as prescribed by the applicable regulations will also govern eligibility to object once the final environmental impact statement and draft record of decision have been published. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, they will not be used to establish eligibility for the objection process.

Objections will be accepted only from those who have previously submitted specific written comments regarding the proposed project during scoping or other designated opportunity for public comment in accordance with 36 CFR 218.5(a), 219.16, and 219.52, as applicable. Issues raised in objections must be based on previously submitted timely, specific written comments regarding the proposed project unless

based on new information arising after designated opportunities.

Permits, Licenses, or Other Authorizations Required

This proposed action will consider the authorization of a long-term special use permit to Colorado Parks and Wildlife to operate and manage the site.

Nature of Decision To Be Made

Given the purpose and need, the responsible official will determine whether the proposed action complies with all applicable laws governing Forest Service actions and with the applicable standards and guidelines found in the forest plan; whether the environmental impact statement has sufficient site-specific environmental analysis to make an informed decision; and whether the proposed action meets the purpose and need for action. With this information, the responsible official must decide whether to select the proposed action or one of any other potential alternatives that may be developed, and what, if any, additional actions should be required.

Substantive Provisions

The following substantive provisions of the 2012 Planning Rule (36 CFR 219.8–11) may be directly related to the proposed forest plan amendment (219.13(b)(5)): 36 CFR 219.8(a) Ecological sustainability; 36 CFR 219.8 (b) Social and economic sustainability; 36 CFR 219.9(a) Ecosystem plan components; 36 CFR 219.9(b) Additional, species specific plan components; 36 CFR 219.9(c) Species of conservation of concern; 36 CFR 219.10(a) Integrated resource management for multiple use; and 36 CFR 219.10(a) Lands not suited for timber production.

Gregory C. Smith,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–09720 Filed 5–3–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2024–0004]

Proposed Revisions to Section 1 of the Field Office Technical Guides for Louisiana and Wisconsin

AGENCY: Natural Resources Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of availability, request for comments.

SUMMARY: NRCS is giving notice that it is proposing revisions to Section 1—General Resource References of the Field Office Technical Guides in Louisiana and Wisconsin to include revised State Offsite Methods for Food Security Act Wetland Identification (SOSM). The proposed changes will replace the existing SOSMs in Louisianna and Wisconsin, which have been in use since June 2015 and October 2016. The revisions are needed to clarify procedures and improve consistency in application. SOSM are used in completing wetland determinations for USDA program eligibility purposes.

DATES: We will consider comments that we receive by June 5, 2024.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for Docket ID NRCS–2024–0004. Follow the online instructions for submitting comments;

All comments received will be made publicly available on *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For Louisiana: Kris Davis; telephone: (318) 473–7680; email: *kris.davis@usda.gov* and for Wisconsin: Josh Odekirk; telephone: (608) 662–4422; email: *josh.odekirk@usda.gov.*

SUPPLEMENTARY INFORMATION: Guidance contained in each state's SOSM will be part of the technical documents and procedures that NRCS uses to determine if wetlands are present on agricultural land as required by 16 U.S.C. 3822. NRCS is required by 16 U.S.C. 3862 to make available for public review and comment all proposed revisions to standards and procedures used to carry out highly erodible land and wetland provisions of the law.

There are separate SOSM documents for each state. To fully understand the proposed revisions, commenters are encouraged to compare the revised SOSMs with each state's current version, as shown in Section 1 of the NRCS Field Office Technical Guide at *https://efotg.sc.egov.usda.gov/#/.* The electronic copies of each state's SOSM are available through *http://www.regulations.gov* by accessing Docket ID NRCS–20240004. Requests for paper versions or inquiries may be directed to the specific State Conservationist as identified in the **FOR FURTHER INFORMATION CONTACT** section above.

In general, both new documents have similar language and technical methodologies with some variations based on natural resource information available and state-specific considerations.

All comments will be considered. If no comments are received, guidance contained in each state's SOSM will be considered final at the end of the comment period for this notice.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunicaions Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *OAC@usda.gov.USDA* is an

equal opportunity provider, employer, and lender.

Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2024–09761 Filed 5–3–24; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a web briefing of the Arizona Advisory Committee (Committee) to the U.S. Commission on Civil Right will convene via ZoomGov on Thursday, May 23, 2024, from 2 p.m.–3:30 p.m. Arizona time. The purpose of the meeting is to debrief testimony received during web briefings focused on pediatric health care disparities in Arizona.

DATES: The meeting will take place on: Thursday, May 23, 2024, from 2 p.m.–3:30 p.m. Arizona time.

ADDRESSES:

Webinar Zoom Link to Join (Audio/Visual): https://www.zoomgov.com/webinar/register/WN_C-uOoAMwTgW-uOWC-rJtSA.

Telephone (Audio Only) Dial: 1–833–435–1820 (US Toll-free); Webinar ID: 161 521 3288.

FOR FURTHER INFORMATION CONTACT: Ana Fortes, DFO, at *afortes@usccr.gov* or (202) 681–0857.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialist, at *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments can be sent via email to Ana Fortes (DFO) at *afortes@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Arizona Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *atrevino@usccr.gov.*

Agenda

I. Welcome, Roll Call, and Announcements
II. Debrief
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: April 30, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–09744 Filed 5–3–24; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Puerto Rico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of three virtual panel briefings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that three panel briefings of the Puerto Rico Advisory Committee to the Commission will convene virtually by web conference to hear from experts on the civil rights impacts of the Insular Cases and the Non-Incorporation Doctrine on the Residents of Puerto Rico.

DATES:

Panel 1 The Right to Vote at the Federal Level—Perspectives from Community Advocates: Tuesday, May 21, 2024; 3:30 p.m. Atlantic Time/Eastern Time

Panel 2 The Right to Vote at the Federal Level—Public Policy, Government, and Political Party Perspectives: Thursday, May 30, 2024; 3:30 p.m. Atlantic Time/Eastern Time

Panel 3 The Right to Vote at the Federal Level—Perspectives from Academics & Researchers: Tuesday, June 4, 2024; 3:30 p.m. Atlantic Time/Eastern Time

ADDRESSES: Panel briefings will be held via Zoom.

Panel 1 May 21 Registration Link (Audio/Visual): http://tinyurl.com/5xdz9nx2; password, if needed: USCCR–PR

Panel 1 Phone (Audio Only): 1–833 435 1820 USA Toll Free; Meeting ID: 160 217 7958 #

Panel 2 May 30 Registration Link (Audio/Visual): https://tinyurl.com/423baeu4; password, if needed: USCCR–PR

Panel 2 Phone (Audio Only): 1–833 435 1820 USA Toll Free; Meeting ID: 160 461 9474 #

Panel 3 June 4 Registration Link (Audio/Visual): https://tinyurl.com/5ap7am93; password, if needed: USCCR–PR

Panel 3 Phone (Audio Only): 1–833 435 1820 USA Toll Free; Meeting ID: 160 962 4965 #

FOR FURTHER INFORMATION CONTACT: Email Victoria Moreno, Designated Federal Officer at *vmoreno@usccr.gov,* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: The virtual briefings will take place in Spanish with English interpretation. These committee meetings are available to the public through the registration links above. Any interested member of the public may listen to the meetings. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive

or learning impairments. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to each meeting date.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meetings. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meetings. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Puerto Rico Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *ebohor@usccr.gov.*

Agenda

1. Welcome, Roll Call, & Chair Opening Remarks
2. Panel 1 | May 21: followed by Committee Q&A
3. Panel 2 | May 30: followed by Committee Q&A
4. Panel 3 | June 4: followed by Committee Q&A
5. Public Comment
6. Adjourn

Dated: April 30, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–09743 Filed 5–3–24; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Texas Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via ZoomGov on Thursday, May 16, 2024, from 12 p.m. to 1 p.m. CT, for the purpose of selecting their new project topic.

DATES: The meeting will take place via Zoom webinar: Thursday, May 16, 2024, from 12 p.m.–1 p.m. CT.

ADDRESSES: Webinar Zoom Link to Join (*Audio/Visual*), *https://www.zoomgov.com/webinar/register/WN_RMQIL7yxSlOwEUbIt6lxSA.*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialist, *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments can be sent via email to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Texas Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *atrevino@usccr.gov.*

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Committee Discussion
IV. Public Comment
V. Adjournment

Dated: April 30, 2024.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2024–09739 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Boundary and Annexation Survey

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed revision of the Boundary and Annexation Survey, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 5, 2024.

ADDRESSES: Interested persons are invited to submit written comments by email to *dcmd.pra@census.gov.* Please reference ''Boundary and Annexation Survey'' in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2024–0012, to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit

attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Michael S. Snow, Program Manager, Decennial Census Management Division, by phone at 301–763–9912 or by email to *dcmd.pra@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau conducts many voluntary geographic partnership programs designed to collect addresses, boundaries, and linear features for incorporation into the Master Address File/Topologically Integrated Geographic Encoding and Referencing (MAF/TIGER) System. The Boundary and Annexation Survey (BAS) is one of these programs. It provides eligible governments, which include tribal, state, and general-purpose local governments, an opportunity to review the Census Bureau's legal boundary data to ensure the Census Bureau has the correct boundary, name, and status information and make necessary updates. BAS also allows for the review and update of census designated place (CDP) boundaries and linear features. It fulfills the agency's responsibility as part of the National Spatial Data Infrastructure, for which the Office of Management and Budget (OMB) Circular A–16 designates the Census Bureau as the lead federal agency for maintaining national data about legal government boundaries, as well as statistical and administrative boundaries. It also supports the geospatial data steward responsibilities of the Geospatial Data Act, the Evidence Act, OMB E-Gov, the Federal Geographic Data Committee, Data.gov, GeoPlatform.gov, the National Map, the Geographic Names Information System, and the Geospatial One-Stop.

The Census Bureau uses the boundaries collected during BAS to tabulate data for various censuses and surveys including the decennial census, American Community Survey (ACS), and Population Estimates Program (PEP). It also uses the boundaries collected through BAS to support other programs such as the Redistricting Data Program, the Economic Census, the Geographic Update Population Certification Program, and the Special Census program.

Other federal programs also rely on accurate boundaries collected through BAS. The Department of Housing and Urban Development uses boundaries to determine jurisdictional eligibility for various grant programs, such as the Community Development Block Grant program. In addition, the Department of Agriculture uses boundaries to determine eligibility for various rural housing and economic development programs.

The BAS participation process, outlined below, is like the Census Bureau's other geographic partnership programs though there are some differences in the universe of eligible governments, requirements, and timeframe of the program.

- The Census Bureau notifies eligible governments about BAS through email. Eligible governments are instructed to review the legal boundary, name, and status information, along with CDP boundaries, linear features, and the highest elected official and program contact information the Census Bureau has on file. They can review their boundaries and linear features using the Census Bureau's TIGERweb application, partnership shapefiles, or PDF maps.
- Eligible governments respond through an online response form or email to indicate if they have legal boundary, CDP, linear feature, or contact updates. Those with updates can choose to create their submission using the BAS Partnership Toolbox, Geographic Update Partnership Software (GUPS), GUPS Web, or paper maps.
- Eligible governments return updates to the Census Bureau. Updates created using the BAS Partnership Toolbox, GUPS, or GUPS Web are returned through the Census Bureau's secure online data sharing portal while paper map updates are returned through the mail.
- The Census Bureau processes and verifies all updates for accuracy and completeness. The updates are inserted into the MAF/TIGER System and quality control is performed.

Legal Information

The Census Bureau reviews and maintains an inventory of each state's legal boundary laws and statutes. This information is made available to eligible governments on the BAS website. The Census Bureau also uses this information to verify that updates provided during BAS are made in accordance with state law.

If it comes to the Census Bureau's attention that an area of non-tribal land is in dispute between two or more governments, the Census Bureau will not make boundary updates until all affected parties come to a written agreement, or there is a documented final court decision regarding the matter and/or dispute. If there is a dispute over an area of tribal land, the Census Bureau will not make boundary updates until the governments provide supporting documents or the U.S. Department of the Interior issues a comment. If necessary, the Census Bureau will request clarification regarding current boundaries or supporting documentation, from the U.S. Department of the Interior, Office of the Solicitor.

BAS Universe

The BAS universe includes approximately 40,000 eligible governments. These include:

- Federally recognized tribes with a reservation or off-reservation trust land (including tribal subdivisions).
- States.
- Counties and county equivalent governments.
- Incorporated places (including consolidated cities).
- Minor civil divisions.
- Hawaiian Home Lands.
- Municipios, barrios, barrio-pueblos, and subbarrios in the Commonwealth of Puerto Rico.
- The U.S. territories of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands.

II. Method of Collection

The following collection methods allow the Census Bureau to coordinate among various levels of governments to obtain the most accurate boundary, CDP, linear feature, and contact information:

- BAS.
- State Certification.
- Boundary Quality Project.

BAS

BAS provides eligible governments, which include tribal, state, and general-purpose local governments, an opportunity to review the Census Bureau's legal boundary data to ensure the Census Bureau has the correct boundary, name, and status information and make necessary updates. BAS also allows for the review and update of CDPs and linear features.

The Census Bureau notifies eligible governments about BAS through email. The email includes program information and directs eligible governments to respond through an online form if they have legal boundary, CDP, linear feature, or contact updates to report. Any eligible government without an email on file with the Census Bureau will be contacted by phone and asked to provide their response.

Those indicating they have updates to provide must create their submission using one of the options listed below.

- *BAS Partnership Toolbox.* The BAS Partnership Toolbox allows eligible governments to create the submission in ArcGIS Pro. The toolbox automates data download, boundary update creation, and exports standardized files for submission.
- *GUPS.* GUPS is a free, customized geographic information system software application provided by the Census Bureau. It is offered as standalone (GUPS Download) and online (GUPS Web) applications.
  - GUPS Download allows eligible governments to manually create boundary updates and export standardized files for submission.
  - GUPS Web allows eligible governments to manually create boundary updates or import local boundary data to automate the creation of boundary updates and export standardized files for submission.
- *Paper maps.* The Census Bureau will ship large format paper maps and instructions for eligible governments to annotate and return their updates to the Census Bureau. The paper map package includes a letter, materials list insert, large format paper maps covering the extent of the government, supplies to update the paper maps, how-to guide, and postage-paid return envelope.

Eligible governments that do have boundary updates can submit both legal boundary changes and boundary corrections. Legal boundary changes include updates that are a result of any legal action taken by the eligible government(s) to add or remove land to their official boundary. Boundary corrections are updates that are the result of spatial inaccuracies and do not substantially alter the Census Bureau's representation of the boundaries.

Updates created using the BAS Partnership Toolbox, GUPS, or GUPS Web are returned through the Census Bureau's secure online data sharing portal, while paper map are returned through the mail.

Eligible governments that do not respond, or those that indicate they have updates to provide, but have not submitted their updates are contacted during *nonresponse* follow-up by email. The email reminds eligible governments to respond through an online response form or email if they have updates to report. Those that indicated they have updates to report are requested to submit those updates by the March 1 or May 31 deadlines.

Refer to the schedule below for a high-level BAS program timeline.

- *January 1*—Legal boundary changes must be legally in effect on or before this date to be reported in the current survey year.
- *January to May*—The Census Bureau conducts BAS. Eligible governments respond to BAS indicating if they have legal boundary, CDP, linear feature, or contact updates to report. Those with updates can choose to create their submission using the Census Bureau's BAS Partnership Toolbox, GUPS, GUPS Web, or paper maps.
- *Early January*—The Census Bureau notifies eligible governments about BAS through email. Eligible governments are contacted through email to determine if they have legal boundary, CDP, linear feature, or contact updates to report. Any eligible government without an email on file with the Census Bureau will be contacted by phone and asked to provide their response.
- *Mid-February, Mid-March, and Mid-April*—The Census Bureau conducts nonresponse follow-up for BAS through email. Eligible governments that have not responded to annual response, along with those that indicated they have updates to report but have not yet submitted those updates, are contacted through email on up to three occasions.
- *March 1*—Legal boundary changes returned by this date will be reflected in the ACS and PEP data and in next year's BAS materials.
- *May 31*—Legal boundary changes returned by this date will be reflected in next year's BAS materials. If time permits, boundary corrections returned by this date may also be reflected in next year's BAS materials.

The Census Bureau maintains state and county (CBAS) agreements that coordinate the sharing of information and resources between the federal government and state or county governments in collecting boundary information for general-purpose local governments. These agreements aim to reduce the duplication of effort across various levels of governments as well as the cost and time burden associated with BAS participation.

To facilitate a state agreement, the Census Bureau enters a Memorandum of Understanding with the state. States interested in establishing an agreement can do so when there is state legislation requiring general-purpose local governments to report all boundary updates to a state agency. The Census Bureau currently maintains two types of state agreements. In the first type of agreement, the state reports boundary updates for all eligible governments within its jurisdiction. Eligible governments in this type of agreement are notified about BAS; however, they do not receive the request to provide updates and are instructed to report all boundary updates to the state. Under the second type of agreement, the state provides the Census Bureau with a list of eligible governments that reported boundary changes. The Census Bureau uses the list to target those general-purpose local governments during BAS.

CBAS agreements allow county or county-equivalent governments to submit updates for the eligible general-purpose local governments within their jurisdiction. Once under an agreement, eligible governments are notified about BAS; however, they do not receive the request to provide updates and are instructed to report all boundary updates to the county or county-equivalent government.

State Certification

The state certification program allows state agencies to verify that the legal boundary, name, and status information received through BAS were reported in accordance with state law. The Census Bureau annually requests that each state governor designate a state certifying official (SCO) to participate in the program. The SCO reviews listings of legal boundary changes, as well as government names and statuses that were submitted through the previous year's BAS. These listings include the attribute information for new incorporations, dissolutions, mergers, consolidations, and legal boundary changes. The listings also include the names and functional statuses of all general-purpose local governments within the state's jurisdiction. The SCO can request that the Census Bureau edit the attribute data, add missing records, or remove invalid records. Invalid records are only removed if the state government maintains an official record of all changes to legal boundaries and governments as mandated by state law. The state certification schedule is as follows:

- *October*—The Census Bureau emails governor's letters requesting the state appoint an SCO to participate in the program.
- *December*—The Census Bureau emails the information required to participate to the SCO.
- *December to February*—The SCO returns submission to the Census Bureau.
- *March*—The Census Bureau distributes discrepancy emails to general-purpose local governments based on feedback from the SCO.

The state certification materials include a governor's letter, an email to the SCO, how-to guide, legal boundary change and government name and status

listings, and discrepancy email to local governments. The listings and how-to guide are available on the BAS website. The SCO returns all updates electronically through the Census Bureau's secure online data sharing portal.

Boundary Quality Project

The boundary quality project is designed to assess, analyze, and improve the spatial quality of legal, statistical, and administrative boundaries within the MAF/TIGER System. Ensuring quality boundaries is a critical component of the geographic preparations for each decennial census and the Census Bureau's ongoing geographic partnership programs. In addition, the improvement of boundary quality is an essential element of the Census Bureau's commitment as the responsible agency for legal boundaries under OMB Circular A–16.

The project represents an effort to systematically target and assess boundary quality within the MAF/TIGER System. Historically, the Census Bureau relied exclusively on geographic partnership programs such as BAS and the Participant Statistical Areas Program (PSAP) to obtain updates to tribal, state, general-purpose local government, and CDP boundaries. While programs like BAS play an essential role in improving boundary quality, the goal of the boundary quality project is to establish a new, more accurate, baseline for legal boundaries and CDPs within an entire state or county. BAS builds on this baseline by collecting individual legal boundary changes and optionally associated addresses, and CDP updates on a transaction basis as they occur over the years.

Feedback

The Census Bureau is adding a feedback component to its geographic partnership programs to allow for the solicitation of feedback to improve the administration of the respective program and potentially reduce the future burden. Eligible governments may be asked to provide their feedback on materials, method(s) of data collection, manner of communications, and the usability of the program applications and tools.

III. Data

OMB Control Number: 0607–0151.

Form Number(s): BAS–6. This is the CBAS agreement form.

Type of Review: Regular submission, request for a revision of a currently approved collection.

Affected Public: Tribal, state, and general-purpose local governments in all fifty states, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands.

Estimated Number of Respondents:

- *BAS/State Certification/Boundary Quality Project:* 40,000 governments.
- *Feedback:* 1,000 governments.

Estimated Time per Response:

- *BAS/State Certification/Boundary Quality Project:* 7.5 hours. This estimate is based on an average of 5 hours for an eligible government with no change and 10 hours for an eligible government with changes.
- *Feedback:* 30 minutes.

Estimated Total Annual Burden Hours: 300,500 hours.

- *BAS/State Certification/Boundary Quality Project:* 300,000 hours.
- *Feedback:* 500 hours.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., section 6.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09793 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Redistricting Data Program

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed revision of the Redistricting Data Program (RDP), prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 5, 2024.

ADDRESSES: Interested persons are invited to submit written comments by email to *dcmd.pra@census.gov.* Please reference ''Redistricting Data Program'' in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2024–0011, to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *https://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in

Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Michael S. Snow, Program Manager, Decennial Census Management Division, by phone at 301–763–9912 or by email to *dcmd.pra@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Redistricting Data Program (RDP) is one of many voluntary geographic partnership programs that collects boundaries and attributes to update the U.S. Census Bureau's geographic database of addresses, streets, and boundaries. The Census Bureau uses its geographic database, *i.e.,* the Master Address File/Topologically Integrated Geographic and Encoding and Referencing (MAF/TIGER) System, to link demographic data from surveys and the decennial census to locations and areas, such as cities, congressional and legislative districts, and counties. To tabulate statistics by localities, the Census Bureau must have accurate addresses, streets, boundaries, and attributes.

The RDP is executed under the provisions of title 13, section 141(c) of the United States Code (U.S.C.). Under the provisions of Public Law 94–171, as amended (title 13, United States Code (U.S.C.), section 141(c)), ''[t]he officers or public bodies having initial responsibility for the legislative apportionment or districting of each State may, not later than 3 years before the decennial census date, submit to the Secretary a plan identifying the geographic areas for which specific tabulations of population are desired.''

The Census Bureau is requesting a clearance to continue activities included in the RDP. As the current OMB Control Number 0607–0988 clearance will expire in November 2024, the new clearance will allow the Census Bureau to provide RDP-specific materials and procedures to participants during the fiscal years (FY) 2025, 2026, and 2027. These activities include:

- Solicitation of Non-Partisan Liaisons (2025)
- Collection of Post-2020 Census Congressional and State Legislative District Plans (2025–2026)
- Block Boundary Suggestion Project (2026–2027)

II. Method of Collection

Solicitation of Non-Partisan Liaisons (2025)

Legislative leadership of all fifty states, the District of Columbia, and the Commonwealth of Puerto Rico will be asked to provide a non-partisan liaison who will serve for the entirety of the 2030 Census RDP and who will create and submit geographic updates and perform verification as a part of the RDP.

Solicitation of Non-Partisan Liaisons Schedule

Legislative leadership will be contacted by mail beginning in January 2025 asking for a non-partisan liaison from each state to be designated to work on the RDP. Contacts will continue through mail, email, and phone until at least one liaison has been assigned from every state, the District of Columbia, and the Commonwealth of Puerto Rico.

Collection of Post-2020 Census Congressional and State Legislative District Plans (2025–2026)

The Census Bureau collaborates with the designated non-partisan liaisons to collect any newly enacted congressional or state legislative districts plans since the collection of the 119th Congressional and 2024 State Legislative Districts plans in 2024. The Census Bureau provides guidelines for submitting their plans. Those that have changes provide a block equivalency file, split block shapefiles (if any), district population, and legislation to the Census Bureau. The Census Bureau processes the new plans into the MAF/TIGER System and provides a new block equivalency file and split block shapefiles (if any) to verify that the districts were inserted correctly.

Collection of Post-2020 Census Congressional and State Legislative District Plans Schedule

- The Census Bureau collects plans from November 2025 through April 2026.
- The verification phase occurs from February 2026 through April 2026.

Block Boundary Suggestion Project (2026–2027)

The Census Bureau collaborates with the designated non-partisan liaisons to collect and verify suggestions for the 2030 Census tabulation blocks as part of the Block Boundary Suggestion Project (BBSP). Liaisons are also able to submit suggested legal boundary updates as well as updates to other geographic areas and features. These actions allow for the construction of the small area geography needed for legislative redistricting. Digital copies of the features and boundaries the Census Bureau has in the MAF/TIGER System are provided to the liaisons. The liaisons can choose to use a free customized geographic information system (GIS) application provided by the Census Bureau, *i.e.,* the Geographic Update Partnership Software (GUPS), or their own GIS mapping software to submit updates and block boundary suggestions.

The BBSP is conducted in two parts, an initial delineation of updates, *i.e.,* delineation phase, and a verification phase to ensure the suggested updates are accurately applied. The verification phase also has the option for liaisons to make additional block suggestions. Those that choose to participate in BBSP receive guidelines and training for providing their suggestions.

BBSP Schedule

- The delineation phase begins in January 2026 and ends in May 2026.
- The verification phase begins in January 2027 and ends in May 2027.

Feedback

The Census Bureau is adding a feedback component to its geographic partnership programs to allow for the solicitation of feedback to improve the administration of the respective program and potentially reduce the future burden. Liaisons may be asked to provide their feedback on materials, method(s) of data collection, manner of communications, and the usability of the program applications and tools.

III. Data

OMB Control Number: 0607–0988.

Form Number(s): Certification Forms (4) and Verification Forms (2).

- 2026 State Legislative Boundary Certification Form for states with a Single Congressional District (Alaska, Delaware, North Dakota, South Dakota, Vermont, and Wyoming).
- District of Columbia 2026 Wards Certification Form.
- 120th Congressional District Boundary and 2026 State Legislative District Boundary Certification Form.
- Commonwealth of Puerto Rico 2026 Legislative District Boundaries Certification Form.
- 2026 State Legislative District Boundaries Verification Form.
- 120th Congressional District Boundaries Verification Form.

Type of Review: Regular submission, request for a revision of a currently approved collection.

Affected Public: All fifty states, the District of Columbia, and the Commonwealth of Puerto Rico.

Estimated Number of Respondents:

- Solicitation of Non-Partisan Liaisons: 52.
- Collection of Post-2020 Census Congressional and State Legislative District Plans: 52.
- BBSP Delineation Phase: 52.
- BBSP Verification Phase: 52.
- Feedback: 52.

Estimated Time per Response:

- Solicitation of Non-Partisan Liaisons: 6 hours.
- Collection of Post-2020 Census Congressional and State Legislative District Plans: 8 hours.
- BBSP Delineation Phase: 124 hours.
- BBSP Verification Phase: 62 hours.
- Feedback: 1 hour.

Estimated Total Annual Burden Hours: 10,452.

- Solicitation of Non-Partisan Liaisons: 312 hours.
- Collection of Post-2020 Census Congressional and State Legislative District Plans: 416 hours.
- BBSP Delineation Phase: 6,448 hours.
- BBSP Verification Phase: 3,224 hours.
- Feedback: 52 hours.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Public Law 94–171, as amended (title 13, United States Code (U.S.C.), section 141(c)).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09794 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–18–2024]

Foreign-Trade Zone (FTZ) 90, Notification of Proposed Production Activity; PPC Broadband, Inc.; (Fiber Optic Conduit); East Syracuse, New York

PPC Broadband, Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in East Syracuse, New York, within Subzone 90C. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on April 26, 2024.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed finished product(s) and material(s)/component(s) would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished product is fiber optic conduit (duty rate, 3.1%).

The proposed foreign-status materials and components include polyester pull cord, copper clad steel wire, polyethylene pellets, and polypropylene pellets (duty rate ranges from duty-free to 7.5%). The request indicates that polyester pull cord will be admitted to the zone in privileged foreign (PF) status (19 CFR 146.41), thereby precluding inverted tariff benefits on such items. The request also indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in PF status.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov*. The closing period for their receipt is June 17, 2024.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Diane Finver at *Diane.Finver@trade.gov*.

Dated: May 1, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–09779 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–887]

Carbon and Alloy Steel Threaded Rod From India: Preliminary Results and Preliminary Rescission of Antidumping Duty Administrative Review, In Part, 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that carbon and alloy steel threaded rod (steel threaded rod) from India was sold in the United States at prices below normal value (NV) during the period of review (POR) April 1, 2022, through March 31, 2023. We are also preliminarily rescinding the review with respect to certain companies that had no entries of the subject merchandise during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable May 6, 2024.

FOR FURTHER INFORMATION CONTACT: Samuel Frost, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8180.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2023, Commerce initiated an administrative review of the

antidumping duty (AD) order on steel threaded rod from India, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[1] Commerce initiated this review for 112 companies.[2] Commerce selected Mangal Steel Enterprises Limited (Mangal) and Shree Luxmi Fasteners (SLF) for individual examination as mandatory respondents.[3]

Commerce extended the time limit for completing the preliminary results of this review until April 29, 2024.[4] For details regarding the events that occurred subsequent to the initiation of the review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The product covered by the scope of this *Order* is carbon and alloy steel threaded rod from India. A complete description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[6]

Preliminary Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR subject to the AD order for which liquidation is suspended, Commerce may rescind an administrative review, in whole or only with respect to a particular exporter or producer.[7]

At the end of the administrative review, any suspended entries are liquidated at the assessment rate computed for the review period.[8] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate. Accordingly, pursuant to 19 CFR 351.213(d)(3), we have preliminarily determined to rescind this administrative review with respect to the 83 companies listed in Appendix III to this notice that have no reviewable, suspended entries of subject merchandise during the POR.[9]

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. We calculated export price and constructed export price in accordance with sections 772(a) and 772(b) of the Act, respectively. We calculated NV in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. *See* Appendix I for a complete list of topics discussed in the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*. In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Rate for Non-Examined Companies

The Act and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we have preliminarily calculated a weighted-average dumping margin of 10.97 percent for SLF/TEI and zero percent for Mangal. Therefore, in accordance with section 735(c)(5)(A) of the Act, we are preliminarily applying SLF/TEI's weighted-average dumping margin of 10.97 percent to the non-examined companies (*see* Appendix II for a full list of these companies), because this is the only rate that is not zero, *de minimis,* or based entirely on facts available.

Preliminary Results of the Review

We preliminarily determine that the following estimated weighted-average dumping margins exist during the period April 1, 2022, through March 31, 2023:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Mangal Steel Enterprises Limited	0.00
Shree Luxmi Fasteners/The Emerging Impex[10]	10.97
Non-Examined Companies[11]	10.97

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[12] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[13]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total,

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023) (*Initiation Notice*); *see also Carbon and Alloy Steel Threaded Rod from India: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 85 FR 19925 (April 9, 2020) (*Order*).

[2] *See Initiation Notice,* 88 FR at 38023–24.

[3] *See* Memorandum, ''Respondent Selection,'' dated June 28, 2023. We are preliminarily treating SLF and its affiliate The Emerging Impex (TEI) as a single entity for purposes of this review. For further details, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Carbon and Alloy Steel Threaded Rod from India; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2022–2023,'' dated December 18, 2023; *see also* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2022–2023,'' dated April 26, 2024.

[5] *See* Preliminary Decision Memorandum.

[6] *Id.* at ''Scope of the *Order*.''

[7] *See, e.g., Forged Steel Fittings from Taiwan: Rescission of Antidumping Duty Administrative Review; 2018–2019,* 85 FR 71317, 71318 (November 9, 2020); *see also Certain Circular Welded Non-Alloy Steel Pipe from Mexico: Rescission of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 54084 (October 26, 2018).

[8] *See* 19 CFR 351.212(b)(1).

[9] *See* Memorandum, ''Release of U.S. Customs and Border Protection Data,'' dated June 14, 2023, at Attachment.

[10] As noted above, Commerce preliminarily determines that SLF and TEI are affiliated and should be collapsed. *See* Preliminary Decision Memorandum.

[11] *See* Appendix II for a list of these companies.

[12] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[14] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[15]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary, filed electronically via ACCESS.[16] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[17] If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm the date and time of the hearing two days before the scheduled date. Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Assessment Rates

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[18]

Upon completion of the final results of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We intend to instruct CBP to assess antidumping duties on all such entries covered by this review. Where an importer-specific assessment rate is zero or *de minimis* in the final results of this review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2).

If, in the final results, we continue to find that the administrative review for companies in Appendix III should be rescinded, we will instruct CBP to assess antidumping duties on any suspended entries that entered under their CBP case numbers (*i.e.,* at that exporter's rate) at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Mangal or SLF/TEI for which these companies did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate established in the original less-than-fair-value (LTFV) investigation [19] (*i.e.,* 0.00 percent) if there is no rate for the intermediate company(ies) involved in the transaction.[20] For the companies which were not selected for individual review, we will assign an assessment rate based on the review-specific average rate, calculated as noted in the ''Preliminary Results of Review'' section above.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication date of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed in the final results of this review will be equal to the weighted-average dumping margin established in the final results of this administrative review except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, or the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 0.00 percent, the all-others rate established in the LTFV investigation as adjusted for the export-subsidy rate in the companion countervailing duty investigation.[21] The cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the

[14] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[15] *See APO and Service Procedures.*

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 351.310.

[18] *See* section 751(a)(2)(C) of the Act.

[19] *See Order,* 85 FR at 19926.

[20] For a full description of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[21] *See Order,* 85 FR at 19926.

subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: April 29, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Preliminary Rescission of Administrative Review, In Part
V. Affiliation and Single Entity Treatment
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

Appendix II—List of Companies Not Individually Examined

1. Aadi Shree Fastener Industries
2. Babu Exports
3. Bhansali Inc.
4. Chirag International
5. Everest Industrial Corporation
6. Fence Fixings
7. Fine Thread Form Industries
8. Ganpati Fastners Pvt., Ltd.
9. GDPA Fasteners
10. Goodgood Manufacturers
11. Idea Fasteners Pvt., Ltd.
12. Kanika Exp.
13. Kapson India
14. Kapurthala Industrial Corporation
15. Kova Fasteners Pvt., Ltd.
16. Maharaja International
17. Maya Enterprises
18. Nishant Steel Industries
19. Nuovo Fastenings Pvt., Ltd.
20. R A Exp
21. R K Fasteners (India)
22. Rods & Fixing Fasteners
23. S K Overseas
24. Singhania International Ltd.
25. The Technocrats Co.
26. Viraj Profiles Ltd.
27. Yogendra International

Appendix III—List of Companies for Which We Are Preliminarily Rescinding the Administrative Review

1. A H Enterprises
2. Aanjaney Micro Engy Pvt., Ltd.
3. Accurate Steel Forgings (I) Ltd.
4. Alps Industries Ltd.
5. Apex Thermocon Pvt., Ltd.
6. Ash Hammer Union
7. Astrotech Steels Pvt., Ltd.
8. Atlantic Container Line Pvt., Ltd.
9. Ats Exp. 07
10. Atz Shipping Trade & Transport Pvt.
11. BA Metal Processing
12. Boston Exp. & Engineering Co.
13. C.H.Robinson International (India)
14. C.P.World Lines Pvt., Ltd.
15. Century Distribution Systems Inc.
16. Charu Enterprises
17. Daksh Fasteners
18. Dedicated Imp. & Exp. Co.
19. Dhiraj Alloy & Stainless Steel
20. Dsv Air and Sea Pvt., Ltd.
21. Eastman Industries Ltd.
22. Eos Precision
23. ESL Steel Ltd
24. Everest Exp.
25. Farmparts Company
26. Galorekart Marketplace Pvt., Ltd.
27. Ganga Acrowools Ltd.
28. Gateway Engineering Solution
29. Gee Pee Overseas
30. Geodis India Pvt., Ltd. (Indel)
31. Jindal Steel And Power Ltd.
32. JSW Steel Ltd.
33. Kanchan Trading Co.
34. Kanhaiya Lal Tandoor (P) Ltd.
35. Karna International
36. Kei Industries Ltd.
37. King Exports
38. Linit Exp. Pvt., Ltd.
39. Mahajan Brothers
40. Meenakshi India, Ltd.
41. Metalink
42. MKA Engineers And Exporters Pvt., Ltd.
43. National Cutting Tools
44. NJ Sourcing
45. Noahs Ark International Exp.
46. Oia Global India Pvt., Ltd.
47. Otsusa India Pvt., Ltd.
48. Paloma Turning Co. Pvt., Ltd.
49. Patton International Ltd.
50. Perfect Tools & Forgings
51. Permali Wallace Pvt., Ltd.
52. Polycab India Ltd.
53. Pommada Hindustan Pvt., Ltd.
54. Poona Forge Pvt., Ltd.
55. Raajratna Ventures Ltd.
56. Raashika Industries Pvt., Ltd.
57. Rajpan Group
58. Rambal Ltd.
59. Randack Fasteners India Pvt., Ltd.
60. Ratnveer Metals Ltd.
61. Rimjhim Ispat Ltd.
62. S.M Forgings & Engineering
63. Sandip Brass Industries
64. Sandiya Exp. Pvt., Ltd.
65. Sansera Engineering Pvt., Ltd.
66. Silverline Metal Engineering Pvt. Lt
67. Sri Satya Sai Enterprises
68. Steampulse Global Llp
69. Steel Authority Of India Ltd.
70. Suchi Fasteners Pvt., Ltd.
71. Supercon Metals Pvt., Ltd.
72. Tekstar Pvt., Ltd.
73. Tijiya Exp. Pvt., Ltd.
74. Tijiya Steel Pvt., Ltd.
75. Tong Heer Fasteners
76. Trans Tool Pvt., Ltd.
77. Universal Engineering and Fabricat
78. V.J Industries Pvt., Ltd.
79. Vidushi Wires Pvt., Ltd.
80. Vrl Automation
81. VV Marine Pvt., Ltd.
82. Zenith Precision Pvt., Ltd.
83. Zenith Steel Pipes And Industries L

[FR Doc. 2024–09780 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting of a Federal advisory committee.

SUMMARY: The Environmental Technologies Trade Advisory Committee (ETTAC) will hold a hybrid meeting, accessible in-person and online, on Tuesday May 21, 2024 at the U.S. Department of Commerce in Washington, DC. The meeting is open to the public with registration instructions provided below. This notice sets forth the schedule and proposed topics for the meeting.

DATES: The meeting is scheduled for Tuesday, May 21, 2024 from 10:00 a.m. to 12:00 p.m. and 1:00 to 3:00 p.m. Eastern Standard Time (EST). The deadline for members of the public to register to participate, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Wednesday, May 15, 2024. Members of the public must register by that date to participate.

ADDRESSES: The meeting will be held virtually as well as in-person in the Commerce Research Library at the U.S. Department of Commerce Herbert Clark Hoover Building, 1401 Constitution Avenue NW, Washington, DC 20230. Requests to register to participate in-person or virtually (including to speak or for auxiliary aids) and any written comments should be submitted via email to Ms. Megan Hyndman, Office of Energy & Environmental Industries, International Trade Administration, at *Megan.Hyndman@trade.gov.* This meeting has a limited number of spaces for members of the public to attend in-person. Requests to participate in-person will be considered on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Ms. Megan Hyndman, Office of Energy & Environmental Industries, International Trade Administration (Phone: 202–823–1839; email: *Megan.Hyndman@trade.gov*).

SUPPLEMENTARY INFORMATION: The ETTAC is mandated by section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), to advise the Environmental Trade Working Group of the Trade Promotion

Coordinating Committee, through the Secretary of Commerce, on the development and administration of programs to expand U.S. exports of environmental technologies, goods, services, and products. The ETTAC was most recently re-chartered through August 16, 2024.

On Tuesday, May 21, 2024 from 10:00 a.m. to 12:00 p.m. and 1:00 to 3:00 p.m. EST, the ETTAC will hold the eighth meeting of its current charter term. During the meeting, committee members will discuss issues of interest to specific environmental technology sectors, deliberate on potential recommendation topics, and hear briefings from the U.S. government related to tax incentives for carbon management projects, among other topics. An agenda will be made available one week prior to the meeting upon request to Megan Hyndman.

The meeting will be open to the public and time will be permitted for public comment before the close of the meeting. Members of the public seeking to attend the meeting are required to register by Wednesday, May 15, at 5:00 p.m. EST, via the contact information provided above. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at *Megan.Hyndman@trade.gov* or (202) 823–1839 no less than one week prior to the meeting. Requests received after this date will be accepted, but it may not be possible to accommodate them.

Written comments concerning ETTAC affairs are welcome any time before or after the meeting. To be considered during the meeting, written comments must be received by Wednesday, May 15, 2024, at 5:00 p.m. EST to ensure transmission to the members before the meeting. Draft minutes will be available within 30 days of this meeting.

Dated: April 30, 2024.

Man K. Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2024–09733 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Northeast Region Observer Providers Requirements

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 31, 2024, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Northeast Region Observer Providers Requirements.

OMB Control Number: 0648–0546.

Form Number(s): None.

Type of Request: Regular submission (extension and revision of a currently approved information collection).

Number of Respondents: 626.

Average Hours per Response: Response time varies between 10 minutes to 10 hours depending on the information collection.

Total Annual Burden Hours: 6,475.

Needs and Uses: Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Steven Act), the Secretary of Commerce (Secretary) has the responsibility for the conservation and management of marine fishery resources. Much of this responsibility has been delegated to the NOAA/National Marine Fisheries Service (NMFS). Under this stewardship role, the Secretary was given certain regulatory authorities to ensure the most beneficial uses of these resources. One of the regulatory steps taken to carry out the conservation and management objectives is to collect data from users of the resource.

Regulations at 50 CFR 648.11(g) require observer service providers to comply with specific requirements in order to operate as an approved provider in the Atlantic sea scallop (scallop) fishery. Observer service providers must comply with the following requirements: submit applications for approval as an observer service provider; formally request observer training by the Northeast Fisheries Observer Program (NEFOP); submit observer deployment reports and biological samples; give notification of whether a vessel must carry an observer within 24 hours of the vessel owner's notification of a prospective trip; maintain an updated contact list of all observers that includes the observer identification number; observer's name mailing address, email address, phone numbers, homeports or fisheries/trip types assigned, and whether or not the observer is ''in service.'' The regulations also require observer service providers submit any outreach materials, such as informational pamphlets, payment notification, and descriptions of observer duties as well as all contracts between the service provider and entities requiring observer services for review to NMFS/NEFOP. Observer service providers also have the option to respond to application denials, and submit a rebuttal in response to a pending removal from the list of approved observer providers. During the 60-day comment period for this renewal NMFS approved an additional observer service provider, increasing the number of providers from three to four. The additional burden hours necessary to accommodate the additional provider are reflected in the updated total burden hours.

Regulations at § 648.11(k)(2) require that limited access, limited access general category individual fishing quota, and Northern Gulf of Maine scallop vessels notify NMFS prior to the beginning of a scallop trip to facilitate the deployment of at-sea observers. Previously, vessels either called or emailed to notify NMFS of an upcoming scallop trip. NMFS has added a new method for notification called the Pre-Trip Notification System (PTNS). The integration of the scallop notification requirement into the PTNS helps standardize observer operations between fisheries and modernize reporting systems. The PTNS is a mobile-friendly website that is more sophisticated and flexible than the aging interactive voice response technology. The change to the PTNS does not affect determination of scallop coverage rates or the compensation analysis. There are no changes to the requirements vessels must abide by if selected to carry an observer, such as equal accommodations, a harassment-free

environment, and other safety requirements. This change is not expected to impact the burden response time, but NOAA will continue to monitor use of this new tool, and will update the collection if it results in any burden changes at our next renewal. There will still be an email and a phone option for vessels to notify. These requirements allow NMFS/NEFOP to effectively administer the scallop observer program.

Affected Public: Business or other for-profit organization.

Frequency: Weekly

Respondent's Obligation: Required to Obtain Benefits.

Legal Authority: Magnuson-Steven Act

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0546.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09800 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD924]

Mid-Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: A sub-panel of the Mid-Atlantic and New England Fishery Management Councils' Scientific and Statistical Committees (SSC) and the Atlantic States Marine Fisheries Commission (ASMFC) Assessment Science Committee will hold a meeting.

DATES: The meeting will be held on Wednesday, May 22, 2024, starting at 9:30 a.m. and continue through 12:30 p.m. on Friday, May 24, 2024. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: This will be an in-person meeting with a virtual option. Participants and members of the public will have the option to participate in person at the Northeast Fisheries Science Center Narragansett Lab, 28 Tarzwell Drive, Narragansett, RI, or virtually via webinar. Webinar connection instructions and briefing materials will be available at: *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The joint sub-panel, consisting of Mid-Atlantic and New England SSC members and ASMFC Assessment Science Committee members, will meet to review and provide input on the Northeast Fisheries Science Center (NEFSC) draft survey mitigation plans relative to offshore wind development. NOAA Fisheries and the Bureau of Ocean Energy Management (BOEM) developed the Federal Survey Mitigation Strategy (Strategy) which describes the impacts of wind energy development on fisheries-independent surveys and outlines the goals, objectives, and actions to guide the development and implementation of a program to mitigate the impacts on fisheries-independent surveys. To address the actions outlined in the Strategy, the NEFSC developed the Northeast Survey Mitigation Program and survey-specific mitigation plans to ensure NEFSC can continue to provide equal or higher quality science for each of the long-term, recurring surveys conducted by NEFSC that will be impacted by offshore wind development. The survey mitigation plans include descriptions of the impacted survey, specific stakeholders for the data collected, impacts of offshore wind development, and planned mitigation measures to address the impacts of wind energy development on scientific surveys.

To ensure the survey mitigation plans represent the best science available, the joint sub-panel will peer review the draft survey mitigation plans prepared by the NEFSC for eight existing fishery-independent surveys and three new supplemental surveys. The sub-panel will evaluate the detail and scientific soundness of the mitigation approaches described in each plan, following a set of Terms of Reference. The NEFSC will consider the feedback received from the sub-panel and will address and/or incorporate into revised survey mitigation plans as appropriate.

A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C 1801 *et seq.*

Dated: May 1, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09765 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD895]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 92 Atlantic Blueline Tilefish Landings Stream Topical Working Group (LS–TWG) Webinar I.

SUMMARY: The SEDAR 92 assessment of the Atlantic stock of blueline tilefish will consist of a series of assessment webinars. SEDAR 92 Webinar I is scheduled for May 22, 2024. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 92 Atlantic Blueline Tilefish LS–TWG Webinar I is scheduled for May 22, 2024, from 1 p.m. to 3 p.m., eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to

members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Julie.Neer@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julie Neer, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *Julie.Neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 92 Atlantic Blueline Tilefish LS–TWG Webinar I are as follows:

Discuss available data sources, review preliminary analysis, and provide guidance for next steps.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 1, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09767 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD894]

Fisheries of the U.S. Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 84 Assessment Webinar II for U.S Caribbean yellowtail snapper and stoplight parrotfish.

SUMMARY: The SEDAR 84 assessment process of U.S. Caribbean yellowtail snapper and stoplight parrotfish will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 84 Assessment Webinar II will be held May 23, 2024, from 2 p.m. to 4 p.m., eastern time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment Webinar II are as follows:

Panelists will review and discuss initial assessment modeling to date.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues

arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 1, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09763 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Tornado Watch/Warning Post-Event Evaluation

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on February 9th, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, Commerce.

Title: Tornado Watch/Warning Post-Event Evaluation.

OMB Control Number: 0648–0797.

Form Number(s): None.

Type of Request: Regular submission: revision.

Number of Respondents: Surveys: 1,200, Interviews: 50.

Average Hours per Response: Surveys: 5–10 minutes, Interviews: 15–30 minutes.

Total Annual Burden Hours: Survey: 200 hours, Interviews: 25 hours.

Needs and Uses: Each year over 1000 tornadoes affect communities across the United States, yet little is known about how individuals receive, interpret, and respond to information from NOAA relating to this hazard. In fact, only a small sample of tornadoes ever receive study, and most often those are only the most violent tornadoes. No generalizable, or even relatively large-scale information on tornado forecast and warning response after real-world events exists. The NOAA National Weather Service (NWS) and National Severe Storms Laboratory (NSSL) designed the data collection instrument to allow for more routine collection of this information. Respondents include members of the United States public who have been in or near a tornado, received a tornado warning, or were in or near a strong storm that made them concerned about tornadoes. They answer questions about the ways they received, understood, and responded to information about the event, including NWS watch and warning information. This survey is delivered through a web application hosted by NSSL called Tornado Tales, available online at *https://inside.nssl.noaa.gov/tornado-tales/.*

After approval of our initial data collection instrument (that shown on the website), the OU Cooperative Institute for Severe and High-Impact Weather Research and Operations (CIWRO) and NOAA NSSL Behavioral Insights Unit carried out post-event data collections for multiple tornado events, validating the questions and identifying issues for improvement. This fieldwork led to several needed improvements, including the addition of questions about the event more broadly, changing some response types, rephrasing some questions that were interpreted too broadly, and including questions about efficacy and the availability of forecast information to individuals. While the revisions have added questions to the survey, their improved clarity should allow for faster response times per question. We estimate the time to complete the survey is five to ten minutes on average. Subject recruitment will primarily be done by NOAA NSSL and its partners advertising the survey via websites and social media outlets. In addition to these efforts, there is also the possibility that during post-storm damage assessment activities NWS forecasters may direct impacted individuals to the Tornado Tales website.

In addition to the changes to the survey instrument, researchers at NOAA NSSL and at the OU CIWRO Behavioral Insights Unit would like to conduct interviews with emergency managers, broadcast meteorologists, and members of the public after certain tornado events. These more in-depth interviews will collect similar information to the survey instrument from members of the public, broadcast meteorologists, and Emergency Management personnel who recently experienced a tornado event. The interviews will walk respondents through a timeline of events leading up to the tornado event. Researchers will use a skip-logic approach, meaning participants will only answer questions about the time periods relevant to their personal experience. The purpose of these interviews will be to more thoroughly explore how residents, broadcast meteorologists, and Emergency Managers received, understood, and responded to tornado forecasts and warnings. Given the in-person nature of these interviews, we expect them to take between 15 and 30 minutes on average.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

Legal Authority: N/A.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0797.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09801 Filed 5–3–24; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0048]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary of Defense, Department of Defense (DoD).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD is establishing a new system of records titled, ''All-domain Anomaly Resolution and Anomalous Phenomena (AARO) Program Records,'' AARO–0001. This system of records describes the AARO's collection, use, and maintenance of correspondence and reports submitted from current or former U.S. government employees, service members, or contractors with direct knowledge of U.S. Government programs or activities related to Unidentified Anomalous Phenomenon (UAP) dating back to 1945. This system also includes correspondence and reports submitted from members of the general public and government-affiliated personnel on reported events related to UAP. The submitted information will be used to carry out AARO's mission, including to inform AARO's congressionally directed Historical Record Report. Additionally, DoD is issuing a direct final rulemaking, which will exempt this system of records from certain provisions of the Privacy Act, elsewhere in this issue of the **Federal Register**.

DATES: This system of records is effective May 6, 2024; however, comments on the Routine Uses will be accepted on or before June 5, 2024. The Routine Uses take effect at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Paul Plescow, Chief of Staff, All-domain Anomaly Resolution Office, Office of the Deputy Secretary of Defense, 5000 Defense Pentagon, 3C949, Washington, DC 20301–5000, ATTN: AARO; *osd.pentagon.ousd-intel-sec.mesg.contact-aaro-mbx@mail.mil;* phone 703–693–6081.

SUPPLEMENTARY INFORMATION:

I. Background

The All-domain Anomalous Resolution Office is an office within the Office of the Secretary of Defense charged with the mission to synchronize efforts across the DoD, and with other U.S. Federal departments and agencies, to detect, identify and attribute objects of interest in, on or near military installations, operating areas, training areas, special use airspace and other areas of interest, and, as necessary, to mitigate any associated threats to safety of operations and national security. This includes anomalous, unidentified space, airborne, submerged and transmedium objects. In furtherance of this mission, the AARO Report System covers the AARO's maintenance of correspondence and reports received from current or former U.S. government employees, service members, or contractor personnel with direct knowledge of U.S. Government programs or activities related to UAP dating back to 1945. This system also includes correspondence and reports received from members of the general public and government-affiliated personnel on events related to UAP. The records include contact information and any other reported information voluntarily provided by submitters.

Additionally, DoD is issuing a direct final rule to exempt this system of records from certain provisions of the Privacy Act elsewhere in today's issue of the **Federal Register**. DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov.*

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, DoD has provided a report of this system of records to the OMB and to Congress.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal RegisterLiaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

All-domain Anomaly Resolution and Anomalous Phenomena Program Records,'' AARO–0001.

SECURITY CLASSIFICATION:

Unclassified; Classified.

SYSTEM LOCATION:

All-domain Anomaly Resolution Office, Office of the Deputy Secretary of Defense, 5000 Defense Pentagon, 3C949, Washington, DC 20301–5000. Information may also be stored within a government-certified cloud, implemented and overseen by the Department's Chief Information Officer (CIO), 6000 Defense Pentagon, Washington, DC 20301–6000.

SYSTEM MANAGER(S):

The system manager for this system of records is the Chief of Staff, All-domain Anomaly Resolution Office, Office of the Deputy Secretary of Defense, 5000 Defense Pentagon, 3C949, Washington, DC 20301–5000, ATTN: AARO; *osd.pentagon.ousd-intel-sec.mesg.contact-aaro-mbx@mail.mil;* phone 703–693–6081.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113, Secretary of Defense; 44 U.S.C. 2107, Acceptance of Records for Historical Preservation; Section 1673 of the National Defense Authorization Act for Fiscal Year 2023 (Pub. Law 117–263).

PURPOSE(S) OF THE SYSTEM:

A. To manage records maintained in furtherance of AARO's mission, including to synchronize efforts across the DoD and with other U.S. Federal departments and agencies to detect, identify, and attribute objects of interest in, on or near military installations, operating areas, training areas, special use airspace and other areas of interest, and, as necessary, to mitigate any associated threats to safety of operations and national security. This includes anomalous, unidentified space, airborne, submerged and transmedium objects.

B. To document, manage, track, and oversee correspondence and reports from current or former U.S. government employees, service members, or contractor personnel with direct knowledge of U.S. Government programs or activities related to UAP dating back to 1945.

C. To document, manage, track, and oversee correspondence and reports from the general public and Government-affiliated personnel concerning events related to UAP.

D. To track and report data, conduct research and statistical analysis, and evaluate program effectiveness.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

A. Current or former U.S. Government employees, uniformed service members, and contractor personnel with direct knowledge of U.S. Government programs or activities related to UAP dating back to 1945 or who report any event related to UAP;

B. Members of the general public and Government-affiliated personnel who provide correspondence or reports concerning events related to UAP.

CATEGORIES OF RECORDS IN THE SYSTEM:

A. Personal information including: Name, DoD ID number, home and email addresses, phone numbers, U.S. Government or contractor employment status, driver's license ID information, security clearance information.

B. Information related to UAPs including: correspondence and reports of events related to UAP, event description or narrative, location relative to the observer, any reported health implications related to UAP, metadata, night vision camera footage, characteristics, including physical state (*e.g.,* size shape, color), observer's assessment of the UAP, including the nature of the phenomenon and whether it was benign, hazard, or a threat, imagery and metadata from photography or recording devices, including mobile phones, and analytical products related to submitted correspondence and reports. The specific types of data in these records may vary widely depending on the nature of the individual's report or correspondence.

RECORD SOURCE CATEGORIES:

Records and information maintained in this system of records are obtained from the individuals; some records may also be obtained from other systems or databases maintained by other DoD or OSD components or other agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, all or a portion of the records or information contained herein may specifically be disclosed outside the DoD as a Routine Use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection, evaluation, or other review as authorized by the Inspector General Act of 1978, as amended.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute, treaty, or other international agreement.

K. To an authorized appeal or grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee.

L. To appropriate Federal, State, local, territorial, tribal, foreign, or international agencies for the purpose of scientific study or counterintelligence activities authorized by U.S. law or Executive Order, or for the purpose of executing or enforcing laws designed to protect the national security or homeland security of the United States, including those relating to the sharing of records or information concerning terrorism, homeland security, or law enforcement.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored electronically or on paper in secure facilities in a locked drawer behind a locked door. Electronic records may be stored locally on digital media; in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name and case number, or combination of both.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Disposition pending; until the National Archives and Records Administration has approved the retention and disposition schedule, treat as permanent.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DoD safeguards records in this system of records according to applicable rules, policies, and procedures, including all applicable DoD automated systems security and access policies. DoD policies require the use of controls to minimize the risk of compromise of personally identifiable information (PII) in paper and electronic form and to enforce access by those with a need to know and with appropriate clearances. Additionally, DoD has established security audit and accountability policies and procedures which support the safeguarding of PII and detection of potential PII incidents. DoD routinely employs safeguards such as the following to information systems and paper recordkeeping systems: Multifactor log-in authentication including Common Access Card (CAC) authentication and password; physical token as required; physical and technological access controls governing access to data; network encryption to protect data transmitted over the network; disk encryption securing disks storing data; key management services to safeguard encryption keys; masking of sensitive data as practicable; mandatory information assurance and privacy training for individuals who will have access; identification, marking, and safeguarding of PII; physical access safeguards including multifactor identification physical access controls, detection and electronic alert systems for access to servers and other network infrastructure; and electronic intrusion detection systems in DoD facilities.

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should follow the procedures in 32 CFR part 310. Individuals should address written inquiries to the Office of the Secretary of Defense/Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington, DC 20301–1155. Signed written requests should contain the name and number of this system of records notice along with the full name, current address, and email address of the individual. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend or correct the content of records about them should follow the procedures in 32 CFR part 310.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The DoD has exempted records maintained in this system from 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f) pursuant to 5 U.S.C. 552a(k)(1). In addition, when exempt records received from other systems of records become part of this system, the DoD also claims the same exemptions for those records that are claimed for the prior system(s) of records of which they were a part, and claims any additional exemptions set forth here. An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and published in 32 CFR part 310.

HISTORY:

None.

[FR Doc. 2024–09608 Filed 5–3–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability of Draft Environmental Assessment for DARPA's Reefense Program, Baker Point, Florida

AGENCY: Defense Advanced Research Projects Agency (DARPA), Department of Defense (DoD).

ACTION: Notice; availability of a draft environmental assessment; request for comments.

SUMMARY: DARPA announces the availability of a Draft Environmental Assessment (EA) for the Reefense Program at Baker Point, Florida. DARPA is requesting comment on this draft EA.

DATES: The 30-day public comment period begins on May 6, 2024, and extends to June 5, 2024. Comments must be submitted electronically via the website no later than 11:59 p.m. Eastern Standard Time on June 5, 2024.

ADDRESSES: DARPA invites all interested parties to submit comments on the Draft EA through the project website *https://hsrl.rutgers.edu/research/darpa-reefense.*

FOR FURTHER INFORMATION CONTACT: Dr. Catherine Campbell, 703–526–2044 (Voice), *Catherine.Campbell@darpa.mil* (Email).

SUPPLEMENTARY INFORMATION: Publication of this notice begins the official public comment period for this draft EA. Per the National Environmental Policy Act (NEPA), the purpose of the draft EA is to evaluate the potential direct, indirect, and cumulative impacts caused by the Reefense program at Baker Point, FL. All comments received will become part of the public record and will be available for review.

Background

DARPA proposes to fund the development of bio-hybrid reef structures to help attenuate wave energy and protect United States (U.S.) DoD and coastal infrastructure through the Reefense Program (the Proposed Action). The strategy of DARPA's Reefense program includes employing recent innovations in materials science, hydrodynamic modeling, and adaptive biology to develop growing structures that are optimized to rapidly implement coastal defenses suited to a changing environment. DARPA's Reefense program involves the construction of custom wave-attenuating base structures to promote growth of reef-building organisms (*e.g.,* coral or oysters). The reef-building organisms would enable the Reefense structures to naturally self-heal and keep pace with sea level rise over time. Reefense structures would also include components to attract non-reef building organisms necessary to help maintain a healthy, growing reef. Finally, adaptive biology would enable improved resilience against disease and temperature stress for organisms present, to ensure compatibility with a changing environment. As soon as the Reefense structures are deployed, they would immediately attenuate coastal wave energy. As the structures facilitate the growth of the reef-building organisms, they would provide a biological benefit (*e.g.,* habitat for

mobile reef species) in just a few months or years that would be equivalent to decades of growth for a similarly-sized naturally-occurring reef.

National Environmental Policy Act

This notice is provided pursuant to NEPA regulations at 40 CFR 1506.6 and the draft EA was prepared in accordance with NEPA regulations at 40 CFR parts 1500–1508.

Alternatives Considered

Preferred Alternative: DARPA's proposed action is the deployment of Reefense structures at Baker Point, Florida. Deployment would occur over two phases with multiple components being proposed for each deployment. Components would consist of reef module breakwaters, mosaic oyster habitat structures (varying in height with low, medium, and high relief structures), and intertidal vegetation planting.

No Action Alternative: Under the No Action Alternative, the Proposed Action would not occur. No deployment of Reefense structures would occur within the proposed action area, and the Baker Point area would be left undeveloped unless/until other in-water construction is proposed as part of a future project. The No Action Alternative would not meet the purpose of and need for the Proposed Action because there would be no furthering of research on climate change-related shoreline protection; however, as required by CEQ Regulations (40 CFR 1502.14), the No Action Alternative is carried forward for analysis in this draft EA. The No Action Alternative will be used to analyze the consequences of not undertaking the Proposed Action, not simply conclude no impact, and will serve to establish a comparative baseline for analysis.

DARPA will publish a record of its final action in the **Federal Register**.

Dated: April 30, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09751 Filed 5–3–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Education Innovation and Research (EIR) Program Early-phase Grants

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2024 for the EIR program Early-phase Grants, Assistance Listing Number 84.411C (Early-phase Grants). This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: May 6, 2024.

Deadline for Notice of Intent to Apply: June 6, 2024.

Deadline for Transmittal of Applications: July 22, 2024.

Deadline for Intergovernmental Review: September 20, 2024.

Pre-Application Information: The Department will post additional competition information for prospective applicants on the EIR program website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/*.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs*.

FOR FURTHER INFORMATION CONTACT: Jamila Smith, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–5900. Telephone: (202) 987–1753. Email: *eir@ed.gov*.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The EIR program, established under section 4611 of the Elementary and Secondary Education Act, as amended (ESEA), provides funding to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based (as defined in this notice), field-initiated innovations to improve student achievement and attainment for high-need students and to rigorously evaluate such innovations. The EIR program is designed to generate and validate solutions to persistent education challenges and to support the expansion of those solutions to serve substantially more students.

The central design element of the EIR program is its multitier structure that links the amount of funding an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project, with the expectation that projects that build this evidence will advance through EIR's grant tiers: ''Early-phase,'' ''Mid-phase,'' and ''Expansion.''

''Early-phase,'' ''Mid-phase,'' and ''Expansion'' grants differ in terms of the level of prior evidence of effectiveness required for consideration for funding, the expectations regarding the kind of evidence and information funded projects should produce, the scale of funded projects, and, consequently, the amount of funding available to support each type of project.

Early-phase grants must demonstrate a rationale (as defined in this notice). Early-phase grants provide funding for the development, implementation, and feasibility testing of a program that prior research suggests has promise, for the purpose of determining whether the program can successfully improve student achievement and attainment for high-need students. Early-phase grants are not intended to simply expand established practices or address needs unique to one particular context. Rather, the goal is to determine whether and in what ways relatively new practices can improve student achievement and attainment for high-need students.

This notice invites applications for Early-phase grants only. The notices inviting applications for Mid-phase grants and Expansion grants are published elsewhere in this issue of the **Federal Register**.

Background:

While this notice is for the Early-phase grants tier only, the premise of the EIR program is that new, innovative, and promising educational programs and practices can help to overcome the persistent and significant challenges to student educational opportunity and success, particularly for underserved and high-need students. Raise the Bar: Lead the World is the Department's call to action to transform pre-kindergarten (Pre-K) through grade 12 education and unite around what works in promoting academic excellence, boldly improving learning conditions, and preparing our Nation's students for global competitiveness.[1] Consistent with that

[1] U.S. Secretary of Education Miguel Cardona laid out his vision for the direction the Department will follow in 2024 to promote academic excellence, improve learning conditions, and prepare our students for a world where global engagement is

Continued

call to action, the priorities used in this competition advance Raise the Bar's goals to promote academic excellence and boldly improve learning conditions.

In FY 2024, the Department is particularly interested in projects that propose services and activities that help students recover from the COVID–19 pandemic, accelerate learning and academic achievement, reimagine schools, and transform our education system. Specifically, the Department is focused on improving student achievement and attainment, as highlighted across Administration and Department efforts for the past several years. Building on the Administration's previous efforts, in January 2024, the Administration announced its Improving Student Achievement Agenda,[2] which aims to drive proven strategies that will support academic success for every child in school. The strategies and evidence discussed in the Improving Student Achievement Agenda focus on (1) increasing student attendance; (2) providing high-dosage tutoring; and (3) increasing summer learning and extended or afterschool learning time. These strategies and the broader Improving Student Achievement Agenda, including a focus on core academic instruction, are well aligned with the EIR program purpose, and the new funding to be released through the FY 2024 EIR competition will help accelerate and scale up sustainable adoption of evidence-based strategies that we expect will improve student achievement and attainment in the school years ahead. The priorities in this competition are designed to create conditions under which students have equitable access to high-quality learning opportunities and experiences. For example, projects may include new approaches to instructional design such as through project-based or experiential learning opportunities for students, schoolwide frameworks, such as small schools or learning communities, that support student connection and engagement and increased interagency coordination to improve academic supports for highly mobile students such as students in foster care and students experiencing homelessness.

Note: The EIR program statute refers to ''high-need students'' but does not define the term, which allows applicants to define it for purposes of their proposed project, population, and setting. Addressing the needs of underserved students (as defined in this notice) is one way to address EIR's statutory requirement to serve ''high-need students.'' In particular, the Department welcomes innovative and promising projects that serve disconnected youth, students who are in foster care, and students performing significantly below grade level.

The EIR program is rooted in innovation; the program is not intended to provide support for practices that are already commonly implemented by educators, unless significant adaptations of such practices warrant testing to determine if they can accelerate achievement or increase the likelihood that the practices can be widely, efficiently, and effectively implemented in new populations and settings. If the evaluation demonstrates that innovations are supported by sufficient evidence of effectiveness, they can be replicated and tested in new populations and settings.

As an EIR project is implemented, grantees are encouraged to learn more about how the practices improve student achievement and attainment, as well as to develop increasingly rigorous evidence of effectiveness and new strategies to efficiently and cost-effectively scale to new school districts, regions, and States. To meet the required evidence level, applicants must develop a logic model (as defined in this notice), theory of action, or another conceptual framework that includes the goals, objectives, outcomes, and key project components (as defined in this notice) of the project.

All EIR applicants and grantees should also consider how they will develop their organizational capacity, project financing, and business plans to sustain their projects and continue implementation and adaptation after Federal funding ends. The Department intends to provide grantees with technical assistance to support dissemination, scaling, and sustainability efforts.

Early-phase grant projects are encouraged to make continuous and iterative improvements in project design and implementation before conducting a full-scale evaluation of effectiveness. Applicants should consider how easily others could implement the proposed practice, and how its implementation could potentially be improved. Additionally, applicants should consider using data from early indicators to gauge initial impact and to consider possible changes in implementation that could increase student achievement and attainment.

Early-phase grant projects should develop, implement, and test the feasibility of their projects. The evaluation of an Early-phase grant project should be an experimental or quasi-experimental design study (both as defined in this notice) that can determine whether the program can successfully improve student achievement and attainment for high-need students. Early-phase grant evaluation designs should demonstrate a statistically significant effect on improving student outcomes or other relevant outcomes (as defined in this notice) based on moderate evidence (as defined in this notice) from at least one well-designed and well-implemented experimental or quasi-experimental design study. The Department intends to provide EIR grantees (including the independent evaluators they contract with as part of their project) with evaluation technical assistance. This could include grantees and their independent evaluators providing to the Department or its contractor updated comprehensive evaluation plans in a format as requested by the technical assistance provider and using such tools as the Department may request. Grantees will be encouraged to update this evaluation plan at least annually to reflect any changes to the evaluation with updates consistent with the scope and objectives of the approved application.

The FY 2024 Early-phase grants competition includes five absolute priorities and two competitive preference priorities. All Early-phase grant applicants must address Absolute Priority 1. Early-phase grant applicants are also required to address one of the other four absolute priorities (applicants may not submit under more than one of the other four absolute priorities). All applicants have the option of addressing the competitive preference priorities and may opt to do so regardless of the absolute priority they select.

Absolute Priority 1—Demonstrates a Rationale establishes the evidence required for this tier of grants. All Early-phase grants applicants must submit prior evidence of effectiveness that demonstrates a rationale.

Absolute Priority 2—Field-Initiated Innovations—General gives applicants the option to propose projects that are field-initiated innovations to improve student achievement and attainment.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Science, Technology, Engineering, and

---

critical to our Nation's standing. In his address Secretary Cardona remarked that ''Raise the Bar: Lead the World'' is not a list of new priorities, but a call to strengthen our will to transform education for the better, building on approaches that we know work in education. More information is available at *https://www.ed.gov/raisethebar.*

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/17/fact-sheet-biden-harris-administration-announces-improving-student-achievement-agenda-in-2024/.*

Mathematics (STEM) is intended to support innovations to improve student achievement and attainment in the STEM education field, consistent with efforts to ensure our Nation's economic competitiveness by improving and expanding STEM learning and engagement.

In Absolute Priority 3, the Department recognizes the importance of funding pre-K through grade 12 STEM education and anticipates that projects would expand opportunities for high-need students. Within this absolute priority, applicants may focus on expanding opportunities in STEM education, including computer science, for underrepresented students in STEM education, including students of color, girls, English learners, students with disabilities, youth from rural communities, and youth from families living at or below the poverty line, to help reduce the enrollment and achievement gaps in a manner consistent with nondiscrimination requirements contained in Federal civil rights laws.

Absolute Priority 4—Field-Initiated Innovations—Meeting Student Social, Emotional, and Academic Needs is intended to promote high-quality social and emotional learning projects. The disruption caused by the pandemic, along with the growth in youth mental health distress, continue to impact student well-being. It is critical to address students' social and emotional needs, not only to benefit student well-being, but also to support their academic success, as student social, emotional, and academic development are interconnected.

Absolute Priority 5—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Educator Recruitment and Retention is intended to elevate and strengthen the educator workforce in ways that prioritize innovation in recruiting and retaining educators to better support high-need students. Applicants are encouraged to address fundamental challenges that schools face in recruiting and retaining fully qualified educators, by addressing the responsibilities and challenges educators continue to face after the pandemic. For example, projects may be designed to improve supports for educators that enhance the ability of schools to recruit and retain staff (*e.g.,* strategies to support educator wellbeing or structuring staffing and schedules to ensure educators and students are appropriately supported, and have sufficient time for planning, collaboration, working with coaches, and observing instruction of other educators) and increase access to leadership opportunities that can lead to increased pay and improved retention for fully certified, experienced, and effective educators, while expanding the impact of great teachers within and beyond their classrooms. Projects may support the recruitment and retention of all school staff or specific staff with acute recruitment and retention challenges (*e.g.,* personnel serving children or students with disabilities).

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners is intended to encourage applicants to propose projects that promote partnerships with entities underrepresented under this program. The Department is eager to increase the volume of projects and partners from entities such as community colleges (as defined in this notice), Historically Black colleges and universities (as defined in this notice), Tribal Colleges and Universities (as defined in this notice), and minority-serving institutions (as defined in this notice). The Department expects applicants addressing this priority will raise the bar to reimagine schools through partnerships with underrepresented groups in ways that benefit underserved and high-need students.

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Supports reflects the Administration's ongoing commitment to addressing the impact of the COVID–19 pandemic on Pre-K through grade 12 education. The pandemic caused unprecedented disruption in schools across the country and drew renewed attention to the ongoing challenges for underserved students. In response to the pandemic, educators mobilized to address the needs of all students. Researchers, educators, parents, and policymakers are continuing to work to understand and address the impact of inconsistent access to instruction, enrichment, peers, services and supports, and the impact of other related challenges. We also know that for students in underserved communities, inequities in educational opportunity and outcomes existed previously, yet were exacerbated by the pandemic.[3] The impact of the COVID–19 pandemic changed the education landscape, especially as students continue to make up for lost classroom instruction. However, it also provides an opportunity to redesign how schools approach teaching and learning in ways that both address long-standing gaps in educational opportunity and better prepare students for college and careers. Over 14 million public school students (31 percent) missed at least 10 percent of school in school year 2021–2022.[4] According to analysis by the Council of Economic Advisors, absenteeism accounted for up to 27 percent of the test score declines in math and 45 percent of the test score declines in reading on the National Assessment of Educational Progress.[5] To that end, the Department seeks projects that develop and evaluate evidence-based, field-initiated innovations to address challenges and inequities caused by the COVID–19 pandemic. The proposed innovations should be designed to better enable students to access the educational opportunities they need to succeed in school and reach their full potential.

Through these priorities, the Department intends to advance innovation, build evidence, and address the learning and achievement of underserved and high-need students in Pre-K through grade 12.

Priorities: This notice includes five absolute priorities and two competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(ii), Absolute Priority 1 is from the Administrative Priorities for Discretionary Grant Programs published in the **Federal Register** on March 9, 2020 (85 FR 13640) (Administrative Priorities). In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 2 is from section 4611(a)(1)(A) of the ESEA. In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priorities 3, 4, and 5 are from section 4611(a)(1)(A) of the ESEA and the Supplemental Priorities and Definitions for Discretionary Grants Programs, published in the **Federal Register** on December 10, 2021 (86 FR 70612) (Supplemental Priorities). The

[3] Dorn, E., Hancock, B., Sarakatsannis, J., & Viruleg, E. (2021, July 27). COVID–19 and education: The lingering effects of unfinished learning. McKinsey & Company. *https://www.mckinsey.com/industries/education/our-insights/covid-19-and-education-the-lingering-effects-of-unfinished-learning.*

[4] U.S. Department of Education. (2023, September 15). Raising the Bar for Consistent School Attendance. *ED.gov* Blog. *https://blog.ed.gov/2023/09/raising-the-bar-for-consistent-school-attendance/.*

[5] The White House. (2023, September 13). Chronic Absenteeism and Disrupted Learning Require an All-Hands-on-Deck Approach | CEA. The White House. *https://www.whitehouse.gov/cea/written-materials/2023/09/13/chronic-absenteeism-and-disrupted-learning-require-an-all-hands-on-deck-approach/.*

competitive preference priorities are from the Supplemental Priorities.

In the Early-phase grant competition, Absolute Priorities 2, 3, 4, and 5 each constitute a separate funding category. The Secretary intends to award grants under each of these absolute priorities provided that applications submitted are of sufficient quality. To ensure that applicants are reviewed under the absolute priority most relevant to their proposed project, applicants must clearly identify the specific absolute priority that the proposed project addresses. If an applicant is interested in proposing separate projects (*e.g.,* one that addresses Absolute Priority 2 and another that addresses Absolute Priority 3), it must submit separate applications.

Absolute Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1 and one additional absolute priority (Absolute Priority 2, Absolute Priority 3, Absolute Priority 4, or Absolute Priority 5).

These priorities are:

Absolute Priority 1—Applications that Demonstrate a Rationale.

Projects that demonstrate a rationale (as defined in this notice).

Absolute Priority 2—Field-Initiated Innovations—General.

Projects that are designed to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: STEM.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Career and technical education programs.

(vi) Out-of-school-time settings.

(vii) Alternative schools and programs.

(viii) Juvenile justice system or correctional facilities; and

(2) That examine the sources of inequity and inadequacy and implement responses, including rigorous, engaging, and well-rounded (*e.g.,* that include music and the arts) approaches to learning that are inclusive with regard to race, ethnicity, culture, language, and disability status and prepare students for college, career, and civic life, including science, technology, engineering, and mathematics (STEM), including computer science coursework.

Absolute Priority 4—Field-Initiated Innovations—Meeting Student Social, Emotional, and Academic Needs.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Improve students' social, emotional, academic, and career development, with a focus on underserved students, through one or more of the following priority areas:

(1) Developing and supporting educator and school capacity to support social and emotional learning and development that—

(i) Fosters skills and behaviors that enable academic progress;

(ii) Identifies and addresses conditions in the learning environment, that may negatively impact social and emotional well-being for underserved students, including conditions that affect physical safety; and

(iii) Is trauma-informed, such as addressing exposure to community-based violence and trauma specific to military- or veteran-connected students (as defined in this notice).

(2) Creating education or work-based settings that are supportive, positive, identity-safe and inclusive with regard to race, ethnicity, culture, language, and disability status, through one or more of the following activities:

(i) Developing trusting relationships between students (including underserved students), educators, families, and community partners.

(ii) Providing high-quality professional development opportunities designed to increase engagement and belonging and build asset-based mindsets for educators working in and throughout schools.

(iii) Engaging students (including underserved students), educators, families, and community partners from diverse backgrounds and representative of the community as partners in school climate review and improvement efforts.

(iv) Developing and implementing inclusive and culturally informed discipline policies and addressing disparities in school discipline policy by identifying and addressing the root causes of those disparities, including by involving educators, students, and families in decision-making about discipline procedures and providing training and resources to educators.

(3) Providing multi-tiered systems of supports that address learning barriers both in and out of the classroom, that enable healthy development and respond to students' needs and which may include evidence-based trauma-informed practices and professional development for educators on avoiding deficit-based approaches.

(4) Developing or implementing policies and practices, consistent with applicable Federal law, that prevent or reduce significant disproportionality on the basis of race or ethnicity with respect to the identification, placement, and disciplining of children or students with disabilities (as defined in this notice).

(5) Providing students equitable access that is inclusive, with regard to race, LGBTQI+, ethnicity, culture, language, and disability status, to social workers, psychologists, counselors, nurses, or mental health professionals and other integrated services and supports, which may include in early learning environments.

(6) Preparing educators to implement project-based or experiential learning opportunities for students to strengthen their metacognitive skills, self-direction, self-efficacy, competency, or motivation, including through instruction that connects to students' prior knowledge and experience; provides rich, engaging, complex, and motivating tasks; and offers opportunities for collaborative learning.

(7) Creating and implementing comprehensive schoolwide frameworks (such as small schools or learning communities, advisory systems, or looping educators) that support strong and consistent student and educator relationships.

(8) Fostering partnerships, including across government agencies (*e.g.,* housing, human services, employment agencies), local educational agencies, community-based organizations, adult learning providers, and postsecondary education institutions, to provide comprehensive services to students and families that support students' social, emotional, mental health, and academic needs, and that are inclusive with regard to race, ethnicity, culture, language, and disability status.

Absolute Priority 5—Field-Initiated Innovations—Promoting Equity in Student Access to Educational

Resources and Opportunities: Educator Recruitment and Retention.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Career and technical education programs.

(vi) Out-of-school-time settings.

(vii) Alternative schools and programs.

(viii) Juvenile justice system or correctional facilities; and

(2) That examine the sources of inequity and inadequacy and implement responses, and that may include one or more of the following:

(i) Increasing the number and proportion of experienced, fully certified, in-field, and effective educators, and educators from traditionally underrepresented backgrounds or the communities they serve, to ensure that underserved students have educators from those backgrounds and communities and are not taught at disproportionately higher rates by uncertified, out-of-field, and novice teachers compared to their peers.

Note: All strategies to increase racial diversity of educators must comply with the nondiscrimination requirements contained in Federal civil rights laws.

(ii) Improving the preparation, recruitment, and early career support and development of educators in shortage areas or hard to staff schools.

(iii) Improving the retention of fully certified, experienced, and effective educators in high-need schools or shortage areas.

Competitive Preference Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 1, and up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 2.

These priorities are:

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners (up to 3 points).

Under this priority, an applicant must demonstrate how the project will be implemented by or in partnership with one or more of the following entities:

(a) Community colleges (as defined in this notice).

(b) Historically Black Colleges and Universities (as defined in this notice).

(c) Tribal Colleges and Universities (as defined in this notice).

(d) Minority-serving institutions (as defined in this notice).

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Supports (up to 3 points).

Projects that are designed to address the impacts of the COVID–19 pandemic, including impacts that extend beyond the duration of the pandemic itself, on the students most impacted by the pandemic, with a focus on underserved students and the educators who serve them through the following priority areas:

(a) Conducting community asset-mapping and needs assessments that may include an assessment of the extent to which students, including subgroups of students, have become disengaged from learning, including students not participating in in-person or remote instruction, and specific strategies for reengaging and supporting students and their families; and

(b) Using evidence-based instructional approaches and supports, such as professional development, coaching, ongoing support for educators, high-quality tutoring, expanded access to rigorous coursework and content across K–12, and expanded learning time to accelerate learning for students in ways that ensure all students have the opportunity to successfully meet challenging academic content standards without contributing to tracking or remedial courses.

Definitions: The following definitions apply to this program. The definitions of ''baseline,'' ''demonstrates a rationale,'' ''experimental study,'' ''logic model,'' ''moderate evidence,'' ''nonprofit,'' ''performance measure,'' ''performance target,'' ''project component,'' ''quasi-experimental design study,'' ''relevant outcome,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1. The definitions of ''community college,'' ''children or students with disabilities,'' ''disconnected youth,'' ''early learning,'' ''educator,'' ''English learner,'' ''historically Black colleges and universities,'' ''military- or veteran-connected student,'' ''minority-serving institutions,'' ''Tribal College or University,'' and ''underserved students'' are from the Supplemental Priorities. The definitions of ''evidence-based,'' ''local educational agency,'' and ''State educational agency'' are from section 8101 of the ESEA.

Baseline means the starting point from which performance is measured and targets are set.

Children or students with disabilities means children with disabilities as defined in section 602(3) of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1401(3)) and 34 CFR 300.8, or students with disabilities, as defined in the Rehabilitation Act of 1973 (29 U.S.C. 705(37), 705(202)(B)).

Community college means ''junior or community college'' as defined in section 312(f) of the Higher Education Act of 1965, as amended (HEA).

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Disconnected youth means an individual, between the ages 14 and 24, who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution.

Early learning means any (a) State-licensed or State-regulated program or provider, regardless of setting or funding source, that provides early care and education for children from birth to kindergarten entry, including, but not limited to, any program operated by a child care center or in a family child care home; (b) program funded by the Federal Government or State or local educational agencies (including any IDEA-funded program); (c) Early Head Start and Head Start program; (d) nonrelative child care provider who is not otherwise regulated by the State and who regularly cares for two or more unrelated children for a fee in a provider setting; and (e) other program that may deliver early learning and development services in a child's home, such as the Maternal, Infant, and Early Childhood Home Visiting Program; Early Head Start; and Part C of IDEA.

Educator means an individual who is an early learning educator, teacher, principal or other school leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early

intervention service personnel), paraprofessional, or faculty.

English learner means an individual who is an English learner as defined in section 8101(20) of the ESEA, or an individual who is an English language learner as defined in section 203(7) of the Workforce Innovation and Opportunity Act.

Evidence-based means an activity, strategy, or intervention that—

(i) Demonstrates a statistically significant effect on improving student outcomes or other relevant outcomes based on—

(I) Strong evidence from at least 1 well-designed and well-implemented experimental study;

(II) Moderate evidence from at least 1 well-designed and well-implemented quasi-experimental study; or

(III) Promising evidence from at least 1 well-designed and well-implemented correlational study with statistical controls for selection bias; or

(ii)(I) Demonstrates a rationale based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes; and

(II) Includes ongoing efforts to examine the effects of such activity, strategy, or intervention.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks (as defined in this notice):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Historically Black colleges and universities means colleges and universities that meet the criteria set out in 34 CFR 608.2.

Local educational agency (LEA) means:

(a) In General. A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) Administrative Control and Direction. The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) Bureau of Indian Education Schools. The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the LEA receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any State educational agency (SEA) (as defined in this notice) other than the Bureau of Indian Education.

(d) Educational Service Agencies. The term includes educational service agencies and consortia of those agencies.

(e) State Educational Agency. The term includes the SEA in a State in which the SEA is the sole educational agency for all public schools.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Military- or veteran-connected student means one or more of the following:

(a) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a member of the uniformed services (as defined by 37 U.S.C. 101), in the Army, Navy, Air Force, Marine Corps, Coast Guard, Space Force, National Guard, Reserves, National Oceanic and Atmospheric Administration, or Public Health Service or is a veteran of the uniformed services with an honorable discharge (as defined by 38 U.S.C. 3311).

(b) A student who is a member of the uniformed services, a veteran of the uniformed services, or the spouse of a service member or veteran.

(c) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a veteran of the uniformed services (as defined by 37 U.S.C. 101).

Minority-serving institution means an institution that is eligible to receive assistance under sections 316 through 320 of part A of title III, under part B of title III, or under title V of the HEA.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study (as defined in this notice) or quasi-experimental design study (as defined in this notice) reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department

using version 4.1 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Nonprofit, as applied to an agency, organization, or institution, means that it is owned and operated by one or more corporations or associations whose net earnings do not benefit, and cannot lawfully benefit, any private shareholder or entity.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

State educational agency (SEA) means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

Tribal College or University has the meaning ascribed it in section 316(b)(3) of the HEA.

Underserved student means a student (which may include children in early learning environments, students in K–12 programs, and students in postsecondary education or career and technical education, as appropriate) in one or more of the following subgroups:

(a) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(b) A student of color.

(c) A student who is a member of a federally recognized Indian Tribe.

(d) An English learner.

(e) A child or student with a disability.

(f) A disconnected youth.

(g) A migrant student.

(h) A student experiencing homelessness or housing insecurity.

(i) A lesbian, gay, bisexual, transgender, queer or questioning, or intersex (LGBTQI+) student.

(j) A student who is in foster care.

(k) A student without documentation of immigration status.

(l) A pregnant, parenting, or caregiving student.

(m) A student impacted by the justice system, including a formerly incarcerated student.

(n) A student who is the first in their family to attend postsecondary education.

(o) A student performing significantly below grade level.

(p) A military- or veteran-connected student.

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 4.1), as well as the more recent What Works Clearinghouse Handbooks released in August 2022 (Version 5.0), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Program Authority: 20 U.S.C. 7261.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Administrative Priorities. (e) The Supplemental Priorities.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $251,000,000.

These estimated available funds are the total available for new awards for all three types of grants under the EIR program (Early-phase, Mid-phase, and Expansion grants).

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Average Size of Awards: Up to $6,000,000.

Maximum Award: We will not make an award exceeding $6,000,000 for a project period of 60 months. Under 34 CFR 75.104(b) the Secretary may reject, without consideration or evaluation, any application that proposes a project funding level that exceeds the stated maximum award amount. The Department intends to fund one or more projects under each of the EIR competitions, including Expansion grants (84.411A), Mid-phase grants (84.411B), and Early-phase grants (84.411C). Entities may submit applications for different projects for more than one competition (Early-phase grants, Mid-phase grants, and Expansion grants). The combined maximum new award amount a grantee may receive under these three competitions is $16,000,000. If an entity is within the funding range for multiple applications,

the Department will award the highest scoring applications up to $16,000,000.

Estimated Number of Awards: 13–23.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Note: Under section 4611(c) of the ESEA, the Department must use at least 25 percent of EIR funds for a fiscal year to make awards to applicants serving rural areas, contingent on receipt of a sufficient number of applications of sufficient quality. For purposes of this competition, we will consider an applicant as rural if the applicant meets the qualifications for rural applicants as described in the *Eligible Applicants* section and the applicant certifies that it meets those qualifications through the application. In implementing this statutory provision and program requirement, the Department may fund high-quality applications from rural applicants out of rank order in the Early-phase grants competition. In addition, from the estimated funds for this competition, the Department intends to award an estimated $87 million in funds for STEM projects and $87 million in funds for social and emotional learning projects, contingent on receipt of a sufficient number of applications of sufficient quality.

III. Eligibility Information

1. *Eligible Applicants:*

(a) An LEA;

(b) An SEA;

(c) The Bureau of Indian Education (BIE);

(d) A consortium of SEAs or LEAs;

(e) A nonprofit (as defined in this notice) organization; and

(f) An LEA, an SEA, the BIE, or a consortium described in clause (d), in partnership with—

(1) A nonprofit organization;

(2) A business;

(3) An educational service agency; or

(4) An IHE.

To qualify as a rural applicant under the EIR program, an applicant must meet both of the following requirements:

(a) The applicant is—

(1) An LEA with an urban-centric district locale code of 32, 33, 41, 42, or 43, as determined by the Secretary;

(2) A consortium of such LEAs;

(3) An educational service agency or a nonprofit organization in partnership with such an LEA; or

(4) A grantee described in clause (1) or (2) in partnership with an SEA; and

(b) A majority of the schools to be served by the program are designated with a locale code of 32, 33, 41, 42, or 43, or a combination of such codes, as determined by the Secretary.

Applicants are encouraged to retrieve locale codes from the National Center for Education Statistics School District search tool (*https://nces.ed.gov/ccd/districtsearch/*), where districts can be looked up individually to retrieve locale codes, and the Public School search tool (*https://nces.ed.gov/ccd/schoolsearch/*), where individual schools can be looked up to retrieve locale codes. More information on rural applicant eligibility will be in the application package for this competition.

Note: An applicant that is a nonprofit organization may, under 34 CFR 75.51, demonstrate its nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

In addition, with respect to IHEs and their affiliates, the following entities may apply for a grant in this competition: (1) As noted above, any IHE that is a partner in an application submitted by an LEA, SEA, BIE, consortium of SEAs or LEAs, or a nonprofit organization; (2) A private IHE that is a nonprofit organization may apply for an EIR grant; (3) A nonprofit organization, such as a development foundation, that is affiliated with a public IHE; and (4) A public IHE with 501(c)(3) status. A public IHE without 501(c)(3) status (even if that entity is tax exempt under Section 115 of the Internal Revenue Code or any other State or Federal provision), or that could not provide any other documentation of nonprofit status described above, however, would not qualify as a nonprofit organization, and therefore would not be eligible to apply for and receive an EIR grant.

2. a. *Cost Sharing or Matching:* Under section 4611(d) of the ESEA, each grant recipient must provide, from Federal, State, local, or private sources, an amount equal to 10 percent of funds provided under the grant, which may be provided in cash or through in-kind contributions, to carry out activities supported by the grant. Applicants must include a budget showing their matching contributions to the budget amount of EIR grant funds and must provide evidence of their matching contributions for the first year of the grant in their grant applications.

Section 4611(d) of the ESEA authorizes the Secretary to waive the matching requirement on a case-by-case basis, upon a showing of exceptional circumstances, such as:

(i) The difficulty of raising matching funds for a program to serve a rural area;

(ii) The difficulty of raising matching funds in areas with a concentration of LEAs or schools with a high percentage of students aged 5 through 17—

(A) Who are in poverty, as counted in the most recent census data approved by the Secretary;

(B) Who are eligible for a free or reduced-price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*);

(C) Whose families receive assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 *et seq.*); or

(D) Who are eligible to receive medical assistance under the Medicaid program; and

(iii) The difficulty of raising funds on Tribal land.

An applicant that wishes to apply for a waiver must include a request in its application, describing the exceptional circumstances that make it difficult for the applicant to meet the matching requirement. Further information about applying for waivers can be found in the application package for this competition.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Other:* a. *Funding Categories:* An applicant will be considered for an award only for the type of EIR grant for which it applies (*i.e.,* Early-phase: Absolute Priority 2, Early-phase:

Absolute Priority 3, or Early-phase: Absolute Priority 4). An applicant may not submit an application for the same proposed project under more than one type of grant (*e.g.,* both an Early-phase grant and Mid-phase grant).

Note: Each application will be reviewed under the competition in which it was submitted in the *Grants.gov* system, and only applications that are successfully submitted by the established deadline will be peer reviewed. Applicants should be careful that they download the intended EIR application package and that they submit their applications under the intended EIR competition.

b. *Evaluation:* The grantee must conduct an independent evaluation of the effectiveness of its project.

c. *High-need students:* The grantee must serve high-need students.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for Early-phase grants, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, will address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative for an Early-phase grant to no more than 25 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; one-page abstract; evidence form; or appendices (*e.g.,* nonprofit documentation, resumes, letters of support, demonstration of match, matching waiver request, list of proprietary information, eligibility checklist, logic model, indirect cost rate agreement). However, the recommended page limit does apply to the entire application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. Applicants may access this form using the link available on the Notice of Intent to Apply section of the competition website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/.* Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for the Early-phase grant competition are from 34 CFR 75.210. The points assigned to each criterion are indicated in the parentheses next to the criterion. Together with the competitive preference priorities, an applicant may earn up to a total of 106 points based on the selection criteria for the application.

A. *Significance (up to 20 points).*

The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies.

B. *Quality of the Project Design (up to 30 points).*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework. (10 points)

(2) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (5 points)

(3) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (15 points)

C. *Quality of Project Personnel (up to 10 points).*

The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel.

D. *Quality of the Management Plan (up to 10 points).*

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan, the Secretary considers the adequacy of the

management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

E. *Quality of the Project Evaluation (up to 30 points).*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards with or without reservations as described in the What Works Clearinghouse Handbook (as defined in this notice). (20 points)

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (5 points)

(3) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation. (5 points)

Note: Applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbooks: *https://ies.ed.gov/ncee/wwc/Handbooks;* (2) ''Technical Assistance Materials for Conducting Rigorous Impact Evaluations'': *http://ies.ed.gov/ncee/projects/evaluationTA.asp;* and (3) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.* In addition, applicants may view an optional webinar recording that was hosted by the Institute of Education Sciences. The webinar focused on more rigorous evaluation designs, discussing strategies for designing and executing experimental studies that meet WWC evidence standards without reservations. This webinar is available at: *https://ies.ed.gov/ncee/wwc/Multimedia/18.*

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine whether applications have met eligibility and other requirements. This screening process may occur at various stages of the process; applicants that are determined to be ineligible will not receive a grant, regardless of peer reviewer scores or comments.

Peer reviewers will read, prepare a written evaluation of, and score the assigned applications, using the selection criteria provided in this notice.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department

grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded Early-phase grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

Note: The evaluation report is a specific deliverable under an Early-phase grant that grantees must make available to the public. Additionally, EIR grantees are encouraged to submit final studies from research supported in whole or in part by EIR to the Educational Resources Information Center (*http://eric.ed.gov*).

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

5. *Performance Measures:* For the purpose of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures (as defined in this notice) for the Early-phase grants.

Annual performance measures: (1) The percentage of grantees that reach their annual target number of students as specified in the application; (2) the percentage of grantees that reach their annual target number of high-need students as specified in the application; (3) the percentage of grantees with ongoing well-designed and independent evaluations designed to provide performance feedback to inform project design; (4) the percentage of grantees with ongoing well-designed and independent evaluations that will provide evidence of their effectiveness at improving student outcomes; (5) the percentage of grantees that implement an evaluation that provides information about the key elements and the approach of the project to facilitate testing, development, or replication in other settings; and (6) the cost per student served by the grant.

Cumulative performance measures: (1) The percentage of grantees that reach the targeted number of students specified in the application; (2) the percentage of grantees that reach the targeted number of high-need students specified in the application; (3) the percentage of grantees that use evaluation data to make changes to their practice(s); (4) the percentage of grantees that complete a well-designed, well-implemented, and independent evaluation that provides evidence of their effectiveness at improving student outcomes; (5) the percentage of grantees with a completed evaluation that provides information about the key elements and the approach of the project so as to facilitate testing, development, or replication in other settings; and (6) the cost per student served by the grant.

Project-Specific Performance Measures: Applicants must propose project-specific performance measures and performance targets (both as defined in this notice) consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) Performance measures. How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) Baseline (as defined in this notice) data. (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) Performance targets. Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) Data collection and reporting. (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other

documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Adam Schott,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2024–09797 Filed 5–3–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Education Innovation and Research (EIR) Program Mid-Phase Grants

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2024 for the EIR program Mid-phase Grants, Assistance Listing Number 84.411B (Mid-phase Grants). This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: May 6, 2024.

Deadline for Notice of Intent to Apply: June 06, 2024.

Deadline for Transmittal of Applications: July 05, 2024.

Deadline for Intergovernmental Review: September 03, 2024.

Pre-Application Information: The Department will post additional competition information for prospective applicants on the EIR program website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Jamila Smith, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–5900. Telephone: 202–987–1753. Email: *eir@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The EIR program, established under section 4611 of the Elementary and Secondary Education Act, as amended (ESEA), provides funding to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based (as defined in this notice), field-initiated innovations to improve student achievement and attainment for high-need students; and to rigorously evaluate such innovations. The EIR program is designed to generate and validate solutions to persistent education challenges and to support the expansion of those solutions to serve substantially more students.

The central design element of the EIR program is its multi-tier structure that links the amount of funding an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project. One of the program's goals is for projects to build evidence that will allow them to advance through EIR's grant tiers: ''Early-phase,'' ''Mid-phase,'' and ''Expansion.''

''Early-phase,'' ''Mid-phase,'' and ''Expansion'' grants differ in terms of the evidence of effectiveness required to be considered for funding, the expectations regarding the kind of evidence and information funded projects should produce, the scale of funded projects, and, consequently, the amount of funding available to support each type of project.

Mid-phase grants are supported by moderate evidence (as defined in this notice). Mid-phase grants provide funding for the implementation and rigorous evaluation of a program that has been successfully implemented under an Early-phase grant or other similar effort, such as developing and testing an innovative education practice at a local level, for the purpose of measuring the program's impact and cost-effectiveness.

This notice invites applications for Mid-phase grants only. The notices inviting applications for Early-phase grants and Expansion grants are published elsewhere in this issue of the **Federal Register**.

Background:

While this notice is for the Mid-phase grants tier only, the premise of the EIR program is that new, effective, and innovative educational programs and practices can help to overcome the persistent and significant challenges to student educational opportunity and success, particularly for underserved and high-need students. Raise the Bar: Lead the World is the Department's call to action to transform pre-kindergarten (Pre-K) through grade 12 education and unite around what truly works by promoting academic excellence, boldly improving learning conditions, and preparing our Nation's students for global competitiveness.[1] Consistent with that call to action, the priorities used in this competition advance Raise the Bar's goals to promote academic excellence and boldly improve learning conditions.

In FY 2024, the Department is particularly interested in projects that propose services and activities that help students recover from the COVID–19 pandemic, accelerate learning and academic achievement, reimagine schools, and transform our education system. Specifically, the Department is focused on improving student achievement and attainment, as highlighted across Administration and Department efforts for the past several years. Building on the Administration's previous efforts, in January 2024, the Administration announced its Improving Student Achievement Agenda,[2] which aims to drive proven strategies that will support academic success for every child in school. The strategies and evidence discussed in the Improving Student Achievement Agenda focus on (1) increasing student attendance; (2) providing high-dosage tutoring; and (3) increasing summer learning and extended or afterschool learning time. These strategies and the

[1] U.S. Secretary of Education Miguel Cardona laid out his vision for the direction the Department will follow in 2024 to promote academic excellence, improve learning conditions, and prepare students for a world where global engagement is critical to our Nation's standing. In his address, Secretary Cardona remarked that ''Raise the Bar: Lead the World'' is not a list of new priorities, but a call to strengthen our will to transform education for the better, building on approaches that we know work in education. More information is available at *https://www.ed.gov/raisethebar.*

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/17/fact-sheet-biden-harris-administration-announces-improving-student-achievement-agenda-in-2024/.*

broader Improving Student Achievement Agenda, including a focus on core academic instruction, are well aligned with the EIR program purpose, and the new funding to be released through the FY 2024 EIR competition will help accelerate and scale up sustainable adoption of evidence-based strategies that we expect will improve student achievement and attainment in the school years ahead. The priorities in this competition are designed to create conditions under which students have equitable access to high-quality learning opportunities and experiences. For example, projects may include new approaches to instructional design such as through project-based or experiential learning opportunities for students, schoolwide frameworks, such as small schools or learning communities, that support student connection and engagement and increased interagency coordination to improve academic supports for highly mobile students such as students in foster care and students experiencing homelessness.

Note: The EIR program statute refers to ''high-need students'' but does not define the term, which allows applicants to define it for purposes of their proposed project, population, and setting. Addressing the needs of underserved students (as defined in this notice) is one way to address EIR's statutory requirement to serve ''high-need students.'' In particular, the Department welcomes innovative and effective projects that serve disconnected youth, students who are in foster care, and students performing significantly below grade level.

The EIR program is rooted in innovation; the program is not intended to provide support for practices that are already commonly implemented by educators, unless significant adaptations and evaluation of such practices might determine if they can accelerate achievement or increase the likelihood that the practices can be widely, efficiently, and effectively implemented in new populations and settings. If the evaluation demonstrates that innovations are supported by moderate or strong evidence (as defined in this notice), then EIR seeks applicants who can replicate and test these innovations in new populations and settings.

As an EIR project is implemented, grantees are encouraged to learn more about how the practices improve student achievement and attainment as well as to develop increasingly rigorous evidence of effectiveness and new strategies to efficiently and cost-effectively scale to new school districts, regions, and States. We encourage applicants to develop a logic model (as defined in this notice), theory of action, or another conceptual framework that includes the goals, objectives, outcomes, and key project components (as defined in this notice) of the project that can support systems of continuous improvement.

All EIR applicants and grantees should also consider how they will develop their organizational capacity, project financing, and business plans to sustain their projects and continue implementation and adaptation after Federal funding ends. The Department intends to provide grantees with technical assistance to support dissemination, scaling, and sustainability efforts.

Mid-phase grant projects are expected to refine and expand the use of practices with prior evidence of effectiveness to improve outcomes for underserved and high-need students. They are also expected to generate information about an intervention's effectiveness, such as for whom and in which contexts a practice is most effective, including cost considerations such as economies of scale. Mid-phase grant projects are uniquely positioned to help answer questions about the process of scaling a practice to the regional or national levels (both as defined in this notice) across geographies as well as locale types. Mid-phase grant projects are encouraged to consider how the cost structure of a practice can change as the intervention scales. Additionally, grantees may want to consider how their project will balance implementation fidelity and flexibility for scaling.

As Mid-phase grant applicants are developing their required program evaluation, they are encouraged to design it with the potential to meet strong evidence. Mid-phase grants should measure the cost-effectiveness of their practices using administrative or other readily available data. These types of efforts are critical to sustaining and scaling EIR-funded effective practices after the EIR grant period ends, assuming that the practice has positive effects on important student outcomes. To support adoption or replication by other entities, the evaluation of a Mid-phase grant project should identify and codify the core elements of the EIR-supported practice that the project implements and examine the effectiveness of the project for any new populations or settings included in the project. The Department intends to provide grantees (including the independent evaluators they contract with as part of their project) with evaluation technical assistance. This could include grantees and their independent evaluators providing to the Department or its contractor updated comprehensive evaluation plans in a format as requested by the technical assistance provider and using such tools as the Department may request. Grantees will be encouraged to update this evaluation plan at least annually to reflect any changes to the evaluation, with updates consistent with the scope and objectives of the approved application.

The FY 2024 Mid-phase grant competition includes five absolute priorities and two competitive preference priorities. All Mid-phase grant applicants must address Absolute Priority 1. Mid-phase grant applicants are also required to address one of the other four absolute priorities (applicants may not submit under more than one of the other four absolute priorities). All applicants have the option of addressing the competitive preference priorities and may opt to do so regardless of the absolute priority they select.

Absolute Priority 1—Moderate Evidence establishes the evidence requirement for this tier of grants. All Mid-phase grants applicants must submit prior evidence of effectiveness that meets the moderate evidence standard.

Absolute Priority 2—Field-Initiated Innovations—General gives applicants the option to propose projects that are field-initiated innovations to improve student achievement and attainment.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Science, Technology, Engineering, and Mathematics (STEM) is intended to support innovations to improve student achievement and attainment in the STEM education field, consistent with efforts to ensure our Nation's economic competitiveness by improving and expanding STEM learning and engagement.

In Absolute Priority 3, the Department recognizes the importance of funding pre-K through grade 12 STEM education and anticipates that projects will expand opportunities for high-need students. Within this absolute priority, applicants may focus on expanding opportunities in STEM education, including computer science, for underrepresented students in STEM education, including students of color, girls, English learners, students with disabilities, youth from rural communities, and youth from families living at or below the poverty line, to help reduce the enrollment and achievement gaps in a manner consistent with nondiscrimination

requirements contained in Federal civil rights laws.

Absolute Priority 4—Field-Initiated Innovations—Meeting Student Social, Emotional, and Academic Needs is intended to promote high-quality projects that support student well-being. The disruption caused by the pandemic, along with the growth in youth mental health distress, continue to impact student well-being. It is critical to address students' social and emotional needs, not only to benefit student well-being, but also to support their academic success, as student social, emotional, and academic development are interconnected.

Absolute Priority 5—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Educator Recruitment and Retention is intended to identify and scale up models to elevate and strengthen the educator workforce in ways that prioritize innovation in recruiting and retaining educators to better support high-need students. Applicants are encouraged to address fundamental challenges schools face in recruiting and retaining qualified educators by addressing the responsibilities and challenges educators continue to face after the pandemic. For example, projects may be designed to improve supports for educators that enhance the ability of schools to recruit and retain staff (*e.g.,* strategies to support educator wellbeing; or structuring staffing and schedules to ensure educators and students are appropriately supported, and have sufficient time for planning, collaboration, and observing instruction of other educators) and increase access to leadership opportunities that can lead to increased pay and improved retention for fully certified, experienced, and effective educators, while expanding the impact of great teachers within and beyond their classrooms. Projects may support the recruitment and retention of all school staff or specific staff with acute recruitment and retention challenges (*e.g.,* personnel serving children or students with disabilities).

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners is intended to encourage applicants to propose projects that involve (as applicants or partners) entities underrepresented in the program's portfolio of grants. The Department is eager to increase the volume of projects and partners from entities such as community colleges (as defined in this notice), Historically Black colleges and universities (as defined in this notice), Tribal Colleges and Universities (as defined in this notice), and minority-serving institutions (as defined in this notice). The Department expects applicants addressing this priority will raise the bar to reimagine schools through partnerships with underrepresented groups in ways that benefit underserved and high-need students.

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Support reflects the Administration's ongoing commitment to addressing the impact of the COVID–19 pandemic on Pre-K through grade 12 education. The pandemic caused unprecedented disruption in schools across the country and drew renewed attention to the ongoing challenges for underserved students. In response to the pandemic, educators mobilized to address the needs of all students. Researchers, educators, parents, and policymakers are working to understand and address the impact of inconsistent access to instruction, enrichment, peers, and services and supports, and the impact of other related challenges. We also know that for students in underserved communities, inequities in educational opportunity and outcomes existed previously, yet they were exacerbated by the pandemic.[3] The impact of the COVID–19 pandemic changed the education landscape, especially as students continue to make up for lost classroom instruction. However, it also provides an opportunity to redesign how schools approach teaching and learning in ways that both address long-standing gaps in educational opportunity and better prepare students for college and careers. Over 14 million public school students (31 percent) missed at least 10 percent of school in school year 2021–2022.[4] According to analysis by the Council of Economic Advisors, absenteeism accounted for up to 27 percent of the test score declines in math and 45 percent of the test score declines in reading on the National Assessment of Educational Progress.[5] To that end, the Department seeks projects that develop and evaluate evidence-based, field-initiated innovations to addresses these challenges and inequities. The proposed innovations should be designed to better enable students to access the educational opportunities they need to succeed in school and reach their full potential.

Through these priorities, the Department intends to advance innovation, build evidence, and address the learning and achievement of underserved and high-need students in Pre-K through grade 12.

Priorities: This notice includes five absolute priorities and two competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(ii), Absolute Priority 1 is from regulations (34 CFR 75.226(d)(2)). In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 2 is from section 4611(a)(1)(A) of the ESEA. In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priorities 3, 4, and 5 are from section 4611(a)(1)(A) of the ESEA and the Supplemental Priorities and Definitions for Discretionary Grants Programs, published in the **Federal Register** on December 10, 2021 (86 FR 70612) (Supplemental Priorities). The competitive preference priorities are from the Supplemental Priorities.

In the Mid-phase grants competition, Absolute Priorities 2, 3, 4, and 5 each constitutes a separate funding category. The Secretary intends to award grants under each of these absolute priorities provided that applications submitted are of sufficient quality. To ensure that applicants are reviewed under the absolute priority most relevant to their proposed project, applicants must clearly identify the specific absolute priority that the proposed project addresses. If an applicant is interested in proposing separate projects (*e.g.,* one that addresses Absolute Priority 2 and another that addresses Absolute Priority 3), it must submit separate applications.

Absolute Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1—Moderate Evidence, and one additional absolute priority (Absolute

[3] Dorn, E., Hancock, B., Sarakatsannis, J., & Viruleg, E. (2021, July 27). COVID–19 and education: The lingering effects of unfinished learning. McKinsey & Company. *https://www.mckinsey.com/industries/education/our-insights/covid-19-and-education-the-lingering-effects-of-unfinished-learning.*

[4] U.S. Department of Education. (2023, September 15). Raising the Bar for Consistent School Attendance. *ED.gov* Blog. *https://blog.ed.gov/2023/09/raising-the-bar-for-consistent-school-attendance/.*

[5] The White House. (2023, September 13). Chronic Absenteeism and Disrupted Learning Require an All-Hands-on-Deck Approach | CEA. The White House. *https://www.whitehouse.gov/cea/written-materials/2023/09/13/chronic-absenteeism-and-disrupted-learning-require-an-all-hands-on-deck-approach/.*

Priority 2, Absolute Priority 3, Absolute Priority 4, or Absolute Priority 5).

These priorities are:

Absolute Priority 1—Moderate Evidence.

Projects supported by evidence that meets the conditions in the definition of ''moderate evidence.''

Note: An applicant must identify up to two studies to be reviewed against the What Works Clearinghouse (WWC) Handbooks (as defined in this notice) for the purposes of meeting the definition of ''moderate evidence.'' The studies may have been conducted by the applicant or by a third party. An applicant must clearly identify the citations for each study in the Evidence form. An applicant must ensure that all cited studies are available to the Department from publicly available sources and provide links or other guidance indicating where each is available. The Department may not review a study that an applicant fails to clearly identify for review.

In addition to including up to two study citations, an applicant must provide in the Evidence form the following information: (1) the positive student outcomes the applicant intends to replicate under its Mid-phase grant and how these outcomes correspond to the positive student outcomes in the cited studies; (2) the characteristics of the population or setting to be served under its Mid-phase grant and how these characteristics correspond to the characteristics of the population or setting in the cited studies; and (3) the practice(s) the applicant plans to implement under its Mid-phase grant and how the practice(s) correspond with the practice(s) in the cited studies.

If the Department determines that an applicant has provided insufficient information, the applicant will not have an opportunity to provide additional information. However, if the WWC team reviewing evidence determines that a study does not provide enough information on key aspects of the study design, such as sample attrition or equivalence of intervention and comparison groups, the WWC may submit a query to the study author(s) to gather information for use in determining a study rating. Authors would be asked to respond to queries within 10 business days. If the author query remains incomplete within 14 days of the initial contact to the study author(s), the study may be deemed ineligible under the grant competition. After the grant competition closes, the WWC will, for purposes of its own curation of studies, continue to include responses to author queries and make updates to study reviews as necessary. However, no additional information will be considered after the competition closes and the initial timeline established for response to an author query passes.

Absolute Priority 2—Field-Initiated Innovations—General.

Projects that are designed to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: STEM.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Career and technical education programs.

(vi) Out-of-school-time settings.

(vii) Alternative schools and programs.

(viii) Juvenile justice system or correctional facilities; and

(2) That examine the sources of inequity and inadequacy and implement responses, including rigorous, engaging, and well-rounded (*e.g.,* that include music and the arts) approaches to learning that are inclusive with regard to race, ethnicity, culture, language, and disability status and prepare students for college, career, and civic life, including science, technology, engineering, and mathematics (STEM), including computer science coursework.

Absolute Priority 4—Field-Initiated Innovations—Meeting Student Social, Emotional, and Academic Needs.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Improve students' social, emotional, academic, and career development, with a focus on underserved students, through one or more of the following priority areas:

(1) Developing and supporting educator and school capacity to support social and emotional learning and development that—

(i) Fosters skills and behaviors that enable academic progress;

(ii) Identifies and addresses conditions in the learning environment, that may negatively impact social and emotional well-being for underserved students, including conditions that affect physical safety; and

(iii) Is trauma-informed, such as addressing exposure to community-based violence and trauma specific to military- or veteran-connected students (as defined in this notice).

(2) Creating education or work-based settings that are supportive, positive, identity-safe and inclusive with regard to race, ethnicity, culture, language, and disability status, through one or more of the following activities:

(i) Developing trusting relationships between students (including underserved students), educators, families, and community partners.

(ii) Providing high-quality professional development opportunities designed to increase engagement and belonging and build asset-based mindsets for educators working in and throughout schools.

(iii) Engaging students (including underserved students), educators, families, and community partners from diverse backgrounds and representative of the community as partners in school climate review and improvement efforts.

(iv) Developing and implementing inclusive and culturally informed discipline policies and addressing disparities in school discipline policy by identifying and addressing the root causes of those disparities, including by involving educators, students, and families in decision-making about discipline procedures and providing training and resources to educators.

(3) Providing multi-tiered systems of supports that address learning barriers both in and out of the classroom, that enable healthy development and respond to students' needs and which may include evidence-based trauma-informed practices and professional development for educators on avoiding deficit-based approaches.

(4) Developing or implementing policies and practices, consistent with applicable Federal law, that prevent or reduce significant disproportionality on the basis of race or ethnicity with respect to the identification, placement, and disciplining of children or students with disabilities (as defined in this notice).

(5) Providing students equitable access that is inclusive with regard to race, LGBTQI+, ethnicity, culture, language, and disability status, to social

workers, psychologists, counselors, nurses, or mental health professionals and other integrated services and supports, which may include in early learning environments.

(6) Preparing educators to implement project-based or experiential learning opportunities for students to strengthen their metacognitive skills, self-direction, self-efficacy, competency, or motivation, including through instruction that connects to students' prior knowledge and experience; provides rich, engaging, complex, and motivating tasks; and offers opportunities for collaborative learning.

(7) Creating and implementing comprehensive schoolwide frameworks (such as small schools or learning communities, advisory systems, or looping educators) that support strong and consistent student and educator relationships.

(8) Fostering partnerships, including across government agencies (*e.g.,* housing, human services, employment agencies), local educational agencies, community-based organizations, adult learning providers, and postsecondary education institutions, to provide comprehensive services to students and families that support students' social, emotional, mental health, and academic needs, and that are inclusive with regard to race, ethnicity, culture, language, and disability status.

Absolute Priority 5—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Educator Recruitment and Retention.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and

(b) Promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Career and technical education programs.

(vi) Out-of-school-time settings.

(vii) Alternative schools and programs.

(viii) Juvenile justice system or correctional facilities; and

(2) That examine the sources of inequity and inadequacy and implement responses, and that may include one or more of the following:

(i) Increasing the number and proportion of experienced, fully certified, in-field, and effective educators, and educators from traditionally underrepresented backgrounds or the communities they serve, to ensure that underserved students have educators from those backgrounds and communities and are not taught at disproportionately higher rates by uncertified, out-of-field, and novice teachers compared to their peers.

Note: All strategies to increase the diversity of educators must comply with the nondiscrimination requirements contained in Federal civil rights laws.

(ii) Improving the preparation, recruitment, and early career support and development of educators in shortage areas or hard to staff schools.

(iii) Improving the retention of fully certified, experienced, and effective educators in high-need schools or shortage areas.

Competitive Preference Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 1, and up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 2.

These priorities are:

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners (up to 3 points).

Under this priority, an applicant must demonstrate how the project will be implemented by or in partnership with one or more of the following entities:

(a) Community colleges (as defined in this notice).

(b) Historically Black colleges and universities (as defined in this notice).

(c) Tribal Colleges and Universities (as defined in this notice).

(d) Minority-serving institutions (as defined in this notice).

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Supports (up to 3 points).

Projects that are designed to address the impacts of the COVID–19 pandemic, including impacts that extend beyond the duration of the pandemic itself, on the students most impacted by the pandemic, with a focus on underserved students and the educators who serve them, through the following priority areas:

(a) Conducting community asset-mapping and needs assessments that may include an assessment of the extent to which students, including subgroups of students, have become disengaged from learning, including students not participating in in-person or remote instruction, and specific strategies for reengaging and supporting students and their families; and

(b) Using evidence-based instructional approaches and supports, such as professional development, coaching, ongoing support for educators, high-quality tutoring, expanded access to rigorous coursework and content across K–12, and expanded learning time to accelerate learning for students in ways that ensure all students have the opportunity to successfully meet challenging academic content standards without contributing to tracking or remedial courses.

Definitions: The following definitions apply to this program. The definitions of ''baseline,'' ''experimental study,'' ''logic model,'' ''moderate evidence,'' ''national level,'' ''nonprofit,'' ''performance measure,'' ''performance target,'' ''project component,'' ''quasi-experimental design study,'' ''regional level,'' ''relevant outcome,'' ''strong evidence,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1. The definitions of ''community college,'' ''children or students with disabilities,'' ''disconnected youth,'' ''early learning,'' ''educator,'' ''English learner,'' ''Historically Black colleges and universities,'' ''military- or veteran-connected student,'' ''minority-serving institutions,'' ''Tribal College or University,'' and ''underserved students'' are from the Supplemental Priorities. The definitions of ''evidence-based,'' ''local educational agency,'' and ''State educational agency'' are from section 8101 of the ESEA.

Baseline means the starting point from which performance is measured and targets are set.

Children or students with disabilities means children with disabilities as defined in section 602(3) of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1401(3)) and 34 CFR 300.8, or students with disabilities, as defined in the Rehabilitation Act of 1973 (29 U.S.C. 705(37), 705(202)(B)).

Community college means ''junior or community college'' as defined in section 312(f) of the Higher Education Act of 1965, as amended (HEA).

Disconnected youth means an individual, between the ages 14 and 24, who may be from a low-income

background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution.

Early learning means any (a) State-licensed or State-regulated program or provider, regardless of setting or funding source, that provides early care and education for children from birth to kindergarten entry, including, but not limited to, any program operated by a child care center or in a family child care home; (b) program funded by the Federal Government or State or local educational agencies (including any IDEA-funded program); (c) Early Head Start and Head Start program; (d) nonrelative child care provider who is not otherwise regulated by the State and who regularly cares for two or more unrelated children for a fee in a provider setting; and (e) other program that may deliver early learning and development services in a child's home, such as the Maternal, Infant, and Early Childhood Home Visiting Program; Early Head Start; and Part C of IDEA.

Educator means an individual who is an early learning educator, teacher, principal or other school leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty.

English learner means an individual who is an English learner as defined in section 8101(20) of the ESEA, or an individual who is an English language learner as defined in section 203(7) of the Workforce Innovation and Opportunity Act.

Evidence-based means an activity, strategy, or intervention that—

(i) Demonstrates a statistically significant effect on improving student outcomes or other relevant outcomes based on—

(I) Strong evidence from at least 1 well-designed and well-implemented experimental study;

(II) Moderate evidence from at least 1 well-designed and well-implemented quasi-experimental study; or

(III) Promising evidence from at least 1 well-designed and well-implemented correlational study with statistical controls for selection bias; or

(ii)(I) Demonstrates a rationale based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes; and

(II) Includes ongoing efforts to examine the effects of such activity, strategy, or intervention.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks (as defined in this notice):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Historically Black colleges and universities means colleges and universities that meet the criteria set out in 34 CFR 608.2.

Local educational agency (LEA) means:

(a) *In General.* A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) *Administrative Control and Direction.* The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) *Bureau of Indian Education Schools.* The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the LEA receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any State educational agency (SEA) (as defined in this notice) other than the Bureau of Indian Education.

(d) *Educational Service Agencies.* The term includes educational service agencies and consortia of those agencies.

(e) *State Educational Agency.* The term includes the SEA in a State in which the SEA is the sole educational agency for all public schools.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Military- or veteran-connected student means one or more of the following:

(a) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a member of the uniformed services (as defined by 37 U.S.C. 101), in the Army, Navy, Air Force, Marine Corps, Coast Guard, Space Force, National Guard, Reserves, National Oceanic and Atmospheric Administration, or Public Health Service or is a veteran of the uniformed services with an honorable discharge (as defined by 38 U.S.C. 3311).

(b) A student who is a member of the uniformed services, a veteran of the uniformed services, or the spouse of a service member or veteran.

(c) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a veteran of the uniformed services (as defined by 37 U.S.C. 101).

Minority-serving institution means an institution that is eligible to receive

assistance under sections 316 through 320 of part A of title III, under part B of title III, or under title V of the HEA.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study (as defined in this notice) or quasi-experimental design study (as defined in this notice) reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

Nonprofit, as applied to an agency, organization, or institution, means that it is owned and operated by one or more corporations or associations whose net earnings do not benefit, and cannot lawfully benefit, any private shareholder or entity.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Regional level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to serve a variety of communities within a State or multiple States, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender). For an LEA-based project, to be considered a regional-level project, a process, product, strategy, or practice must serve students in more than one LEA, unless the process, product, strategy, or practice is implemented in a State in which the SEA is the sole educational agency for all schools.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

State educational agency (SEA) means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D).

Tribal College or University has the meaning ascribed it in section 316(b)(3) of the HEA.

Underserved student means a student (which may include children in early learning environments, students in K–12 programs, and students in postsecondary education or career and technical education, as appropriate) in one or more of the following subgroups:

(a) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(b) A student of color.

(c) A student who is a member of a federally recognized Indian Tribe.

(d) An English learner.

(e) A child or student with a disability.
(f) A disconnected youth.
(g) A migrant student.
(h) A student experiencing homelessness or housing insecurity.
(i) A lesbian, gay, bisexual, transgender, queer or questioning, or intersex (LGBTQI+) student.
(j) A student who is in foster care.
(k) A student without documentation of immigration status.
(l) A pregnant, parenting, or caregiving student.
(m) A student impacted by the justice system, including a formerly incarcerated student.
(n) A student who is the first in their family to attend postsecondary education.
(o) A student performing significantly below grade level.
(p) A military- or veteran-connected student.

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 4.1), as well as the more recent What Works Clearinghouse Handbooks released in August 2022 (Version 5.0), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Program Authority: 20 U.S.C. 7261.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $251,000,000.

These estimated available funds are the total available for new awards for all three types of grants under the EIR program (Early-phase, Mid-phase, and Expansion grants).

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications.

Estimated Average Size of Awards: Up to $10,000,000.

Maximum Award: We will not make an award exceeding $10,000,000 for a project period of 60 months. Under 34 CFR 75.104(b) the Secretary may reject, without consideration or evaluation, any application that proposes a project funding level that exceeds the stated maximum award amount. The Department intends to fund one or more projects under each of the EIR competitions, including Expansion grants (84.411A), Mid-phase grants (84.411B), and Early-phase grants (84.411C). Entities may submit applications for different projects for more than one competition (Early-phase grants, Mid-phase grants, and Expansion grants). The combined maximum new award amount a grantee may receive under these three competitions, is $16,000,000. If an entity is within funding range for multiple applications, the Department will award the highest scoring applications up to $16,000,000.

Estimated Number of Awards: 8–15.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Note: Under section 4611(c) of the ESEA, the Department must use at least 25 percent of EIR funds for a fiscal year to make awards to applicants serving rural areas, contingent on receipt of a sufficient number of applications of sufficient quality. For purposes of this competition, we will consider an applicant as rural if the applicant meets the qualifications for rural applicants as described in the *Eligible Applicants* section and the applicant certifies that it meets those qualifications through the application.

In implementing this statutory provision and program requirement, the Department may fund high-quality applications from rural applicants out of rank order in the Mid-phase grants competition.

In addition, from the estimated available funds for this competition, the Department intends to award an estimated $87 million in funds for STEM projects and $87 million in funds for social and emotional learning projects, contingent on receipt of a sufficient number of applications of sufficient quality.

III. Eligibility Information

1. *Eligible Applicants:*
(a) An LEA;
(b) An SEA;
(c) The Bureau of Indian Education (BIE);
(d) A consortium of SEAs or LEAs;
(e) A nonprofit organization; and
(f) An LEA, an SEA, the BIE, or a consortium described in clause (d), in partnership with—
(1) A nonprofit (as defined in this notice) organization;
(2) A business;
(3) An educational service agency; or
(4) An IHE.

To qualify as a rural applicant under the EIR program, an applicant must meet both of the following requirements:
(a) The applicant is—
(1) An LEA with an urban-centric district locale code of 32, 33, 41, 42, or 43, as determined by the Secretary;
(2) A consortium of such LEAs;
(3) An educational service agency or a nonprofit organization in partnership with such an LEA; or
(4) A grantee described in clause (1) or (2) in partnership with an SEA; and
(b) A majority of the schools to be served by the program are designated with a locale code of 32, 33, 41, 42, or 43, or a combination of such codes, as determined by the Secretary.

Applicants are encouraged to retrieve locale codes from the National Center for Education Statistics School District search tool (*https://nces.ed.gov/ccd/districtsearch/*), where districts can be looked up individually to retrieve locale codes, and the Public School search tool (*https://nces.ed.gov/ccd/schoolsearch/*), where individual schools can be looked up to retrieve locale codes. More information on rural applicant eligibility will be in the application package for this competition.

Note: An applicant that is a nonprofit organization may, under 34 CFR 75.51, demonstrate its nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal

Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

In addition, with respect to IHEs and their affiliates, the following entities may apply for a grant under this competition: (1) As noted above, any IHE that is a partner in an application submitted by an LEA, SEA, BIE, consortium of SEAs or LEAs, or a nonprofit organization; (2) A private IHE that is a nonprofit organization; (3) A nonprofit organization, such as a development foundation, that is affiliated with a public IHE; and (4) A public IHE with 501(c)(3) status. A public IHE without 501(c)(3) status (even if that entity is tax exempt under Section 115 of the Internal Revenue Code or any other State or Federal provision), or that could not provide any other documentation of nonprofit status described above, however, would not qualify as a nonprofit organization, and therefore would not be eligible to apply for and receive an EIR grant.

2. a. *Cost Sharing or Matching:* Under section 4611(d) of the ESEA, each grant recipient must provide, from Federal, State, local, or private sources, an amount equal to 10 percent of funds provided under the grant, which may be provided in cash or through in-kind contributions, to carry out activities supported by the grant. Applicants must include a budget showing their matching contributions to the budget amount of EIR grant funds and must provide evidence of their matching contributions for the first year of the grant in their grant applications.

Section 4611(d) of the ESEA authorizes the Secretary to waive the matching requirement on a case-by-case basis, upon a showing of exceptional circumstances, such as:

(i) The difficulty of raising matching funds for a program to serve a rural area;

(ii) The difficulty of raising matching funds in areas with a concentration of LEAs or schools with a high percentage of students aged 5 through 17—

(A) Who are in poverty, as counted in the most recent census data approved by the Secretary;

(B) Who are eligible for a free or reduced-price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*);

(C) Whose families receive assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 *et seq.*); or

(D) Who are eligible to receive medical assistance under the Medicaid program; and

(iii) The difficulty of raising funds on Tribal land.

An applicant that wishes to apply for a waiver must include a request in its application, describing the exceptional circumstances that make it difficult for the applicant to meet the matching requirement. Further information about applying for waivers can be found in the application package for this competition.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Other:* a. *Funding Categories:* An applicant will be considered for an award only for the type of EIR grant for which it applies (*i.e.,* Mid-phase: Absolute Priority 2, Mid-phase: Absolute Priority 3, or Mid-phase: Absolute Priority 4). An applicant may not submit an application for the same proposed project under more than one type of grant (*e.g.,* both an Early-phase grant and Mid-phase grant).

Note: Each application will be reviewed under the competition in which it was submitted in the *Grants.gov* system, and only applications that are successfully submitted by the established deadline will be peer reviewed. Applicants should be careful that they download the intended EIR application package and that they submit their applications under the intended EIR competition.

b. *Evaluation:* The grantee must conduct an independent evaluation of the effectiveness of its project.

c. *High-need students:* The grantee must serve high-need students.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs*, which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for Mid-phase grants, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, will address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative for a Mid-phase grant to no more than 30 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.

• Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; one-page abstract; evidence form; or appendices (*e.g.,* nonprofit documentation, resumes, letters of support, demonstration of match, matching waiver request, list of proprietary information, eligibility checklist, logic model, indirect cost rate agreement). However, the recommended page limit does apply to the entire application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. Applicants may access this form using the link available on the Notice of Intent to Apply section of the competition website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/.* Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for the Mid-phase grants competition are from 34 CFR 75.210. The points assigned to each criterion are indicated in the parentheses next to the criterion. Together with the competitive preference priorities, an applicant may earn up to a total of 106 points based on the selection criteria for the application.

A. *Significance (up to 15 points).*

The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies.

B. *Strategy to Scale (up to 40 points).*

The Secretary considers the applicant's strategy to scale the proposed project. In determining the applicant's capacity to scale the proposed project, the Secretary considers the following factors:

(1) The extent to which the applicant identifies a specific strategy or strategies that address a particular barrier or barriers that prevented the applicant, in the past, from reaching the level of scale that is proposed in the application. (10 points)

(2) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (5 points)

(3) The applicant's capacity (*e.g.,* in terms of qualified personnel, financial resources, or management capacity) to bring the proposed project to scale on a national or regional level (as defined in this notice) working directly, or through partners, during the grant period. (10 points)

(4) The mechanisms the applicant will use to broadly disseminate information on its project so as to support further development or replication. (10 points)

(5) The likely utility of the products (such as information, materials, processes, or techniques) that will result from the proposed project, including the potential for their being used effectively in a variety of other settings. (5 points)

C. *Quality of the Project Design (up to 20 points).*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework. (5 points)

(2) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (5 points)

(3) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (10 points)

D. *Quality of the Project Evaluation (up to 25 points).*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards without reservations as described in the What Works Clearinghouse Handbook (as defined in this notice). (15 points)

(2) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings. (5 points)

(3) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation. (5 points)

Note: Applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbooks: *https://ies.ed.gov/ncee/wwc/Handbooks;* (2) ''Technical Assistance Materials for Conducting Rigorous Impact Evaluations'': *http://ies.ed.gov/ncee/projects/evaluationTA.asp;* and (3) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.* In addition, applicants may view an optional webinar recording that was hosted by the Institute of Education Sciences. The webinar focused on more rigorous evaluation designs, discussing strategies for designing and executing experimental studies that meet WWC evidence standards without reservations. This webinar is available at: *https://ies.ed.gov/ncee/wwc/Multimedia/18.*

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine whether applications have met eligibility and other requirements. This screening process may occur at various stages of the process; applicants

that are determined to be ineligible will not receive a grant, regardless of peer reviewer scores or comments.

Peer reviewers will read, prepare a written evaluation of, and score the assigned applications, using the selection criteria provided in this notice.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

Note: The evaluation report is a specific deliverable under a Mid-phase grant that grantees must make available to the public. Additionally, EIR grantees are encouraged to submit final studies resulting from research supported in whole or in part by EIR to the Educational Resources Information Center (*http://eric.ed.gov*).

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html*.

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

5. *Performance Measures:* For the purpose of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures (as defined in this notice) for the Mid-phase grants.

Annual performance measures: (1) The percentage of grantees that reach their annual target number of students as specified in the application; (2) the percentage of grantees that reach their annual target number of high-need students as specified in the application; (3) the percentage of grantees with ongoing well-designed and independent evaluations that will provide evidence of their effectiveness at improving student outcomes in multiple contexts; (4) the percentage of grantees that implement an evaluation that provides information about the key practices and the approach of the project so as to facilitate replication; (5) the percentage of grantees that implement an evaluation that provides information on

the cost-effectiveness of the key practices to identify potential obstacles and success factors to scaling; and (6) the cost per student served by the grant.

Cumulative performance measures: (1) The percentage of grantees that reach the targeted number of students specified in the application; (2) the percentage of grantees that reach the targeted number of high-need students specified in the application; (3) the percentage of grantees that complete a well-designed, well-implemented, and independent evaluation that provides evidence of their effectiveness at improving student outcomes at scale; (4) the percentage of grantees that complete a well-designed, well-implemented, and independent evaluation that provides information about the key elements and the approach of the project so as to facilitate replication or testing in other settings; (5) the percentage of grantees with a completed evaluation that provides information on the cost-effectiveness of the key practices to identify potential obstacles and success factors to scaling; and (6) the cost per student served by the grant.

Project-Specific Performance Measures: Applicants must propose project-specific performance measures and performance targets (both as defined in this notice) consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) Performance measures. How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) Baseline (as defined in this notice) data. (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) Performance targets. Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) Data collection and reporting. (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Adam Schott,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary. Education.

[FR Doc. 2024–09796 Filed 5–3–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0016]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; High School Equivalency Program (HEP) Annual Performance Report

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 5, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Katrina Ballard, (202) 987–0702.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner;

(3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: High School Equivalency Program (HEP) Annual Performance Report.

OMB Control Number: 1810–0684.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 54.

Total Estimated Number of Annual Burden Hours: 1,242.

Abstract: This is a request for a revision of the 1810–0684 High School Equivalency Program (HEP) Annual Performance Report collection. These revisions include language replacements, removals, and additions that are intended to ensure compliance with EDGAR 34 CFR 75.110 and OMB Circular A–110, improve the clarity of instructions and data collection, and remove duplicative language. Substantive changes include the addition of a data element related to mode of instruction. For a complete list of revisions, please see the attached summary, which will be shared with the public and OMB as a supplemental document. The Office of Migrant Education (OME) is collecting information for the High School Equivalency Program (HEP) which is authorized under title IV, section 418A of the Higher Education Act of 1965, as amended by section 408 of the Higher Education Opportunity Act (HEOA) (20 U.S.C. 1070d–2) (special programs for students whose families are engaged in migrant and seasonal farm work) and 2 CFR 200.328 which requires that recipients of discretionary grants submit an Annual Performance Report (APR) to best inform improvements in program outcomes and productivity.

Although the Education Department continues to use the generic 524B, OME is requesting to continue the use of a customized APR that goes beyond the generic 524B APR to facilitate the collection of more standardized and comprehensive data to inform performance indicators, to improve the overall quality of data collected, and to increase the quality of data that can be used to inform policy decisions.

Although the Education Department continues to use the generic 524B, OME is requesting to continue the use of a customized APR that goes beyond the generic 524B APR to facilitate the collection of more standardized and comprehensive data to inform Government Performance Results Act (GPRA) indicators, to improve the overall quality of data collected, and to increase the quality of data that can be used to inform policy decisions.

Dated: April 30, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–09741 Filed 5–3–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Education Innovation and Research (EIR) Program Expansion Grants

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2024 for the EIR program Expansion Grants, Assistance Listing Number 84.411A (Expansion Grants). This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: May 6, 2024.

Deadline for Notice of Intent to Apply: June 06, 2024.

Deadline for Transmittal of Applications: July 05, 2024.

Deadline for Intergovernmental Review: September 03, 2024.

Pre-Application Information: The Department will post additional competition information for prospective applicants on the EIR program website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Jamila Smith, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–5900. Telephone: 202–987–1753. Email: *eir@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The EIR program, established under section 4611 of the Elementary and Secondary Education Act, as amended (ESEA), provides funding to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based (as defined in this notice), field-initiated innovations to improve student achievement and attainment for high-need students and to rigorously evaluate such innovations. The EIR program is designed to generate and validate solutions to persistent education challenges and to support the expansion of those solutions to serve substantially higher numbers of students.

The central design element of the EIR program is its multitier structure that links the amount of funding an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project. A goal of the program is for projects that build this evidence to advance through EIR's grant tiers: ''Early-phase,'' ''Mid-phase,'' and ''Expansion.''

''Early-phase,'' ''Mid-phase,'' and ''Expansion'' grants differ in terms of the evidence of effectiveness required to be considered for funding, the expectations regarding the kind of evidence and information funded projects should produce, the scale of funded projects, and, consequently, the amount of funding available to support each type of project.

Expansion grants are supported by strong evidence (as defined in this notice) for at least one population and setting, and grantees are encouraged to implement at the national level (as defined in this notice). Expansion grants provide funding for the implementation and rigorous evaluation of a program that has been found to produce sizable, significant impacts under a Mid-phase grant or other effort meeting similar criteria, for the purposes of (a) determining whether such impacts can be successfully reproduced and sustained over time, and (b) identifying

the conditions in which the program is most effective.

This notice invites applications for Expansion grants only. The notices inviting applications for Early-phase grants and Mid-phase grants are published elsewhere in this issue of the **Federal Register**.

Background:

While this notice is for the Expansion grants tier only, the premise of the EIR program is that new, effective, and innovative educational programs and practices can help to overcome the persistent and significant challenges to student educational opportunity and success, particularly for underserved and high-need students. Raise the Bar: Lead the World is the Department's call to action to transform pre-kindergarten (Pre-K) through grade 12 education and unite around what evidence demonstrates works by in promoting academic excellence, boldly improving learning conditions, and preparing our Nation's students for global competitiveness.[1] Consistent with that call to action, the priorities used in this competition advance Raise the Bar's goals to promote academic excellence and boldly improve learning conditions.

In FY 2024, the Department is particularly interested in projects that propose services and activities that help students recover from the COVID–19 pandemic, accelerate learning and academic achievement, reimagine schools, and transform our education system. Specifically, the Department is focused on improving student achievement and attainment, as highlighted across Administration and Department efforts for the past several years. Building on the Administration's previous efforts, in January 2024, the Administration announced its Improving Student Achievement Agenda,[2] which aims to drive proven strategies that will support academic success for every child in school. The strategies and evidence discussed in the Improving Student Achievement Agenda focus on (1) increasing student attendance; (2) providing high-dosage tutoring; and (3) increasing summer learning and extended or afterschool learning time. These strategies and the broader Improving Student Achievement Agenda, including a focus on core academic instruction, are well aligned with the EIR program purpose, and the new funding to be released through the FY 2024 EIR competition will help accelerate and scale up sustainable adoption of evidence-based strategies that we expect will improve student achievement and attainment in the school years ahead. The priorities in this competition are designed to create conditions under which students have equitable access to high-quality learning opportunities and experiences. For example, projects may include new approaches to instructional design such as through project-based or experiential learning opportunities for students, schoolwide frameworks, such as small schools or learning communities, that support student connection and engagement, and increased interagency coordination to improve academic supports for highly mobile students such as students in foster care and students experiencing homelessness.

Note: The EIR program statute refers to ''high-need students'' but does not define the term, which allows applicants to define it for purposes of the applicant's proposed project, population, and setting. Addressing the needs of underserved students (as defined in this notice) is one way to address EIR's statutory requirement to serve ''high-need students.'' In particular, the Department welcomes innovative projects that serve disconnected youth, students who are in foster care, and students performing significantly below grade level.

The EIR program is rooted in innovation; the program is not intended to provide support for practices that are already commonly implemented by educators, unless significant adaptations of such practices warrant testing to determine if they can accelerate achievement or increase the likelihood that the practices can be widely, efficiently, and effectively implemented in new populations and settings. If the evaluation demonstrates that innovations are supported by strong evidence, then EIR seeks applicants who can replicate and test these innovations in new populations and settings.

As an EIR project is implemented, grantees are encouraged to learn more about how the practices improve student achievement and attainment as well as to develop increasingly rigorous evidence of effectiveness and new strategies to efficiently and cost-effectively scale to new school districts, regions, and States. We encourage applicants to develop a logic model (as defined in this notice), theory of action, or another conceptual framework that includes the goals, objectives, outcomes, and key project components (as defined in this notice) of the project that can support systems of continuous improvement.

All EIR applicants and grantees should also consider how they will develop their organizational capacity, project financing, and business plans to sustain their projects and continue implementation and adaptation after Federal funding ends. The Department intends to provide grantees with technical assistance to support dissemination, scaling, and sustainability efforts.

Expansion grant projects are expected to scale practices that have prior evidence of effectiveness to improve outcomes for high-need and underserved students. They are also expected to generate important information about an intervention's effectiveness, such as for whom and in which contexts a practice is most effective, including cost considerations such as economies of scale. Expansion grant projects are uniquely positioned to help answer critical questions about the process of scaling a practice to the national level across geographies as well as locale types. Expansion grant applicants are encouraged to consider how the cost structure of a practice can change as the intervention scales. Additionally, grantees may want to consider how their project will balance implementation fidelity and flexibility for scaling.

Expansion grant applicants are encouraged to design an evaluation that has the potential to meet strong evidence. Expansion grants should measure the cost—effectiveness of their practices using administrative or other readily available data. These types of efforts are critical to sustaining and scaling EIR-funded effective practices after the EIR grant period ends (assuming that the practice has positive effects on important student outcomes). To support adoption or replication by other entities, the evaluation of an Expansion grant project should identify and codify the core elements of the EIR-supported practice that the project implements, as well as examine the effectiveness of the project for any new populations or settings included in the project. The Department intends to provide grantees (including the independent evaluators they contract with as part of their project) with evaluation technical assistance. This could include grantees and their independent evaluators providing to the

[1] U.S. Secretary of Education Miguel Cardona laid out his vision for the direction the agency will follow in 2024 to promote academic excellence, improve learning conditions, and prepare our students for a world where global engagement is critical to our Nation's standing. In his address, Secretary Cardona remarked that ''Raise the Bar: Lead the World'' is not a list of new priorities, but a call to strengthen our will to transform education for the better, building on approaches that we know work in education. More information is available at *https://www.ed.gov/raisethebar.*

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/17/fact-sheet-biden-harris-administration-announces-improving-student-achievement-agenda-in-2024/.*

Department or its contractor updated comprehensive evaluation plans in a format as requested by the technical assistance provider and using such tools as the Department may request. Grantees will be encouraged to update this evaluation plan at least annually to reflect any changes to the evaluation. Updates must be consistent with the scope and objectives of the approved application.

The FY 2024 Expansion grant competition includes three absolute priorities and two competitive preference priorities. All Expansion grant applicants must address Absolute Priority 1. Expansion grant applicants are also required to address one of the other two absolute priorities (applicants may not submit under more than one of the other 2 absolute priorities). All applicants have the option of addressing the competitive preference priorities and may opt to do so regardless of the absolute priority they select.

Absolute Priority 1—Strong Evidence establishes the evidence requirement for this tier of grants. All Expansion grants applicants must submit prior evidence of effectiveness that meets the strong evidence standard.

Absolute Priority 2—Field-Initiated Innovations—General gives applicants the option to propose projects that are field-initiated innovations to improve student achievement and attainment.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Educator Recruitment and Retention is intended to elevate and strengthen the educator workforce in ways that prioritize innovation in recruiting and retaining educators to better support high-need students. Applicants are encouraged to address fundamental challenges schools face in recruiting and retaining qualified educators by addressing the responsibilities and challenges educators continue to face after the pandemic. For example, projects may be designed to improve supports for educators that enhance the ability of schools to recruit and retain staff (*e.g.,* strategies to support educator wellbeing or structuring staffing and schedules to ensure educators and students are appropriately supported, and have sufficient time for planning, collaboration, working with coaches, and observing instruction of other educators) and increase access to leadership opportunities that can lead to increased pay and improved retention for fully certified, experienced, and effective educators, while expanding the impact of great teachers within and beyond their classrooms. Projects may support the recruitment and retention of all school staff or specific staff with acute recruitment and retention challenges (*e.g.,* personnel serving children or students with disabilities) and increasing access to leadership opportunities that can lead to increased pay and improved retention for fully certified, experienced, and effective educators, while expanding the impact of great teachers within and beyond their classrooms. Projects may support the recruitment and retention of all school staff or specific staff with acute recruitment and retention challenges (*e.g.,* personnel serving children or students with disabilities).

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners is intended to encourage applicants to propose projects that involve (as applicants or partners) entities underrepresented in the program's portfolio of grants. The Department is eager to increase the volume of applicants and partners from entities such as community colleges (as defined in this notice), Historically Black Colleges and Universities (as defined in this notice), Tribal Colleges and Universities (as defined in this notice), and minority-serving institutions (as defined in this notice).

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Supports reflects the Administration's ongoing commitment to addressing the impact of the COVID–19 pandemic on Pre-K through grade 12 education. The pandemic caused unprecedented disruption in schools across the country and drew renewed attention to the ongoing challenges for underserved students. In response to the pandemic, educators mobilized to address the needs of all students. Researchers, educators, parents, and policymakers are working to understand and address the impact of inconsistent access to instruction, enrichment, peers, and services and supports, and the impact of other related challenges. We also know that for students in underserved communities, inequities in educational opportunity and outcomes existed previously, and have been exacerbated by the pandemic.[3] The COVID–19 pandemic has changed the education landscape, as students continue to make up for lost classroom instruction. However, it also provides an opportunity to redesign how schools approach teaching and learning in ways that both address long-standing gaps in educational opportunity and better prepare students for college and careers. Over 14 million public school students (31 percent) missed at least 10 percent of school in school year 2021–2022.[4] According to analysis by the Council of Economic Advisors, absenteeism accounted for up to 27 percent of the test score declines in math and 45 percent of the test score declines in reading on the National Assessment of Educational Progress.[5] To that end, the Department seeks projects that build the evidence base on effective educational practices to improve achievement for high-need students by expanding existing innovative education practices to address these challenges and inequities. The proposed innovations should be designed to better enable students to access the educational opportunities they need to succeed in school and reach their full potential.

Through these priorities, the Department intends to advance innovation, build evidence, and address the learning and achievement of underserved and high-need students in Pre-K through grade 12.

Priorities: This notice includes three absolute priorities and two competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(ii), Absolute Priority 1 is from regulations (34 CFR 75.226(d)(2)). In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 2 is from section 4611(a)(1)(A) of the ESEA. Absolute Priority 3 is from section 4611(a)(1)(A) of the ESEA and the Supplemental Priorities and Definitions for Discretionary Grants Programs, published in the **Federal Register** on December 10, 2021 (86 FR 70612) (Supplemental Priorities). The competitive preference priorities are from the Supplemental Priorities.

Absolute Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded

[3] Dorn, E., Hancock, B., Sarakatsannis, J., & Viruleg, E. (2021, July 27). COVID–19 and education: The lingering effects of unfinished learning. McKinsey & Company. *https://www.mckinsey.com/industries/education/our-insights/covid-19-and-education-the-lingering-effects-of-unfinished-learning.*

[4] U.S. Department of Education. (2023, September 15). Raising the Bar for Consistent School Attendance. *ED.gov* Blog. *https://blog.ed.gov/2023/09/raising-the-bar-for-consistent-school-attendance/*.

[5] The White House. (2023, September 13). Chronic Absenteeism and Disrupted Learning Require an All-Hands-on-Deck Approach | CEA. The White House. *https://www.whitehouse.gov/cea/written-materials/2023/09/13/chronic-absenteeism-and-disrupted-learning-require-an-all-hands-on-deck-approach/.*

applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1 and one additional absolute priority.

These priorities are:

Absolute Priority 1—Strong Evidence.

Projects supported by evidence that meets the conditions in the definition of ''strong evidence.''

Note: An applicant must identify up to four studies to be reviewed against the What Works Clearinghouse (WWC) Handbooks (as defined in this notice) for the purposes of meeting the definition of ''strong evidence.'' The studies may have been conducted by the applicant or by a third party. An applicant must clearly identify the citation for each study in the Evidence form. An applicant must ensure that all cited studies are available to the Department from publicly available sources and provide links or other guidance indicating where each is available. The Department may not review a study that an applicant fails to clearly identify for review.

In addition to including up to four study citations, an applicant must provide in the Evidence form the following information: (1) the positive student outcomes the applicant intends to replicate under its Expansion grant and how these outcomes correspond to the positive student outcomes in the cited studies; (2) the characteristics of the population to be served under its Expansion grant and how these characteristics correspond to the characteristics of the students in the cited studies; (3) the characteristics of the setting to be served under its Expansion grant and how these characteristics correspond to the settings in the cited studies; and (4) the practice(s) the applicant plans to implement under its Expansion grant and how the practice(s) correspond with the practice(s) in the cited studies.

If the Department determines that an applicant has provided insufficient information, the applicant will not have an opportunity to provide additional information. However, if the WWC team reviewing evidence determines that a study does not provide enough information on key aspects of the study design, such as sample attrition or equivalence of intervention and comparison groups, the WWC may submit a query to the study author(s) to gather information for use in determining a study rating. Authors would be asked to respond to queries within 10 business days. If the author query remains incomplete within 14 days of the initial contact with the study author(s), the study may be deemed ineligible under the grant competition. After the grant competition closes, the WWC will, for purposes of its own curation of studies, continue to include responses to author queries and make updates to study reviews as necessary. However, no additional information will be considered after the competition closes and the initial timeline established for response to an author query passes.

Absolute Priority 2—Field-Initiated Innovations—General.

Projects designed to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students.

Absolute Priority 3—Field-Initiated Innovations—Promoting Equity in Student Access to Educational Resources and Opportunities: Educator Recruitment and Retention.

Projects that are designed to—

(a) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated

innovations to improve student achievement and attainment for high-need students; and

(b) Promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Career and technical education programs.

(vi) Out-of-school-time settings.

(vii) Alternative schools and programs.

(viii) Juvenile justice system or correctional facilities; and

(2) That examine the sources of inequity and inadequacy and implement responses, and that may include one or more of the following:

(i) Increasing the number and proportion of experienced, fully certified, in-field, and effective educators, and educators from traditionally underrepresented backgrounds or the communities they serve, to ensure that underserved students have educators from those backgrounds and communities and are not taught at disproportionately higher rates by uncertified, out-of-field, and novice teachers compared to their peers.

Note: All strategies to increase racial diversity of educators must comply with the nondiscrimination requirements contained in Federal civil rights laws.

(ii) Improving the preparation, recruitment, and early career support and development of educators in shortage areas or hard to staff schools.

(iii) Improving the retention of fully certified, experienced, and effective educators in high-need schools or shortage areas.

Competitive Preference Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 1, and up to an additional 3 points to an application, depending on how well the application addresses Competitive Preference Priority 2.

These priorities are:

Competitive Preference Priority 1—Promoting Equity in Student Access to Educational Resources and Opportunities: Implementers and Partners (up to 3 points).

Under this priority, an applicant must demonstrate how the project will be implemented by or in partnership with one or more of the following entities:

(a) Community colleges (as defined in this notice).

(b) Historically Black colleges and universities (as defined in this notice).

(c) Tribal Colleges and Universities (as defined in this notice).

(d) Minority-serving institutions (as defined in this notice).

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty: Community Asset-Mapping and Needs Assessment and Evidence-Based Instructional Approaches and Supports (up to 3 points).

Projects that are designed to address the impacts of the COVID–19 pandemic, including impacts that extend beyond the duration of the pandemic itself, on the students most impacted by the pandemic, with a focus on underserved students and the educators who serve them, through the following priority areas:

(a) Conducting community asset-mapping and needs assessments that may include an assessment of the extent to which students, including subgroups of students, have become disengaged from learning, including students not participating in in-person or remote instruction, and specific strategies for reengaging and supporting students and their families; and

(b) Using evidence-based instructional approaches and supports, such as professional development, coaching,

ongoing support for educators, high quality tutoring, expanded access to rigorous coursework and content across K–12, and expanded learning time to accelerate learning for students in ways that ensure all students have the opportunity to successfully meet challenging academic content standards without contributing to tracking or remedial courses.

Definitions: The following definitions apply to this program. The definitions of ''baseline,'' ''experimental study,'' ''logic model,'' ''strong evidence,'' ''national level,'' ''nonprofit,'' ''performance measure,'' ''performance target,'' ''project component,'' ''relevant outcome,'' and ''What Works Clearinghouse Handbooks (WWC Handbooks)'' are from 34 CFR 77.1. The definitions of ''evidence-based,'' ''local educational agency,'' and ''State educational agency'' are from section 8101 of the ESEA. The definitions of ''community college,'' ''children or students with disabilities,'' ''disconnected youth,'' ''early learning,'' ''educator,'' ''English learner,'' ''Historically Black colleges and universities,'' ''military- or veteran-connected student,'' ''minority-serving institutions,'' ''Tribal College or University,'' and ''underserved student'' are from the Supplemental Priorities.

Baseline means the starting point from which performance is measured and targets are set.

Children or students with disabilities means children with disabilities as defined in section 602(3) of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1401(3)) and 34 CFR 300.8, or students with disabilities, as defined in the Rehabilitation Act of 1973 (29 U.S.C. 705(37), 705(202)(B)).

Community college means ''junior or community college'' as defined in section 312(f) of the Higher Education Act of 1965, as amended (HEA).

Disconnected youth means an individual, between the ages 14 and 24, who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution.

Early learning means any (a) State-licensed or State-regulated program or provider, regardless of setting or funding source, that provides early care and education for children from birth to kindergarten entry, including, but not limited to, any program operated by a child care center or in a family child care home; (b) program funded by the Federal Government or State or local educational agencies (including any IDEA-funded program); (c) Early Head Start and Head Start program; (d) non-relative child care provider who is not otherwise regulated by the State and who regularly cares for two or more unrelated children for a fee in a provider setting; and (e) other program that may deliver early learning and development services in a child's home, such as the Maternal, Infant, and Early Childhood Home Visiting Program; Early Head Start; and Part C of IDEA.

Educator means an individual who is an early learning educator, teacher, principal or other school leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty.

English learner means an individual who is an English learner as defined in section 8101(20) of the ESEA, or an individual who is an English language learner as defined in section 203(7) of the Workforce Innovation and Opportunity Act.

Evidence-based means an activity, strategy, or intervention that—

(i) Demonstrates a statistically significant effect on improving student outcomes or other relevant outcomes based on—

(I) Strong evidence from at least 1 well-designed and well-implemented experimental study;

(II) Moderate evidence from at least 1 well-designed

and well-implemented quasi-experimental study; or

(III) Promising evidence from at least 1 well-designed and well-implemented correlational study with statistical controls for selection bias; or

(ii)(I) Demonstrates a rationale based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes; and

(II) Includes ongoing efforts to examine the effects of such activity, strategy, or intervention.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks (as defined in this notice):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Historically Black colleges and universities means colleges and universities that meet the criteria set out in 34 CFR 608.2.

Local educational agency (LEA) means:

(a) In General. A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) Administrative Control and Direction. The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) Bureau of Indian Education Schools. The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the LEA receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any State educational agency (SEA) (as defined in this notice)

other than the Bureau of Indian Education.

(d) Educational Service Agencies. The term includes educational service agencies and consortia of those agencies.

(e) State Educational Agency. The term includes the SEA in a State in which the SEA is the sole educational agency for all public schools.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Military- or veteran-connected student means one or more of the following:

(a) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a member of the uniformed services (as defined by 37 U.S.C. 101), in the Army, Navy, Air Force, Marine Corps, Coast Guard, Space Force, National Guard, Reserves, National Oceanic and Atmospheric Administration, or Public Health Service or is a veteran of the uniformed services with an honorable discharge (as defined by 38 U.S.C. 3311).

(b) A student who is a member of the uniformed services, a veteran of the uniformed services, or the spouse of a service member or veteran.

(c) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a veteran of the uniformed services (as defined by 37 U.S.C. 101).

Minority-serving institution means an institution that is eligible to receive assistance under sections 316 through 320 of part A of title III, under part B of title III, or under title V of the HEA.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that can be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

Nonprofit, as applied to an agency, organization, or institution, means that it is owned and operated by one or more corporations or associations whose net earnings do not benefit, and cannot lawfully benefit, any private shareholder or entity.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. *State educational agency* (SEA) means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement in this paragraph (iii)(D).

Tribal College or University has the meaning ascribed it in section 316(b)(3) of the HEA.

Underserved student means a student (which may include children in early learning environments, students in K–12 programs, and students in postsecondary education or career and technical education, as appropriate) in one or more of the following subgroups:

(a) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(b) A student of color.

(c) A student who is a member of a federally recognized Indian Tribe.

(d) An English learner.

(e) A child or student with a disability.

(f) A disconnected youth.

(g) A migrant student.

(h) A student experiencing homelessness or housing insecurity.

(i) A lesbian, gay, bisexual, transgender, queer or questioning, or intersex (LGBTQI+) student.

(j) A student who is in foster care.

(k) A student without documentation of immigration status.

(l) A pregnant, parenting, or caregiving student.

(m) A student impacted by the justice system, including a formerly incarcerated student.

(n) A student who is the first in their family to attend postsecondary education.

(o) A student performing significantly below grade level.

(p) A military- or veteran-connected student.

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC

standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 4.1), as well as the more recent What Works Clearinghouse Handbooks released in August 2022 (Version 5.0), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Program Authority: 20 U.S.C. 7261.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $251,000,000.

These estimated available funds are the total available for new awards for all three types of grants under the EIR program (Early-phase, Mid-phase, and Expansion grants).

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications.

Estimated Average Size of Awards: Up to $15,000,000.

Maximum Award: We will not make an award exceeding $15,000,000 for a project period of 60 months. Under 34 CFR 75.104(b) the Secretary may reject, without consideration or evaluation, any application that proposes a project funding level that exceeds the stated maximum award amount. The Department intends to fund one or more projects under each of the EIR competitions, including Expansion grants (84.411A), Mid-phase grants (84.411B), and Early-phase grants (84.411C). Entities may submit applications for different projects for more than one competition (Early-phase grants, Mid-phase grants, and Expansion grants). The combined maximum new award amount a grantee may receive under these three competitions, is $16,000,000. If an entity is within funding range for multiple applications, the Department will award the highest scoring applications up to $16,000,000.

Estimated Number of Awards: 4–8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Note: Under section 4611(c) of the ESEA, the Department must use at least 25 percent of EIR funds for a fiscal year to make awards to applicants serving rural areas, contingent on receipt of a sufficient number of applications of sufficient quality. For purposes of this competition, we will consider an applicant as rural if the applicant meets the qualifications for rural applicants as described in the *Eligible Applicants* section and the applicant certifies that it meets those qualifications through the application. In implementing this statutory provision and program requirement, the Department may fund high-quality applications from rural applicants out of rank order in the Expansion grants competition.

In addition, from the estimated funds for this competition, the Department intends to award an estimated $87 million in funds for Science, Technology, Engineering and Math (STEM) projects and $87 million in funds for social and emotional learning projects, contingent on receipt of a sufficient number of applications of sufficient quality.

III. Eligibility Information

1. *Eligible Applicants:*

(a) An LEA;

(b) An SEA;

(c) The Bureau of Indian Education (BIE);

(d) A consortium of SEAs or LEAs;

(e) A nonprofit (as defined in this notice) organization; and

(f) An LEA, an SEA, the BIE, or a consortium described in clause (d), in partnership with—

(1) A nonprofit organization;

(2) A business;

(3) An educational service agency; or

(4) An IHE.

To qualify as a rural applicant under the EIR program, an applicant must meet both of the following requirements:

(a) The applicant is—

(1) An LEA with an urban-centric district locale code of 32, 33, 41, 42, or 43, as determined by the Secretary;

(2) A consortium of such LEAs;

(3) An educational service agency or a nonprofit organization in partnership with such an LEA; or

(4) A grantee described in clause (1) or (2) in partnership with an SEA; and

(b) A majority of the schools to be served by the program are designated with a locale code of 32, 33, 41, 42, or 43, or a combination of such codes, as determined by the Secretary.

Applicants are encouraged to retrieve locale codes from the National Center for Education Statistics School District search tool (*https://nces.ed.gov/ccd/districtsearch/*), where districts can be looked up individually to retrieve locale codes, and the Public School search tool (*https://nces.ed.gov/ccd/schoolsearch/*), where individual schools can be looked up to retrieve locale codes. More information on rural applicant eligibility will be in the application package for this competition.

Note: An applicant that is a nonprofit organization may, under 34 CFR 75.51, demonstrate its nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

In addition, with respect to IHEs and their affiliates, the following entities may apply for a grant under this competition: (1) As noted above, any IHE that is a partner in an application submitted by an LEA, SEA, BIE, consortium of SEAs or LEAs, or a nonprofit organization; (2) A private IHE that is a nonprofit organization; (3) A nonprofit organization, such as a development foundation, that is affiliated with a public IHE; and (4) A public IHE with 501(c)(3) status. A public IHE without 501(c)(3) status (even if that entity is tax exempt under Section 115 of the Internal Revenue Code or any other State or Federal provision), or that could not provide any other documentation of nonprofit status described above, however, would

not qualify as a nonprofit organization, and therefore would not be eligible to apply for and receive an EIR grant.

2. a. *Cost Sharing or Matching:* Under section 4611(d) of the ESEA, each grant recipient must provide, from Federal, State, local, or private sources, an amount equal to 10 percent of funds provided under the grant, which may be provided in cash or through in-kind contributions, to carry out activities supported by the grant. Applicants must include a budget showing their matching contributions to the budget amount of EIR grant funds and must provide evidence of their matching contributions for the first year of the grant in their grant applications.

Section 4611(d) of the ESEA authorizes the Secretary to waive the matching requirement on a case-by-case basis, upon a showing of exceptional circumstances, such as:

(i) The difficulty of raising matching funds for a program to serve a rural area;

(ii) The difficulty of raising matching funds in areas with a concentration of LEAs or schools with a high percentage of students aged 5 through 17—

(A) Who are in poverty, as counted in the most recent census data approved by the Secretary;

(B) Who are eligible for a free or reduced-price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*);

(C) Whose families receive assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 *et seq.*); or

(D) Who are eligible to receive medical assistance under the Medicaid program; and

(iii) The difficulty of raising funds on Tribal land.

An applicant that wishes to apply for a waiver must include a request in its application, describing the exceptional circumstances that make it difficult for the applicant to meet the matching requirement. Further information about applying for waivers can be found in the application package for this competition.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Other:* a. *Funding Categories:* An applicant will be considered for an award only for the type of EIR grant for which it applies. An applicant may not submit an application for the same proposed project under more than one type of grant (*e.g.,* both an Expansion grant and Mid-phase grant).

Note: Each application will be reviewed under the competition in which it was submitted in the *Grants.gov* system, and only applications that are successfully submitted by the established deadline will be peer reviewed. Applicants should be careful that they download the intended EIR application package and that they submit their applications under the intended EIR competition.

b. *Evaluation:* The grantee must conduct an independent evaluation of the effectiveness of its project.

c. *High-need students:* The grantee must serve high-need students.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for Expansion grants, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, will address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative for an Expansion grant to no more than 35 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; one-page abstract; evidence form; or appendices (*e.g.,* nonprofit documentation, resumes, letters of support, demonstration of match, matching waiver request, list of proprietary information, eligibility checklist, logic model, indirect cost rate agreement). However, the recommended page limit does apply to the entire application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. Applicants may access this form using the link available on the Notice of Intent to Apply section of the competition website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2024-competition/.* Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for the Expansion grant competition are from 34 CFR 75.210. The points assigned to each criterion are indicated in the parentheses next to the criterion. Together with the competitive preference priorities, an applicant may earn up to a total of 106 points based on the selection criteria for the application.

A. *Significance (up to 15 points).*

The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies.

B. *Strategy to Scale (up to 40 points).*

The Secretary considers the applicant's strategy to scale the proposed project. In determining the applicant's capacity to scale the proposed project, the Secretary considers the following factors:

(1) The extent to which the applicant identifies a specific strategy or strategies that address a particular barrier or barriers that prevented the applicant, in the past, from reaching the level of scale that is proposed in the application. (10 points)

(2) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (5 points)

(3) The applicant's capacity (*e.g.,* in terms of qualified personnel, financial resources, or management capacity) to bring the proposed project to scale on a national or regional level (as defined in this notice) working directly, or through partners, during the grant period. (10 points)

(4) The mechanisms the applicant will use to broadly disseminate information on its project so as to support further development or replication. (10 points)

(5) The likely utility of the products (such as information, materials, processes, or techniques) that will result from the proposed project, including the potential for their being used effectively in a variety of other settings. (5 points)

C. *Quality of the Project Design (up to 20 points).*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework. (5 points)

(2) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (5 points)

(3) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (10 points)

D. *Quality of the Project Evaluation (up to 25 points).*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards without reservations as described in the What Works Clearinghouse Handbook (as defined in this notice). (15 points)

(2) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings. (5 points)

(3) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation. (5 points)

Note: Applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbooks: *https://ies.ed.gov/ncee/wwc/Handbooks;* (2) ''Technical Assistance Materials for Conducting Rigorous Impact Evaluations'': *http://ies.ed.gov/ncee/projects/evaluationTA.asp;* and (3) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.* In addition, applicants may view an optional webinar recording that was hosted by the Institute of Education Sciences. The webinar focused on more rigorous evaluation designs, discussing strategies for designing and executing experimental studies that meet WWC evidence standards without reservations. This webinar is available at: *https://ies.ed.gov/ncee/wwc/Multimedia/18.*

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine whether applications have met eligibility and other requirements. This screening process may occur at various stages of the process; applicants that are determined to be ineligible will not receive a grant, regardless of peer reviewer scores or comments.

Peer reviewers will read, prepare a written evaluation of, and score the assigned applications, using the selection criteria provided in this notice.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that

over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

Note: The evaluation report is a specific deliverable under an Expansion grant that grantees must make available to the public. Additionally, EIR grantees are encouraged to submit final studies resulting from research supported in whole or in part by EIR to the Educational Resources Information Center (*http://eric.ed.gov*).

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

5. *Performance Measures:* For the purpose of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures (as defined in this notice) for the Expansion grants.

Annual performance measures: (1) The percentage of grantees that reach their annual target number of students as specified in the application; (2) the percentage of grantees that reach their annual target number of high-need students as specified in the application; (3) the percentage of grantees with ongoing well-designed and independent evaluations that will provide evidence of their effectiveness at improving student outcomes in multiple contexts; (4) the percentage of grantees that implement an evaluation that provides information about the key practices and the approach of the project so as to facilitate replication; (5) the percentage of grantees that implement an evaluation that provides information on the cost-effectiveness of the key practices to identify potential obstacles and success factors to scaling; and (6) the cost per student served by the grant.

Cumulative performance measures: (1) The percentage of grantees that reach the targeted number of students specified in the application; (2) the percentage of grantees that reach the targeted number of high-need students specified in the application; (3) the percentage of grantees that complete a well-designed, well-implemented, and independent evaluation that provides evidence of effectiveness at improving student outcomes at scale; (4) the percentage of grantees that complete a well-designed, well-implemented, and independent evaluation that provides information about the key elements and the approach of the project so as to facilitate replication or testing in other settings; (5) the percentage of grantees with a completed evaluation that provides information on the cost-effectiveness of the key practices to identify potential obstacles and success

factors to scaling; and (6) the cost per student served by the grant.

Project-Specific Performance Measures: Applicants must propose project-specific performance measures and performance targets (both as defined in this notice) consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) Performance measures. How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) Baseline (as defined in this notice) data. (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) Performance targets. Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) Data collection and reporting. (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Adam Schott,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2024–09795 Filed 5–3–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Privacy Act of 1974; System of Records

AGENCY: Department of Energy.

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circulars A–108 and A–130, the Department of Energy (DOE or the Department) is publishing notice of a modification to an existing Privacy Act system of records. DOE proposes to amend System of Records DOE–1, *Grievance Records.* This System of Records Notice (SORN) is being modified to align with new formatting requirements, published by OMB, and to ensure appropriate Privacy Act coverage of business processes and Privacy Act information. While there are no substantive changes to the ''Categories of Individuals'' or ''Categories of Records'' sections covered by this SORN, substantive changes have been made to the ''System Locations,'' ''Routine Uses,'' and ''Administrative, Technical and Physical Safeguards'' sections to provide greater transparency. Changes to ''Routine Uses'' include new provisions related to responding to breaches of information held under a Privacy Act SORN as required by OMB's Memorandum M–17–12, ''Preparing for and Responding to a Breach of Personally Identifiable Information'' (January 3, 2017). Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

DATES: This modified SORN will become applicable following the end of the public comment period on June 5, 2024 unless comments are received that result in a contrary determination.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW, Washington, DC 20503 and to Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm 8H–085, Washington, DC 20585 or by facsimile at (202) 586–8151 or by email at *privacy@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm 8H–085, Washington, DC 20585 or by facsimile at (202) 586–8151, by email at *privacy@hq.doe.gov,* or by telephone at (240) 686–9485.

SUPPLEMENTARY INFORMATION: On January 9, 2009, DOE published a Compilation of its Privacy Act systems of records, which included System of Records DOE–1, *Grievance Records.* This notice proposes amendments to the System Locations section of that system of records by removing System Locations where DOE–1 is no longer applicable. These locations are as follows: Alaska Power Administration, Environmental Consolidated Business Center, Southeastern Power

Administration, and the Office of Repository Development. Addresses for the National Energy Technology Laboratory's (NETL) sites in Pittsburgh, Morgantown, and Albany have been updated. Addresses for NETL's offices in Oklahoma and Alaska have been removed as they no longer require coverage. Finally, the Office of River Protection, Richland Operations Office, and Southwestern Power Administration addresses have been updated. The system manager's office title has been changed to ''Office of Policy, Labor and Employee Relations.'' The data element ''Social Security numbers'' has been removed from the ''Categories of Records in the System'' and ''employee identification numbers'' has been added. In the ''Routine Uses'' section, this modified notice deletes a previous routine use concerning efforts responding to a suspected or confirmed loss of confidentiality of information as it appears in DOE's compilation of its Privacy Act systems of records (January 9, 2009) and replaces it with one to assist DOE with responding to a suspected or confirmed breach of its records of Personally Identifiable Information (PII), modeled with language from OMB's Memorandum M–17–12, ''Preparing for and Responding to a Breach of Personally Identifiable Information'' (January 3, 2017). Further, this notice adds one new routine use to ensure that DOE may assist another agency or entity in responding to the other agency's or entity's confirmed or suspected breach of PII, as appropriate, as aligned with OMB's Memorandum M–17–12. An administrative change required by the FOIA Improvement Act of 2016 extends the length of time a requestor is permitted to file an appeal under the Privacy Act from 30 to 90 days. Both the ''System Locations'' and ''Administrative, Technical and Physical Safeguards'' sections have been modified to reflect the Department's usage of cloud-based services for records storage. Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

SYSTEM NAME AND NUMBER:

DOE–1, *Grievance Records.*

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATIONS:

Systems leveraging this SORN may exist in multiple locations. All systems storing records in a cloud-based server are required to use government-approved cloud services and follow National Institute of Standards and Technology (NIST) security and privacy standards for access and data retention. Records maintained in a government-approved cloud server are accessed through secure data centers in the continental United States.

U.S. Department of Energy, Headquarters, 1000 Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, National Nuclear Security Administration (NNSA) Headquarters, 1000 Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, NNSA John A. Gordon, Albuquerque Complex, 24600 20th Street SE, Albuquerque, NM 87116.

U.S. Department of Energy, NNSA Naval Reactors Field Office, Pittsburgh Naval Reactors, P.O. Box 109, West Mifflin, PA 15122–0109.

U.S. Department of Energy, NNSA Naval Reactors Field Office, Schenectady Naval Reactors, P.O. Box 1069, Schenectady, NY 12301.

Nevada Field Office, 232 Energy Way North, Las Vegas, NV 89030.

U.S. Department of Energy, Bonneville Power Administration, P.O. Box 3621, Portland, OR 97208.

U.S. Department of Energy, Office of Science, Chicago Office, Consolidated Service Center, 9800 South Cass Avenue, Lemont, IL 60439.

U.S. Department of Energy, Office of Science, Consolidated Service Center, P.O. Box 2001, Oak Ridge, TN 37831.

U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, Idaho Falls, ID 83415.

U.S. Department of Energy, National Energy Technology Laboratory (Pittsburgh), 626 Cochran Mill Road, Pittsburgh, PA 15236.

U.S. Department of Energy, National Energy Technology Laboratory (Morgantown), 3610 Collins Ferry Road, Morgantown, WV 26505.

U.S. Department of Energy, National Energy Technology Laboratory (Albany), 1450 Queen Avenue SW, Albany, OR 97321.

U.S. Department of Energy, Office of River Protection, P.O. Box 450, Richland, WA 99352.

U.S. Department of Energy, Richland Operations Office, P.O. Box 550, Richland, WA 99352.

U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29801.

U.S. Department of Energy, Southwestern Power Administration, One West Third Street, Suite 1500, Tulsa, OK 74103.

U.S. Department of Energy, Strategic Petroleum Reserve Project Management Office, 900 Commerce Road East, New Orleans, LA 70123.

U.S. Department of Energy, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213.

SYSTEM MANAGER(S):

Office of Policy, Labor and Employee Relations, Office of the Chief Human Capital Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 7101 *et seq.;* 50 U.S.C. 2401 *et seq.;* 5 U.S.C. 7121, and 5 CFR part 771.

PURPOSE(S) OF THE SYSTEM:

The records in this system are used by management officials in the resolution of employee concerns about conditions of employment, working conditions, administration of the agency's grievance process, labor-management relations, work processes, or other similar issues.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former DOE employees including NNSA employees, consultants, board members, and applicants, related to grievances filed in accordance with the Department's grievance process or pursuant to a negotiated grievance procedure.

CATEGORIES OF RECORDS IN THE SYSTEM:

Grievances; names; unique identifiers for Department employees and applicants for employment with the Department (*e.g.,* DOE OneID, employee number, and any other government identifier excluding Social Security number), work and home address; work and home telephone numbers; applicable demographic information; job titles, series, and grade levels; organization; supervisors' names and telephone numbers; copies of employee records, such as personnel actions, electronic official personnel files, performance appraisals, pay and leave records, and security clearance documents; management reports; witness statements; affidavits; checklists; notes; and relevant correspondence.

RECORD SOURCE CATEGORIES:

The grievant or complainant, applicable management officials, program office records, congressional offices, witnesses, and fact finders' notes and reports.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. A record from this system may be disclosed as a routine use to union officials acting in their official capacity

as a representative of the grievant or affected employees under 5 U.S.C. 7101 *et seq.*

2. A record from this system may be disclosed as a routine use to a member of Congress submitting a request involving a constituent when the constituent has requested assistance from the member concerning the subject matter of the record. The member of Congress must provide a copy of the constituent's signed request for assistance.

3. A record from this system may be disclosed as a routine use to an appropriate Federal, State, or local agency that is authorized to review and resolve the issue(s) raised in the grievance.

4. A record from this system may be disclosed as a routine use for the purpose of an investigation, settlement of claims, or the preparation and conduct of litigation to (1) persons representing the Department in the investigation, settlement or litigation, and to individuals assisting in such representation; (2) others involved in the investigation, settlement, and litigation, and their representatives and individuals assisting those representatives; (3) witnesses, potential witnesses, or their representatives and assistants; and any other person who possess information pertaining to the matter when it is necessary to obtain information or testimony relevant to the matters who possess information pertaining to the matter when it is relevant and necessary to obtain information or testimony relevant to the matter.

5. A record from this system may be disclosed as a routine use to DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties. Those provided information under this routine use are subject to the same limitations applicable to Department officers and employees under the Privacy Act.

6. A record from this system may be disclosed as a routine use to appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the system of records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOE (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. A record from this system may be disclosed as a routine use to another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are on paper or in digital or other electronic form. Digital and other electronic images are stored on a storage area network in a secured environment. Records, whether paper or electronic, may be stored in a separate, secure location at the Department of Energy Headquarters or at the Department field sites.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by the name of the grievant or the employing organizational element, type of grievance/matter being grieved, or other unique identifier, such as employee identification number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposition of these records is in accordance with the National Archives and Records Administration-approved records disposition schedule with a retention of 4 years.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records may be secured and maintained on a cloud-based software server and operating system that resides in Federal Risk and Authorization Management Program (FedRAMP) and Federal Information Security Modernization Act (FISMA) hosting environment. Data located in the cloud-based server is firewalled and encrypted at rest and in transit. The security mechanisms for handling data at rest and in transit are in accordance with DOE encryption standards. Records are protected from unauthorized access through the following appropriate safeguards:

- *Administrative:* Access to all records is limited to lawful government purposes only, with access to electronic records based on role and either two-factor authentication or password protection. The system requires passwords to be complex and to be changed frequently. Users accessing system records undergo frequent training in Privacy Act and information security requirements. Security and privacy controls are reviewed on an ongoing basis.
- *Technical:* Computerized records systems are safeguarded on Departmental networks configured for role-based access based on job responsibilities and organizational affiliation. Privacy and security controls are in place for this system and are updated in accordance with applicable requirements as determined by NIST and DOE directives and guidance.
- *Physical:* Computer servers on which electronic records are stored are located in secured Department facilities, which are protected by security guards, identification badges, and cameras. Paper copies of all records are locked in file cabinets, file rooms, or offices and are under the control of authorized personnel. Access to these facilities is granted only to authorized personnel and each person granted access to the system must be an individual authorized to use or administer the system.

RECORD ACCESS PROCEDURES:

The Department follows the procedures outlined in 10 CFR 1008.4. Valid identification of the individual making the request is required before information will be processed, given, access granted, or a correction considered, to ensure that information is processed, given, corrected, or records disclosed or corrected only at the request of the proper person.

CONTESTING RECORD PROCEDURES:

Any individual may submit a request to the System Manager and request a copy of any records relating to them. In accordance with 10 CFR 1008.11, any individual may appeal the denial of a request made by him or her for information about or for access to or correction or amendment of records. An appeal shall be filed within 90 calendar days after receipt of the denial. When an appeal is filed by mail, the postmark is conclusive as to timeliness. The appeal shall be in writing and must be signed by the individual. The words ''PRIVACY ACT APPEAL'' should appear in capital letters on the envelope and the letter. Appeals of denials relating to records maintained in government-wide system of records reported by Office of Personnel

Management (OPM), shall be filed, as appropriate, with the Assistant Director for Agency Compliance and Evaluation, OPM, 1900 E Street NW, Washington, DC 20415. All other appeals relating to DOE records shall be directed to the Director, Office of Hearings and Appeals (OHA), 1000 Independence Avenue SW, Washington, DC 20585.

NOTIFICATION PROCEDURES:

In accordance with the DOE regulation implementing the Privacy Act, 10 CFR part 1008, a request by an individual to determine if a system of records contains information about themselves should be directed to the U.S. Department of Energy, Headquarters, Privacy Act Officer. The request should include the requester's complete name and the time period for which records are sought.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in the **Federal Register**, 88 FR 87760–87762, on December 19, 2023.

Signing Authority

This document of the Department of Energy was signed on May 1, 2024, by Ann Dunkin, Senior Agency Official for Privacy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–09798 Filed 5–3–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Privacy Act of 1974; System of Records

AGENCY: Department of Energy.

ACTION: Notice of a modified system of records.

SUMMARY: As required by the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circulars A–108 and A–130, the Department of Energy (DOE or the Department) is publishing notice of a modification to an existing Privacy Act System of Records. DOE proposes to amend System of Records DOE–8 Intergovernmental Personnel Act (IPA).

This System of Records Notice (SORN) is being modified to align with new formatting requirements, published by OMB, and to ensure appropriate Privacy Act coverage of business processes and Privacy Act information. While there are no substantive changes to the ''Categories of Individuals'' or ''Categories of Records'' sections covered by this SORN, substantive changes have been made to the ''System Locations,'' ''Routine Uses,'' and ''Administrative, Technical and Physical Safeguards'' sections to provide greater transparency. Changes to ''Routine Uses'' include new provisions related to responding to breaches of information held under a Privacy Act SORN as required by OMB's Memorandum M–17–12, ''Preparing for and Responding to a Breach of Personally Identifiable Information'' (January 3, 2017). Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

DATES: This modified SORN will become applicable following the end of the public comment period on June 5, 2024 unless comments are received that result in a contrary determination.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW, Washington, DC 20503 and to Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm 8H–085, Washington, DC 20585, or by facsimile at (202) 586–8151, or by email at *privacy@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Ken Hunt, Chief Privacy Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Rm 8H–085, Washington, DC 20585, or by facsimile at (202) 586–8151, by email at *privacy@hq.doe.gov,* or telephone at (240) 686–9485.

SUPPLEMENTARY INFORMATION: On January 9, 2009, DOE published a Compilation of its Privacy Act Systems of Records, which included System of Records DOE–8 Intergovernmental Personnel Act (IPA). This notice proposes the following amendments. The following system locations have been removed as they are no longer applicable: Naval Reactors Field Office, Alaska Power Administration, Office of Science's Chicago and Oak Ridge Offices, Environmental Management Consolidated Business Center, both National Energy Technology Laboratory locations, Richland Operations Office, Savannah River Operations Office, and Southwestern Power Administration. The following addresses have been updated: John A. Gordon Albuquerque Complex, and Golden Field Office. The National Nuclear Security Administration in Washington, DC has been added. In the ''Routine Uses'' section, this modified notice deletes a previous routine use concerning efforts responding to a suspected or confirmed loss of confidentiality of information as it appears in DOE's compilation of its Privacy Act Systems of Records (January 9, 2009) and replaces it with one to assist DOE with responding to a suspected or confirmed breach of its records of Personally Identifiable Information (PII), modeled with language from OMB's Memorandum M–17–12, ''Preparing for and Responding to a Breach of Personally Identifiable Information'' (January 3, 2017). Further, this notice adds one new routine use to ensure that DOE may assist another agency or entity in responding to the other agency's or entity's confirmed or suspected breach of PII, as appropriate, as aligned with OMB's Memorandum M–17–12. An administrative change required by the FOIA Improvement Act of 2016 extends the length of time a requestor is permitted to file an appeal under the Privacy Act from 30 to 90 days. Both the ''System Locations'' and ''Administrative, Technical and Physical Safeguards'' sections have been modified to reflect the Department's usage of cloud-based services for records storage. Language throughout the SORN has been updated to align with applicable Federal privacy laws, policies, procedures, and best practices.

SYSTEM NAME AND NUMBER:

DOE–8 Intergovernmental Personnel Act (IPA).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATIONS:

Systems leveraging this SORN may exist in multiple locations. All systems storing records in a cloud-based server are required to use government-approved cloud services and follow National Institute of Standards and Technology (NIST) security and privacy standards for access and data retention. Records maintained in a government-approved cloud server are accessed

through secure data centers in the continental United States.

U.S. Department of Energy, Headquarters, 1000 Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, National Nuclear Security Administration, 1000 Independence Avenue SW, Washington, DC 20585.

U.S. Department of Energy, Headquarters, Germantown, 19901 Germantown Road, Germantown, MD 20585.

U.S. Department of Energy, National Nuclear Security Administration, John A. Gordon Albuquerque Complex, 24600 20th Street SE, Albuquerque, NM 87116.

U.S. Department of Energy, Bonneville Power Administration, P.O. Box 3621, Portland, OR 97208.

U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401.

U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, Idaho Falls, ID 83415.

U.S. Department of Energy, Southeastern Power Administration, 1166 Athens Tech Road, Elberton, GA 30635–6711.

U.S. Department of Energy, Strategic Petroleum Reserve Project Management Office, 900 Commerce Road East, New Orleans, LA 70123.

U.S. Department of Energy, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213.

SYSTEM MANAGER(S):

Headquarters: Director of Human Capital Management, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585.

Field Offices: The Human Capital Directors at the field locations listed above under ''Systems Locations'' are the system managers for their respective portions of this system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 7101 *et seq.;* 50 U.S.C. 2401 *et seq.;* 5 U.S.C. chapter 33, subchapter VI, 36 CFR subpart E 1236, General Records Schedule 4.2 item 150, and title 5 CFR part 334.

PURPOSE(S) OF THE SYSTEM:

Records in this system are maintained and used by DOE to provide a basis for payments under the terms of the IPA agreements, provide employment histories, and provide information for reports and program evaluations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are now, or have been, under an IPA agreement to or from DOE, including NNSA.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, home and work addresses, Social Security number, unique identifiers for Department employees and applicants for employment with the Department (*e.g.,* DOE OneID, employee number, and any other government identifier), home and work telephone numbers, salary, and related correspondence.

RECORD SOURCE CATEGORIES:

The subject individual and current or prospective employer.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. A record from this system may be disclosed to any organization eligible to receive an assigned individual under the Intergovernmental Personnel Act, including tribal, state, and local governments, institutions of higher education, Federally Funded Research and Development Centers, and other organizations certified under IPA rules.

2. A record from this system may be disclosed as a routine use to DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties. Those provided information under this routine use are subject to the same limitations applicable to Department officers and employees under the Privacy Act.

3. A record from this system may be disclosed as a routine use to a member of Congress submitting a request involving a constituent when the constituent has requested assistance from the member concerning the subject matter of the record. The member of Congress must provide a copy of the constituent's signed request for assistance.

4. A record from this system may be disclosed as a routine use to appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the System of Records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOE (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

5. A record from this system may be disclosed as a routine use to another Federal agency or Federal entity, when the Department determines that information from this System of Records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored as electronic media or paper records.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name or Social Security number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention and disposition of these records is in accordance with the National Archives and Records Administration approved schedule with a 250-year retention.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Electronic records may be secured and maintained on a cloud-based software server and operating system that resides in Federal Risk and Authorization Management Program (FedRAMP) and Federal Information Security Modernization Act (FISMA) hosting environment. Data located in the cloud-based server is firewalled and encrypted at rest and in transit. The security mechanisms for handling data at rest and in transit are in accordance with DOE encryption standards. Records are protected from unauthorized access through the following appropriate safeguards:

- Administrative: Access to all records is limited to lawful government purposes only, with access to electronic records based on role and either two-factor authentication or password protection. The system requires passwords to be complex and to be changed frequently. Users accessing system records undergo frequent training in Privacy Act and information security requirements. Security and privacy controls are reviewed on an ongoing basis.
- Technical: Computerized records systems are safeguarded on Departmental networks configured for role-based access based on job responsibilities and organizational affiliation. Privacy and security controls

are in place for this system and are updated in accordance with applicable requirements as determined by NIST and DOE directives and guidance.

• Physical: Computer servers on which electronic records are stored are located in secured Department facilities, which are protected by security guards, identification badges, and cameras. Paper copies of all records are locked in file cabinets, file rooms, or offices and are under the control of authorized personnel. Access to these facilities is granted only to authorized personnel and each person granted access to the system must be an individual authorized to use or administer the system.

RECORD ACCESS PROCEDURES:

The Department follows the procedures outlined in 10 CFR 1008.4. Valid identification of the individual making the request is required before information will be processed, given, access granted, or a correction considered, to ensure that information is processed, given, corrected, or records disclosed or corrected only at the request of the proper person.

CONTESTING RECORD PROCEDURES:

Any individual may submit a request to the System Manager and request a copy of any records relating to them. In accordance with 10 CFR 1008.11, any individual may appeal the denial of a request made by him or her for information about or for access to or correction or amendment of records. An appeal shall be filed within 90 calendar days after receipt of the denial. When an appeal is filed by mail, the postmark is conclusive as to timeliness. The appeal shall be in writing and must be signed by the individual. The words ''PRIVACY ACT APPEAL'' should appear in capital letters on the envelope and the letter. Appeals relating to DOE records shall be directed to the Director, Office of Hearings and Appeals (OHA), 1000 Independence Ave. SW, Washington, DC 20585.

NOTIFICATION PROCEDURES:

In accordance with the DOE regulation implementing the Privacy Act, 10 CFR part 1008, a request by an individual to determine if a System of Records contains information about themselves should be directed to the U.S. Department of Energy, Headquarters, Privacy Act Officer. The request should include the requester's complete name and the time period for which records are sought.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in the **Federal Register**, 74 FR 1006–1007, on January 9, 2009.

Signing Authority

This document of the Department of Energy was signed on May 1, 2024, by Ann Dunkin, Senior Agency Official for Privacy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 1, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–09799 Filed 5–3–24; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2003–0004; FRL–11939–01–OCSPP]

Access to Confidential Business Information by General Dynamics Information Technology (GDIT)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized its contractor General Dynamics Information Technology (GDIT) of Falls Church, VA, to access information which has been submitted to EPA under all sections of the Toxic Substances Control Act (TSCA). Some of the information may be claimed or determined to be Confidential Business Information (CBI).

DATES: Access to the confidential data will occur no sooner than May 13, 2024.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Colby Lintner or Adam Schwoerer, Program Management and Operations Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8182; email address: *lintner.colby@epa.gov* or (202) 564–4767; *schwoerer.adam@epa.gov* or (202) 564–4767.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to all who manufacture, process, or distribute industrial chemicals. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2003–0004, is available at *https://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

Under contract number 47QTCK18D0003, task order number 47QFCA22F0018, contractor GDIT of 3150 Fairview Park Drive, Falls Church, VA 22042 will assist the Office of Pollution Prevention and Toxics (OPPT) by hosting the servers and managing the infrastructure where TSCA CBI resides.

In accordance with 40 CFR 2.306(j), EPA has determined that under EPA contract number 47QTCK18D0003, task order number 47QFCA22F0018, GDIT will require access to CBI submitted under all sections of TSCA. EPA has determined that GDIT will need access to TSCA CBI submitted to EPA under all Sections of TSCA to perform successfully the duties specified under the contract. GDIT's personnel will be given access to information claimed or determined to be CBI information

submitted to EPA under all sections of TSCA.

EPA is issuing this notice to inform all submitters of information under all sections of TSCA that EPA will provide GDIT access to these CBI materials on a need-to-know basis only. All access to TSCA CBI under this contract will take place at the National Computer Center in RTP, NC and telework locations of EPA and GDIT staff in accordance with EPA's *TSCA CBI Protection Manual* and the Rules of Behavior for Virtual Desktop Access to OPPT Materials, including TSCA CBI.

Access to TSCA data, including CBI, will continue until April 24, 2029. If the contract is extended, this access will also continue for the duration of the extended contract without further notice.

GDIT personnel will be required to sign nondisclosure agreements and will be briefed on specific security procedures for TSCA CBI.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: April 30, 2024.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2024–09738 Filed 5–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0751; FRL–11909–01–OCSPP]

Pesticide Registration Review; Decisions for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decision for bromine. The notice also announces the availability of EPA's final registration review decisions for the following chemicals: *Agrobacterium radiobacter,* polybutene resins, and porcine zona pellucida (PZP).

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in table 1 of unit I.

For general information on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0701; email address: *biscoe.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's interim or final registration review decisions for the pesticides shown in table 1. The interim and final registration review decisions are supported by rationales included in the docket established for each chemical.

TABLE 1—INTERIM AND FINAL REGISTRATION REVIEW DECISIONS BEING ISSUED

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Agrobacterium radiobacter, Case Number 4101	EPA–HQ–OPP–2022–0860	Joseph Mabon, *mabon.joseph@epa.gov,* (202) 566–1535.
Bromine, Case Number 4015	EPA–HQ–OPP–2021–0034	Megan Snyderman, *snyderman.megan@epa.gov,* (202) 566–0639.
Polybutene Resins, Case Number 4076	EPA–HQ–OPP–2022–0799	Michelle Nolan, *nolan.michelle@epa.gov,* (202) 566–2237.
Porcine Zona Pellucida (PZP), Case Number 7801	EPA–HQ–OPP–2022–0153	Christian Bongard, *bongard.christian@epa.gov,* (202) 566–2248.

II. Background

EPA is conducting its registration review of the chemicals listed in table 1 of unit I pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that pesticide registrations are to be reviewed every 15 years. Consistent with 40 CFR 155.57, in its final registration review decision, EPA will ultimately determine whether a pesticide continues to meet the registration standard in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). As part of the registration review process, the Agency has completed interim or final registration review decisions for the pesticides in table 1 of unit I.

Prior to completing the interim or final registration review decisions in table 1 of unit I, EPA posted proposed interim decisions or proposed registration review decisions for these chemicals and invited the public to submit any comments or new information, consistent with 40 CFR 155.58(a). EPA considered and responded to any comments or information received during these public comment periods in the respective interim decision or final registration review decisions.

For additional background on the registration review program, see: *https://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 30, 2024.

Timothy Kiely,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2024–09768 Filed 5–3–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0720; FRL–11905–01–OCSPP]

Pesticide Registration Review; Pesticide Dockets Opened for Review and Comment; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of the EPA's work plans and registration review case dockets for the following chemicals: Cornmint Oil, Humates (as derived from Leonardite), and Refined oil of *Nepeta cataria.* EPA is opening a 60-day public comment period for these work plans and case dockets.

DATES: Comments must be received on or before July 5, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2017–0720,

through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in Table 1 of Unit I.

For general questions on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0701; email address: *biscoe.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

Pursuant to 40 CFR 155.50(b), this notice announces the availability of the EPA's work plans and registration review case dockets for the pesticides shown in Table 1 and opens a 60-day public comment period on the work plans and case dockets.

TABLE 1—WORK PLANS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Cornmint Oi, Case Number 6345	EPA–HQ–OPP–2023–0528	Hector Andres Maldonado, *maldonado.hector@epa.gov,* (202) 566–1373.
Humates (as derived from Leonardite), Case Number 6323.	EPA–HQ–OPP–2024–0017	Andrew Queen, *queen.andrew@epa.gov,* (202) 566–1539.
Refined oil of *Nepeta cataria,* Case Number 6361	EPA–HQ–OPP–2024–0019	Bibiana Oe, *oe.bibiana@epa.gov*, (202) 566–1538.

II. Background

EPA is conducting its registration review of the chemicals listed in Table 1 of Unit I pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that pesticide registrations are to be reviewed every 15 years. Consistent with 40 CFR 155.57, in its final registration review decision, EPA will ultimately determine whether a pesticide continues to meet the registration standard in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)).

Pursuant to 40 CFR 155.50, EPA initiates a registration review by establishing a public docket for a pesticide registration review case. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency has consider during registration review. Consistent with 40 CFR 155.50(a), these dockets may include information from the Agency's files including, but not limited to, an overview of the registration review case status, a list of current product registrations and registrants, any **Federal Register** notices regarding any pending registration actions, any **Federal Register** notices regarding current or pending tolerances, risk assessments, bibliographies concerning current registrations, summaries of incident data, and any other pertinent data or information. EPA includes in these dockets a Preliminary Work Plan (PWP), and in some cases a continuing work plan (CWP), summarizing information EPA has on the pesticide and the anticipated path forward.

Consistent with 40 CFR 155.50(b), EPA provides for at least a 60-day public comment period on work plans and registration review dockets. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary changes to a pesticide's workplan. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

For additional background on the registration review program, see: *https://www.epa.gov/pesticide-reevaluation.*

III. What should I consider as I prepare a comment for EPA?

This notice is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in Table 1 of Unit I. In submitting a comment to EPA, please consider the following:

1. *Submitting CBI.* Do not submit this information to the EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

All comments should be submitted using the methods in **ADDRESSES** and must be received by the EPA on or before the closing date. These comments will become part of the docket for the pesticides included in Table 1 of Unit I. The Agency will consider all comments received by the closing date and may respond to comments in a ''Response to Comments Memorandum'' in the docket or the Final Work Plan (FWP), as appropriate.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 30, 2024.

Timothy Kiely,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2024–09764 Filed 5–3–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0188; Docket No. 2024–0053; Sequence No. 4]

Submission for OMB Review; Combating Trafficking in Persons

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding combating trafficking in persons.

DATES: Submit comments on or before June 5, 2024.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB control number, Title, and any Associated Form(s)

OMB Control # 9000–0188, Combating Trafficking in Persons.

B. Need and Uses

This clearance covers the information that offerors and contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

52.222–50, Combating Trafficking in Persons

Notification. Paragraph (d) of this clause requires contractors to notify the contracting officer and the agency Inspector General of—

- Any credible information they receive from any source that alleges a contractor employee, subcontractor, or subcontractor employee, or their agent has engaged in conduct that violates the policy in paragraph (b) of the clause 52.222–50; and
- Any actions taken against a contractor employee, subcontractor, subcontractor employee, or their agent pursuant to this clause.

Compliance Plan and Annual Certification. Paragraph (h) of the clause contains an additional requirement for contracts for supplies (other than commercially available off-the-shelf (COTS) items) to be acquired outside the United States and contracts for services to be performed outside the United States, with an estimated value exceeding $550,000, where the contractor is to maintain a compliance plan during the performance of the contract. This compliance plan must include an awareness program, a process for employees to report activity inconsistent with the zero-tolerance policy, a recruitment and wage plan, a housing plan, and procedures to prevent subcontractors from engaging in trafficking in persons.

- Contractors are required to provide the compliance plan to the contracting officer upon request.
- Contractors are required to submit a certification to the contracting officer annually after receiving an award, asserting that they have the required compliance plan in place and that there have been no abuses, or that appropriate actions have been taken if abuses have been found.
- For those subcontractors required to submit a certification (see next bullet on flow down), contractors shall require that submission prior to award of the subcontract and annually thereafter.

Portions of this clause flows down to all subcontractors. The requirements related to the compliance plan only flow down to subcontracts exceeding $550,000 for supplies (other than COTS items) acquired and services performed outside the United States.

This clause applies to commercial acquisitions, except the portions related to the compliance plan do not apply to acquisitions of COTS items.

52.222–56, Certification Regarding Trafficking in Persons Compliance Plan

This provision requires apparently successful offerors to submit a certification, prior to award, that they have implemented a compliance plan and that there have been no abuses, or that appropriate actions have been taken if abuses have been found.

The provision requires this certification for the portion of contracts exceeding $550,000 for supplies (other than COTS items) acquired and services performed outside the United States.

This provision applies to commercial acquisitions, except acquisitions of COTS items.

FAR 52.222–50, paragraph (d)—Notification. The Government uses this notification of potential violations of trafficking in persons requirements to investigate and take appropriate action if a violation has occurred.

FAR 52.222–50, paragraph (h)—Compliance Plan. The Government uses the compliance plan to ascertain compliance with the Trafficking Victims Protection Act (22 U.S.C. 7104), Executive Order 13627, Strengthening Protections Against Trafficking in Persons in Federal Contracts dated September 25, 2012 (77 FR 60029, October 2, 2012) and Title XVII of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239, enacted January 2, 2013) or any other applicable law or regulation.

FAR 52.222–50, paragraph (h) and FAR 52.222–56—Certification. The Government uses the certification to obtain reasonable assurance that the contractor and its subcontractors are aware of and complying with the requirements of the Executive Order and statute.

C. Annual Burden

Respondents/Recordkeepers: 5,944.
Total Annual Responses: 11,778.
Total Burden Hours: 165,818. (27,194 reporting hours + 138,624 recordkeeping hours).

D. Public Comment

A 60-day notice was published in the **Federal Register** at 89 FR 14497, on February 27, 2024. A comment was received in *Regulations.gov* but not posted to be publicly viewable because it was not relevant or responsive to the

request for comments. The comment seems to be unsolicited bulk email.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0188, Combating Trafficking in Persons.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2024–09781 Filed 5–3–24; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Webinar: National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webinar.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is announcing a closed meeting and public webinar to share information on the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People (VBD National Strategy). The full meeting will be by invitation only to ensure representation and inclusion of researchers, clinicians, public health officials, vector control officials, and patient advocates. However, the public is invited to listen virtually to the opening and closing sessions (attendance via livestream is unlimited).

DATES: The public webinar will be held on May 23, 2024, from 10:00 a.m. to 11:00 a.m. and 3:00 p.m. to 4:00 p.m., Eastern time.

ADDRESSES: The public webinar will be available by livestream. To access the meeting visit this page on the day of the event: *https://www.hhs.gov/live/index.html.*

FOR FURTHER INFORMATION CONTACT: Sue Visser, DrPH, MS, Deputy Director for Policy and Extramural Program; Fort Collins, CO (Offices and Laboratories), 3156 Rampart Road, Fort Collins, CO 80521; Telephone: 404–498–3008; Email: *vbdstrategy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: Leaders from CDC's Division of Vector-Borne Disease (DVBD) will host an in-person and online meeting about the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People (VBD National Strategy). The VBD National Strategy was developed by the Department of Health and Human Services in response to congressional direction in the Kay Hagan Tick Act, passed as part of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94). The primary purpose of the meeting is to increase awareness of the VBD National Strategy and inform future implementation efforts.

The public is invited to attend the opening and closing sessions of the meeting. In the opening session, speakers will describe the VBD National Strategy and federal agency representatives will present 2023 success stories. After the opening session, invited participants will participate in a set of interactive activities to collect individual opinions from a range of invited meeting participants with vector-borne disease experience. The public will be invited to a closing session at which time a summary of the interactive sessions will be shared.

This meeting follows previous public engagement activities, including the two Requests for Information previously published in the **Federal Register** on April 27, 2021, (86 FR 23391) and November 21, 2022, (87 FR 70836). Additional information and public comments can be found on *www.regulations.gov* in dockets HHS–OASH–2021–0012 and HHS–OASH–2022–0019.

Public Webinar: The opening and closing sessions will be open to the public to an unlimited number of viewers via livestream.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–09774 Filed 5–3–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10636, CMS–10874, and CMS–319]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 5, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS—10636 Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans

CMS—10874 Part D Drug Management Program

CMS—319 State Medicaid Eligibility Quality Control Sample Selection Lists and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans; *Use:* CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS regulations at § 422.116 outline network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network; *Form Number:* CMS–10636 (OMB control number: 0938–1346); *Frequency:* Yearly; *Affected Public:* Private sector; *Number of Respondents:* 502; *Number of Responses:* 2,753; *Total Annual Hours:* 27,470. (For policy questions regarding this collection contact Jackie Ford at 410–786–7767.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Part D Drug Management Program (DMP); *Use:* Section 1860D–4(c)(5)(A) of the Social Security Act requires that Part D sponsors have a DMP for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). The information in this collection of information request is necessary for sponsor conformance with DMP requirements at § 423.153(f), including communicating with prescribers and pharmacies, informing beneficiaries that they have been identified as a PARB or ARB, and informing beneficiaries and CMS whether a beneficiary's access to FADs will be restricted to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit. Part D sponsors will use the standardized and model documents to communicate with providers, enrollees, and other sponsors. Specifically, Part D sponsors may use the Model Part D Drug Management Program Prescriber Inquiry Letter to inform providers that their patient's pattern of use or history of use of FADs is potentially unsafe and has prompted a case management review under the plan's DMP. Part D sponsors must use the standardized Initial Notice and Second Notice, or Alternate Second Notice, to inform enrollees, following identification by CMS's OMS and subsequent case management, whether the beneficiaries have been identified as being potentially at risk or at risk for abuse or misuse of FADs. Part D sponsors may use the Model Part D Drug Management Program Sponsor Information Transfer Memorandum to communicate to a gaining sponsor the enrollee's history of misuse or abuse of FADs; *Form Number:* CMS–10874 (OMB control number: 0938–1465); *Frequency:* Yearly and once; *Affected Public:* Private sector; *Number of Respondents:* 319; *Number of Responses:* 62,248; *Total Annual Hours:* 152,585. (For policy questions regarding this collection contact Valerie Yingling at 667–290–8657.)

3. *Type of Information Collection Request:* Reinstatement with change to the previously approved information collection: *Title of Information Collection:* State Medicaid Eligibility Quality Control Sample Selection Lists and Supporting Regulations; *Use:* Title XIX and Title XXI State agencies are required to submit the MEQC pilot planning document in accordance with § 431.814(b), and the MEQC case level and CAP reports based on pilot findings in accordance with §§ 431.816 and 431.820, respectively. The primary users of this information are State Medicaid (and where applicable CHIP) agencies and CMS. State agencies are expected to use the information collected for continuous quality improvement purposes. They will identify patterns of error in their eligibility processing operations and systems and take corrective actions to address issues and improve the eligibility determination process. CMS will use the data collected to identify and help those States that are most in need of technical assistance. CMS will also use the data set to identify potential weaknesses in Federal regulations. It will propose regulatory modifications designed to ensure that there are more effective quality controls in the eligibility determination process.; *Form Number:* CMS–319 (OMB control number: 0938–0147); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Number of Responses:* 647; *Total Annual Hours:* 9,840. (For policy questions regarding this collection contact Camiel Rowe at 410–786–0069.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–09812 Filed 5–3–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1800–NC3]

Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' draft guidance for the second cycle of the Medicare Drug Price Negotiation Program and manufacturer effectuation of the maximum fair price for 2026 and 2027 for the implementation of the Inflation Reduction Act. This and other Inflation Reduction Act-related guidance can be viewed on the dedicated Inflation Reduction Act section of the CMS website at *https://www.cms.gov/inflation-reduction-act-and-medicare/*.

DATES: Comments must be received by July 2, 2024.

ADDRESSES: Written comments should be sent to *IRARebateandNegotiation@cms.hhs.gov* with the relevant subject line, ''Medicare Drug Price Negotiation Program Draft Guidance.''

FOR FURTHER INFORMATION CONTACT: Elizabeth Daniel, *Elizabeth.daniel@cms.hhs.gov* or (667) 290–8793.

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act (IRA) (*Pub. L. 117–169*) was signed into law on August 16, 2022. Sections 11001 and 11002 of the IRA established the Medicare Drug Price Negotiation Program (hereafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act as added by sections 11001 and 11002 of the IRA. The draft guidance describes how CMS intends to implement the Negotiation Program for Initial Price Applicability Year (IPAY) 2027 (January 1, 2027 to December 31, 2027), and specifies the requirements for manufacturer effectuation of the MFPs for 2026 and 2027.

To obtain copies of the Negotiation Program draft guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: *https://www.cms.gov/inflation-reduction-act-and-medicare*. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at *https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates*.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 30, 2024.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–09750 Filed 5–3–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10054]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 5, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10054 New Technology Services for Ambulatory Payment Classifications under the Outpatient Prospective Payment System

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register**

concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* New Technology Services for Ambulatory Payment Classifications Under Outpatient Prospective Payment System; *Use:* In the April 7, 2000 final rule with comment period first implementing the hospital outpatient prospective payment system (OPPS), we created a set of New Technology ambulatory payment classifications (APCs) to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not covered by the transitional pass-through payments provisions authorized by the Balanced Budget Refinement Act (BBRA) of 1999.

Since implementation of the hospital outpatient prospective payment system (OPPS) on August 1, 2000, transitional pass-through payments have been made to hospitals for certain drugs, biologicals, and medical devices. These are temporary additional payments required by section 1833(t)(6) of the Social Security Act (the Act), which was added by section 201(b) of the Balanced Budget Act of 1999 (BBRA). The law required the Secretary to make these additional payments to hospitals for at least 2 but no more than 3 years.

In the April 7, 2000 final rule with comment period, we specified an application process and the information that must be supplied for us to consider a request for payment under the New Technology APCs (65 FR 18478). We posted the application process on our website at *www.cms.hhs.gov.* Services were only considered eligible for assignment to a New Technology APC if we listed them in one of a number of lists published in Medicare Program Memoranda, which are posted to our website (*https://www.cms.gov/medicare/regulations-guidance/transmittals/cms-program-memoranda*). We established a quarterly application process by which interested parties could submit applications to us for particular services. We assign new services to the New Technology APCs that we determine cannot be placed appropriately in clinical APCs. Under our current policy, we retain services in a New Technology APC until we gain sufficient information about actual hospital costs incurred to furnish a new technology service. *Form Number:* CMS–10054 (OMB control number: 0938–0860); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 25; *Number of Responses:* 25; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Josh Mcfeeters at 410–786–9732.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–09745 Filed 5–3–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1133]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Pharmaceutical Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #290 (VICH GL61) entitled ''Pharmaceutical Development.'' This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance describes the suggested contents for the Pharmaceutical Development section, which provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management to the development of a product and its manufacturing process.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1133 for ''Pharmaceutical Development.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mai Huynh, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0669, *Mai.Huynh@fda.hhs.gov*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #290 (VICH GL61) entitled ''Pharmaceutical Development.'' This draft guidance describes the suggested contents for the Pharmaceutical Development section, which provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management to the development of a product and its manufacturing process. The Pharmaceutical Development section is intended to provide a comprehensive understanding of the product and manufacturing process for reviewers and investigators.

FDA has participated in efforts to enhance international harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries. FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The goal of the VICH is to develop harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and receives input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA—Center for Veterinary Medicine and U.S. Department of Agriculture—Center for Veterinary Biologics; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry and Fisheries; and the Japanese Veterinary Products Association. There are 10 observers to the VICH Steering Committee: one representative from government and one representative from industry of Australia, New Zealand, Canada, South Africa, and the United Kingdom. The World Organisation for Animal Health is an associate member of the VICH. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pharmaceutical Development.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: May 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09777 Filed 5–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

The Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 26, 2024, from 9 a.m. to 4:30 p.m. EST.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. The

public will have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://fda.zoomgov.com/j/1604157441?pwd=YkVzZ28vNHQrVXh3ZlhrTmlHaFVzZz09.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On June 26, 2024, the Center for Tobacco Product's TPSAC will convene for one open session, during which the committee will discuss the renewal of a risk modification order, submitted by Swedish Match USA, Inc. for the following loose snus and portioned snus products:

- MR0000020: General Loose
- MR0000021: General Dry Mint Portion Original Mini
- MR0000022: General Portion Original Large
- MR0000024: General Classic Blend Portion White Large—12 ct
- MR0000025: General Mint Portion White Large
- MR0000027: General Nordic Mint Portion White Large—12 ct
- MR0000028: General Portion White Large
- MR0000029: General Wintergreen Portion White Large

Additional discussion about broader Modified Risk Tobacco Products program developments related to the conceptualization and measurement of consumer understanding will also occur.

The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 20, 2024. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. EST on June 26, 2024. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants, whether they would like to present online or in person, on or before June 11, 2024, by 5 p.m. Eastern Time. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in person. The contact person will notify interested persons regarding their request to speak by June 12, 2024.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting (see **FOR FURTHER INFORMATION CONTACT**).

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: May 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09786 Filed 5–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5365]

Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' This draft guidance, when finalized, will describe the factors FDA intends to assess when deciding to issue an enforcement policy regarding test manufacturers' offering of certain unapproved tests and unapproved uses of approved tests during a declared emergency. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–5365 for ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

During an emergency, appropriately safe and effective diagnostic tests are critical to the diagnosis, treatment, tracking, and interruption of transmission of infectious diseases during outbreaks, as well as for diagnosing and treating diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents. FDA is issuing this draft guidance that, when finalized, will describe the factors FDA plans to assess in deciding whether to issue an enforcement policy regarding test manufacturers' offering of certain unapproved tests and unapproved uses of approved tests for the diagnosis of a disease or other condition to help quickly increase test availability when appropriate during a declared emergency under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This draft guidance describes the factors FDA intends to assess when issuing an enforcement policy including: (1) the need for accelerated availability of tests; (2) the known or potential risks of such tests; (3) the availability of appropriate alternative tests that are authorized or approved; and (4) the availability of sufficient mitigations to address risks of false results. When issuing an enforcement policy, FDA generally intends to describe the circumstances in which the Agency intends to exercise enforcement discretion, including, for example, when the test has been validated. FDA may also identify the initial duration in which an enforcement policy is intended to be in effect.

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov and https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007009 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
803	Medical Device Reporting	0910–0437
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988'' (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08933 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, May 7, 2024, 10:00 a.m. to May 8, 2024, 3:30 p.m., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Rooms A, B, & C, Bethesda, MD 20817 which was published in the **Federal Register** on April 9, 2024, FR Doc. 2024–07500, 89 FR 24846.

This notice is being amended to replace the Contact Person from Ranga V. Srinivas, Ph.D. to Philippe Marmillot, Ph.D. Director, Office of Extramural Activities, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Room 2118, Bethesda, MD 20892, (301) 443–2861, *marmillotp@mail.nih.gov.* Additionally, the meeting end time on May 8, 2024, has changed from 3:30 p.m. to 3:45 p.m. The meeting on May 7, 2024, is partially closed to the public in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the meeting on May 8, 2024, is open to the public.

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09727 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–NS–24–021: HEAL Initiative: Individual Differences in Human Pain Conditions.

Date: June 3–4, 2024.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Mark Allen Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, 301–402–4128, *mark.vosvick@nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: June 3–4, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Salamander Hotel, Washington, DC, 1330 Maryland Ave. SW, Washington, DC 2024.

Contact Person: Stephanie Nagle Emmens, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–6604, *nagleemmenssc@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: June 4–5, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurotoxicology and Alcohol Study Section.

Date: June 4–5, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: John N. Stabley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0566, *stableyjn@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: June 4–5, 2024.

Time: 9:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carmen Bertoni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805B, Bethesda, MD 20892, (301) 867–5309, *bertonic2@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 30, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09749 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be access from the NIH Videocasting website *http://videocast.nih.gov/or https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: June 4, 2024

Closed: 8:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892.

Open: 10:00 a.m. to 4:00 p.m.

Agenda: To discuss program policies and issues.

Place: Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892.

Meeting Format: In Person.

Virtual Access: The meeting will be videocast and can be accessed from the NIH Videocast. *http://videocast.nih.gov/* or *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.* Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Valerie L. Prenger, Ph.D., Acting Division Director, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive Room 7214, Bethesda, MD 20892–7924, 301–435–0270, *Valerie.Prenger@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on the notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09722 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Grants Review Committee.

Date: June 25–26, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiwu Cheng, Ph.D., Scientific Review Officer, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20982, (301) 594–4859, *chengai@mail.nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Small Research Grants (R03) for Secondary Data Analysis PARs.

Date: June 28, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas John O'Farrell, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892, (301) 584–4859, *tom.ofarrell@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09748 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative K99.

Date: June 6, 2024.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Emma Perez-Costas, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20892, (240) 936–6720, *emma.perez-costas@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Bidirectional Influences Between Adolescent Social Media Use and Mental Health.

Date: June 13, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, (240) 796–6785, *regina.dolan-sewell@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Early Psychosis Intervention Network (EPINET).

Date: June 17, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, (240) 796–6785, *regina.dolan-sewell@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09724 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Lung Endothelial Cell Amyloids.

Date: June 3, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–T, Bethesda, MD 20892–7924, (301) 827–7984, *ssehnert@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Integrating advanced sensing, omics, and machine learning to mitigate cardiometabolic disorders for Mexican American Communities (iMITIGATE).

Date: June 3, 2024.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nawazish Ali Naqvi, Ph.D., Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Y, Bethesda, MD 20892–7924, (301) 827–7911, *nawazish.naqvi@nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; T32 Diversity Grant Review.

Date: June 4, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nawazish Ali Naqvi, Ph.D., Scientific Review Officer, Office of

Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Y, Bethesda, MD 20892–7924, (301) 827–7911, *nawazish.naqvi@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Mentored Career Development Awards to Enhance Research Faculty Diversity.

Date: June 5, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shelley Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 208–T, Bethesda, MD 20817, (301) 827–7984, *ssehnert@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI PPG Review SEP.

Date: June 10, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zhihong Shan, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–J, Bethesda, MD 20892 (301) 827–7085, *zhihong.shan@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Short-Term Research Education Program to Enhance Diversity in Health-Related Research R25 Review.

Date: June 12, 2024.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sun Saret, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–S, Bethesda, MD 20892, (301) 435–0270, *sun.saret@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; T32 Member Conflicts SEP.

Date: June 21, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cynthia D. Anderson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes Health, 6705 Rockledge Drive, Room 207–E, Bethesda, MD 20892, *cynthia.anderson@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; R38 StARR Review Meeting.

Date: June 26, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 209–B, Bethesda, MD 20892, (301) 827–7953, *kristen.page@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09723 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Epidemiology, Prevention and Behavior Research Study Section.

Date: June 4, 2024.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna Ghambaryan, M.D., Ph.D. ,Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892 301–443–4032, *anna.ghambaryan@nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Biomedical Research Study Section.

Date: June 5, 2024.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Clinical, Treatment and Health Services Research Study Section.

Date: June 10, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (In-Person and Virtual).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700b Rockledge Drive, Room 2109, MSC 6902, Bethesda, MD 20892, (301) 443–8599, *espinozala@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Neuroscience and Behavior Study Section.

Date: June 12, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20892, (301) 443–0800, *bbuzas@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism, Special Emphasis Panel, Collaborative Study on the Genetics of Alcoholism, (COGA)—RFA–AA–24–003.

Date: July 11, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and

Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20892, (301) 443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09725 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/A0A501010.999900]

Rate Adjustments for Indian Irrigation Projects

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) owns or has an interest in irrigation projects located on or associated with various Indian reservations throughout the United States. We are required to establish irrigation assessment rates to recover the costs to administer, operate, maintain, and rehabilitate these projects. The BIA proposes to adjust the irrigation operation and maintenance (O&M) assessment rate at Duck Valley Irrigation Project (DVIP). We request your comments on the proposed rate adjustment.

DATES: Interested parties may submit comments on the proposed rate adjustments on or before July 5, 2024.

ADDRESSES: All comments on the proposed rate adjustments must be in writing. You may send comments via email to *comments@bia.gov.* Please reference ''Rate Adjustment for Duck Valley Irrigation Project'' in the subject line. Or you may submit comments to the Program Specialist, Division of Water and Power, Office of Trust Services, 2021 4th Avenue North, Billings, Montana 59101.

FOR FURTHER INFORMATION CONTACT: Jonathan Cody, Irrigation Engineer, BIA Western Regional Office, (480) 235–3848.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rate Adjustment was published in the **Federal Register** on February 8, 2024 (89 FR 8707) to propose adjustments to the irrigation assessment rates at several BIA irrigation projects. After further review and coordination with the Shoshone-Paiute Tribes, we decided to adjust the proposed rate assessment for DVIP from $5.30 to $11.00 per acre. The first table in this notice provides contact information for individuals who can give further information about DVIP. The second table provides the proposed rate for calendar year (CY) 2025.

What is the meaning of the key terms used in this notice?

In this notice:

Administrative costs mean all costs we incur to administer our irrigation projects at the local project level and are a cost factor included in calculating your operation and maintenance assessment. Costs incurred at the local project level do not normally include agency, region, or central office costs unless we state otherwise in writing.

Assessable acre means lands designated by us to be served by one of our irrigation projects, for which we collect assessments in order to recover costs for the provision of irrigation service. (*See also* ''total assessable acres.'')

BIA means the Bureau of Indian Affairs.

Bill means our statement to you of the assessment charges and/or fees you owe the United States for administration, operation, maintenance, and/or rehabilitation. The date we mail or hand-deliver your bill will be stated on it.

Costs means the costs we incur for administration, operation, maintenance, and rehabilitation to provide direct support or benefit to an irrigation facility. (*See* administrative costs, operation costs, maintenance costs, and rehabilitation costs).

Customer means any person or entity to whom or to which we provide irrigation service.

Due date is the date on which your bill is due and payable. This date will be stated on your bill.

I, me, my, you and *your* mean all persons or entities that are affected by this notice.

Irrigation project means a facility or portion thereof for the delivery, diversion, and storage of irrigation water that we own or have an interest in, including all appurtenant works. The term ''irrigation project'' is used interchangeably with irrigation facility, irrigation system, and irrigation area.

Irrigation service means the full range of services we provide customers of our irrigation projects. This includes our activities to administer, operate, maintain, and rehabilitate our projects in order to deliver water.

Maintenance costs means costs we incur to maintain and repair our irrigation projects and associated equipment and is a cost factor included in calculating your operation and maintenance assessment.

Operation and maintenance (O&M) assessment means the periodic charge you must pay us to reimburse costs of administering, operating, maintaining, and rehabilitating irrigation projects consistent with this notice and our supporting policies, manuals, and handbooks.

Operation or operating costs means costs we incur to operate our irrigation projects and equipment and is a cost factor included in calculating your O&M assessment.

Past due bill means a bill that has not been paid by the close of business on the 30th day after the due date as stated on the bill. Beginning on the 31st day after the due date, we begin assessing additional charges accruing from the due date.

Rehabilitation costs means costs we incur to restore our irrigation projects or features to original operating condition or to the nearest state which can be achieved using current technology and is a cost factor included in calculating your O&M assessment.

Responsible party means an individual or entity that owns, leases, or uses land as authorized by the Tribe within the assessable acreage of one of our irrigation projects and is responsible for providing accurate information to our billing office and paying a bill for an annual irrigation rate assessment.

Total assessable acres mean the total acres served by one of our irrigation projects.

Water delivery is an activity that is part of the irrigation service we provide our customers when water is available.

We, us, and *our* mean the United States Government, the Secretary of the Interior, the BIA, and all who are authorized to represent us in matters covered under this notice.

Does this notice affect me?

This notice affects you if you irrigate land by permit or lease, as authorized by the Tribe, within the assessable acreage of DVIP.

Where can I get information on the regulatory and legal citations in this notice?

You can contact the DVIP. Please use the table in the **SUPPLEMENTARY INFORMATION** section to contact the

regional or local office where the project is located.

Why are you publishing this notice?

We are publishing this notice to inform you that we propose to adjust our irrigation assessment rate for DVIP. DVIP is a federally-owned irrigation project, which is operated and maintained by the Shoshone-Paiute Tribes of the Duck Valley Reservation under a self-governance compact. The irrigation project is located in Elko County, Nevada and Owyhee County, Idaho. This notice is published in accordance with the BIA's regulations governing its operation and maintenance of irrigation projects, found at 25 CFR part 171. This regulation provides for the establishment and publication of the proposed rates for annual irrigation assessments as well as related information about our irrigation projects.

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior by 5 U.S.C. 301 and the Act of August 14, 1914 (38 Stat. 583; 25 U.S.C. 385). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under Part 209, Chapter 8.1A, of the Department of the Interior's Departmental Manual.

When will you put the rate adjustments into effect?

We will put the rate adjustments into effect for CY 2025.

How do you calculate irrigation rates?

Pursuant to the self-governance compact, we calculate annual irrigation assessment rates in accordance with 25 CFR part 171.500 by estimating the annual costs of DVIP operation and maintenance and then dividing by the total assessable acres for DVIP. The result of this calculation is stated in the rate table in this notice.

What kinds of expenses do you consider in determining the estimated annual costs of operation and maintenance?

Consistent with 25 CFR part 171.500, these expenses include the following:

(a) Personnel salary and benefits for the project engineer/manager and project employees under the project engineer/manager's management or control;

(b) Materials and supplies;

(c) Vehicle and equipment repairs;

(d) Equipment costs, including lease fees;

(e) Depreciation;

(f) Acquisition costs;

(g) Maintenance of a reserve fund available for contingencies or emergency costs needed for the reliable operation of the irrigation facility infrastructure;

(h) Maintenance of a vehicle and heavy equipment replacement fund;

(i) Systematic rehabilitation and replacement of project facilities;

(j) Contingencies for unknown costs and omitted budget items; and

(k) Other expenses we determine necessary to properly perform the activities and functions characteristic of an irrigation project.

When should I pay my irrigation assessment?

Under the self-governance compact and applicable Federal law, BIA bills and collects DVIP's annual O&M assessment directly from the Shoshone-Paiute Tribes. The Shoshone-Paiute Tribes are responsible for billing and collecting the annual O&M assessment from persons who irrigate land by permit or lease within the assessable acreage of the DVIP. You should pay your bill by the due date stated on your bill.

What information must I provide for billing purposes?

The BIA billing and collection process for DVIP is established by the self-governance compact and related authorities. BIA is not involved in the billing and collection process between the Shoshone-Paiute Tribes and the persons who irrigate land by permit or lease within the assessable acreage of the DVIP. The Shoshone-Paiute Tribes are required to provide us with the following information for billing purposes:

(1) Full legal name;

(2) Correct mailing address; and

(3) Taxpayer identification number.

Why is BIA collecting the Shoshone-Paiute Tribes' taxpayer identification number?

Public Law 104–134, the Debt Collection Improvement Act of 1996, requires that we collect the taxpayer identification number before billing a responsible party and as a condition to servicing the account.

If the Shoshone-Paiute Tribes allow the annual bill owed to BIA to become past due, could this affect my water delivery?

Yes. 25 CFR 171.545(a) states: ''We will not provide you irrigation service until: (1) Your bill is paid; or (2) You make arrangement for payment pursuant to § 171.550 of this part.'' If we do not receive payment before the close of business on the 30th day after the due date stated on the bill, we will send a past due notice to the Shoshone-Paiute Tribes. This past due notice will have additional information concerning the Shoshone-Paiute Tribes' rights. We will consider the past due notice as delivered no later than five business days after the day we mail it. We follow the procedures provided in 31 CFR 901.2, ''Demand for Payment,'' when demanding payment of the Shoshone-Paiute Tribes past due bill.

Are there any additional charges to the Shoshone-Paiute Tribes if it is late paying the bill?

Yes. We are required to assess interest, penalties, and administrative costs on past due bills in accordance with 31 U.S.C. 3717 and 31 CFR 901.9. The rate of interest is established annually by the Secretary of the United States Treasury (Treasury) and accrues from the date the bill is past due. If the bill becomes more than 90 days past due, the Shoshone-Paiute Tribes will be assessed a penalty charge of no more than six percent per year, which accrues from the date the bill became past due. Each time we try to collect the past due bill, the Shoshone-Paiute Tribes will be charged an administrative fee of $12.50 for processing and handling.

What else will happen to the Shoshone-Paiute Tribes' past due bill?

If the Shoshone-Paiute Tribes do not pay its bill or make payment arrangements to which we agree, we are required to transfer the past due bill to Treasury for further action. Pursuant to 31 CFR 285.12, bills that are 120 days past due will be transferred to Treasury.

Who can I contact for further information?

The contact table below contains the regional and project/agency contacts for DVIP.

Western Region Contacts	
Jessie Durham, Regional Director, Bureau of Indian Affairs, Western Regional Office, 2600 North Central Avenue, 4th Floor Mailroom, Phoenix, AZ 85004. Telephone: (602) 379–6600.	
Duck Valley Irrigation Project	Phaline Conklin, Superintendent, (Project O&M compacted to Shoshone-Paiute Tribes under PL 93–638), 2719 Argent Avenue, Suite 4, Gateway Plaza, Elko, NV 89801. Telephones: Superintendent (775) 738–5165; Pawan Upadhyay, Tribal Water Resources Director (208) 759–3100 Ext. 1228.

What irrigation assessments or charges are proposed for adjustment by this notice?

The rate table below contains the final CY 2024 rate for DVIP, where we recover costs of administering, operating, maintaining, and rehabilitating the project. The table also contains the proposed CY 2025 rate.

Project Name	Rate category	Final 2024 rate	Proposed 2025 rate
Western Region Rate Table			
Duck Valley Irrigation Project	Basic per acre	$5.30	$11.00

Consultation and Coordination With Tribal Governments (Executive Order 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this notice under the Department's consultation policy and under the criteria of Executive Order 13175 and have determined there to be substantial direct effects on federally recognized Tribes because the irrigation projects are located on or associated with Indian reservations. To fulfill its consultation responsibility to Tribes and Tribal organizations, BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of water delivery, water availability, and costs of administration, operation, maintenance, and rehabilitation of projects that concern them. This is accomplished at the individual irrigation project by project, agency, and regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of our overall coordination and consultation process to provide notice to, and request comments from, these entities when we adjust irrigation assessment rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

The proposed rate adjustments are not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Regulatory Planning and Review (Executive Order 12866)

These proposed rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

These proposed rate adjustments are not a rule for the purposes of the Regulatory Flexibility Act because they establish ''a rule of particular applicability relating to rates.'' 5 U.S.C. 601(2).

Unfunded Mandates Reform Act of 1995

These proposed rate adjustments do not impose an unfunded mandate on state, local, or Tribal governments in the aggregate, or on the private sector, of more than $130 million per year. They do not have a significant or unique effect on State, local, or Tribal governments or the private sector. Therefore, the Department is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Takings (Executive Order 12630)

These proposed rate adjustments do not effect a taking of private property or otherwise have ''takings'' implications under Executive Order 12630. The proposed rate adjustments do not deprive the public, State, or local governments of rights or property.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, these proposed rate adjustments do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because they will not affect the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This notice complies with the requirements of Executive Order 12988. Specifically, in issuing this notice, the Department has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct as required by section 3 of Executive Order 12988.

Paperwork Reduction Act of 1995

These proposed rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0141 and expires March 31, 2026.

National Environmental Policy Act

The Department has determined that these proposed rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the

National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370(d)), pursuant to 43 CFR 46.210(i). In addition, the proposed rate adjustments do not present any of the 12 extraordinary circumstances listed at 43 CFR 46.215.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2024–09807 Filed 5–3–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 245S180110; S2D2S SS08011000 SX064A000 24XS501520; OMB Control Number 1029–0040]

Agency Information Collection Activities; Requirements for Permits for Special Categories of Mining

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 1544–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0040 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on January 17, 2024 (89 FR 2979). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The information is being collected to meet the requirements of sections 507, 508, 510, 515, 701 and 711 of the Surface Mining Control and Reclamation Act of 1977, which require applicants for special types of mining activities to provide descriptions, maps, plans and data of the proposed activity. This information will be used by the regulatory authority in determining if the applicant can meet the applicable performance standards for the special type of mining activity.

Title of Collection: Requirements for Permits for Special Categories of Mining.

OMB Control Number: 1029–0040.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses and State governments.

Total Estimated Number of Annual Respondents: 50.

Total Estimated Number of Annual Responses: 70.

Estimated Completion Time per Response: Varies from 10 hours to 1,000 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 4,448.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 2024–09816 Filed 5–3–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 245S180110; S2D2S SS08011000 SX064A000 24XS501520; OMB Control Number 1029–0112]

Agency Information Collection Activities; Requirements for Coal Exploration

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 1544–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0112 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on January 17, 2024 (89 FR 2978). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: OSMRE and State regulatory authorities use the information collected under 30 CFR part 772 to keep track of coal exploration activities, evaluate the need for an exploration permit, and ensure that exploration activities comply with the environmental protection and reclamation requirements of 30 CFR parts 772 and 815, and section 512 of SMCRA (30 U.S.C. 1262).

Title of Collection: Requirements for Coal Exploration.

OMB Control Number: 1029–0112.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses and State governments.

Total Estimated Number of Annual Respondents: 110.

Total Estimated Number of Annual Responses: 195.

Estimated Completion Time per Response: Varies from 30 minutes to 70 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 757.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: $310.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 2024–09817 Filed 5–3–24; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1400]

Certain Cameras, Camera Systems, and Accessories Used Therewith; Notice of Institution of Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on March 29, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of GoPro, Inc. of San Mateo, California. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain cameras, camera systems, and accessories used therewith by reason of the infringement of certain claims of U.S. Patent No. 10,015,413 (''the '413 patent''); U.S. Patent No. 10,529,052 (''the '052 patent''); U.S. Patent No. 10,574,894 (''the '894 patent''); U.S. Patent No. 10,958,840 (''the '840 patent''); U.S. Patent No. 11,336,832 (''the '832 patent''); and U.S. Design Patent No. D789,435 (''the D'435 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advisedthat information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2024).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 30, 2024, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–12 of the '413 patent; claims 1–10 of the '052 patent; claims 1–20 of the '894 patent; claims 1–21 of the '840 patent; claims 1–10 of the '832 patent; and the claim of the D'435 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''action and 360-degree cameras and systems, as well as camera-mounting systems, frames, and camera-wearable systems used therewith'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: GoPro, Inc., 3025 Clearview Way, San Mateo, CA 94402.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Arashi Vision Inc. d/b/a Insta360, 12F, Building T2, Hengyu Qianhai Financial Center, Nanshan District, Shenzhen, China

Arashi Vision (U.S.) LLC d/b/a Insta360, 2323 Main St., Unit 16, Irvine, CA 92614

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: May 1, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–09809 Filed 5–3–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Sensors with Pixels and Products Containing the Same,* DN 3744; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of SiOnyx, LLC on April 30, 2024. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sensors with pixels and products containing the same. The complaint names as respondents: Samsung Electronics, Co., Ltd. of Korea; Samsung Electronics America, Inc. of Ridgefield Park, NJ; and Samsung Semiconductor, Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondent

alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3744'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[1])

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: April 30, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–09766 Filed 5–3–24; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[USITC SE–24–017]

Sunshine Act Meetings

Agency Holding the Meeting: United States International Trade Commission.

TIME AND DATE: May 10, 2024 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.

2. Minutes.

3. Ratification List.

4. Commission vote on Inv. Nos. 701–TA–712–715 and 731–TA–1679–1682 (Preliminary) (Ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia). The Commission currently is scheduled to complete and file its determinations on May 13, 2024; views of the Commission currently are scheduled to be completed and filed on May 20, 2024.

5. Commission vote on Inv. No. 731–TA–860 (Fourth Review) (Tin- and Chromium-Coated Steel Sheet from Japan). The Commission currently is scheduled to complete and file its determination and views of the Commission on May 28, 2024.

6. Outstanding action jackets: none.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: May 1, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–09866 Filed 5–2–24; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Amended Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received an amended complaint entitled *Certain Dynamic Random Access Memory Device and Product Containing Same, DN 3729;* the Commission is soliciting comments on any public interest issues raised by the amended complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received an amended complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Wen T. Lin on April 29, 2024. The original complaint was filed on March 4, 2024 and a notice of receipt of complaint; solicitation of comments relating to the public interest published in the **Federal Register** on March 11, 2024. The amended complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dynamic random access memory device and product containing same. The amended complaint names as respondents: Etron Technology, Inc. of Taiwan; Etron Technology America, Inc. of Santa Clara, CA; and DigiKey Corporation of Thief River Falls, MN. The complainant requests that the Commission issue an exclusion order and cease and desist orders.

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3729'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. Government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

By order of the Commission.

Issued: April 30, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–09746 Filed 5–3–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1360]

Bulk Manufacturer of Controlled Substances Application: Pisgah Laboratories Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Pisgah Laboratories Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 5, 2024. Such persons may also file a written request for a hearing on the application on or before July 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 15, 2024, Pisgah Laboratories Inc., 3222 Old Hendersonville Highway, Pisgah Forest, North Carolina 28768, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Diphenoxylate	9170	II
Meperidine	9230	II
Methadone	9250	II
Tapentadol	9780	II

The company plans to bulk manufacture the above-listed controlled substances in bulk for internal research purposes and distribution to its customers. No other activities for these drug codes are authorized for this registration.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09810 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1354]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Entheogen Pharmaceuticals Inc

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.''

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all

applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on December 11, 2023, Entheogen Pharmaceuticals Inc, 17349 Muskrat Avenue, Adelanto, California, 92301 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Ibogaine	7260	I
Lysergic Acid Diethylamide	7315	I
Marihuana Extract	7350	I
Marihuana	7360	I
Mescaline	7381	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

In reference to drug codes 7260 (Ibogaine), 7315 (Lysergic Acid Diethylamide), 7381 (Mescaline), 7435 (Dimethyltryptamine), 7437 (Psilocybin), and 7438 (Psilocyn), the company plans to bulk manufacture the listed controlled substances for internal research and analytical development purposes. No other activities for these drug codes are authorized for this registration.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09789 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1358]

Importer of Controlled Substances Application: Lipomed

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Lipomed has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 5, 2024. Such persons may also file a written request for a hearing on the application on or before June 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 7, 2024, Lipomed, 150 Cambridgepark Drive, Suite 705, Cambridge, Massachusetts 02140–2300, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
3-Fluoro-N-methylcathinone (3–FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4–FMC)	1238	I
Pentedrone (α-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4–MEC)	1249	I
Naphyrone	1258	I
N-Ethylamphetamine	1475	I
N,N-Dimethylamphetamine	1480	I
Fenethylline	1503	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
Mecloqualone	2572	I
Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine	2780	I

Controlled substance	Drug code	Schedule
Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine)	2785	I
Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2786	I
Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2788	I
Diclazepam (7-chloro-5-(2-chloro-5-(2-chlorophenyl)-1- methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one	2789	I
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR–18 (Also known as RCS–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I
5-Fluoro-UR–144 and XLR11 ([1-(5-Fluoro-pentyl)1H-indol-3-yl] (2,2,3,3-tetramethylcyclopropyl)methanone)	7011	I
AB–FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
JWH–019 (1-Hexyl-3-(1-naphthoyl) indole)	7019	I
MDMB–FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
FUB–AMB, MMB–FUBINACA, AMB–FUBINACA (2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate)	7021	I
AB–PINACA (N-(1-amino-3-methyl-	7023	I
1-oxobutan-2-yl)-1-pentyl-1H-indazole-)3-carboxamide		
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-	7024	I
yl](naphthalen-1-yl)methanone)		
5F–AB–PINACA (N-(1-amino-3methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7025	I
AB–CHMINACA (N-(1-amino-3-methyl-1-	7031	I
oxobutan-2-yl)-1-(cyclohexylmethyl)-		
1H-indazole-3-carboxamide)		
MAB–CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I
5F–AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I
5F–ADB; 5F–MDMB–PINACA (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7034	I
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido) 3,3-dimethylbutanoate)	7036	I
MDMB–CHMICA, MMB–CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate).	7042	I
MMB–CHMICA, AMB–CHMICA (methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate)	7044	I
N-(Adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboximide)	7047	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
5F–APINACA, 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7049	I
JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
1-(5-Fluoropentyl)-1H-indazole-3-carboxamide	7083	I
5F–CUMYL–P7AICA (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide)	7085	I
4–CN–CUMYL–BUTINACA, 4-cyano-CUMYL–BUTINACA, 4–CN–CUMYL BINACA, CUMYL–4CN–BINACA, SGT–78 (1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide).	7089	I
SR–19 (Also known as RCS–4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I
JWH–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I
UR–144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone)	7144	I
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
NM2201, CBL2201 (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7221	I
PB–22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I
5F–PB–22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
4-methyl-alpha-ethylaminopentiophenone (4–MEAP)	7245	I
N-ethylhexedrone	7246	I
Alpha-ethyltryptamine	7249	I
Ibogaine	7260	I
CP–47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7297	I
CP–47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol)	7298	I
Lysergic acid diethylamide	7315	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C–T–7)	7348	I
Marihuana extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Parahexyl	7374	I
Mescaline	7381	I
2C–T–2, (2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine)	7385	I
3,4,5-Trimethoxyamphetamine	7390	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
2,5-Dimethoxyamphetamine	7396	I
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
2,5-Dimethoxy-4-ethylamphetamine	7399	I
3,4-Methylenedioxyamphetamine	7400	I
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I
4-Methoxyamphetamine	7411	I

Controlled substance	Drug code	Schedule
5-Methoxy-N–N-dimethyltryptamine	7431	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
4-chloro-alpha-pyrrolidinovalerophenone (4-chloro-a-PVP)	7443	I
N-Ethyl-1-phenylcyclohexylamine	7455	I
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	7473	I
N-Ethyl-3-piperidyl benzilate	7482	I
N-Methyl-3-piperidyl benzilate	7484	I
N-Benzylpiperazine	7493	I
4-MePPP (4-Methyl-alphapyrrolidinopropiophenone)	7498	I
2C–D (2-(2,5-Dimethoxy-4-methylphenyl) ethanamine)	7508	I
2C–E (2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine)	7509	I
2C–H (2-(2,5-Dimethoxyphenyl) ethanamine)	7517	I
2C–I (2-(4-iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I
2C–C (2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine)	7519	I
2C–N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I
2C–P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I
2C–T–4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine)	7532	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
25B–NBOMe (2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7536	I
25C–NBOMe (2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7537	I
25I–NBOMe (2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7538	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
N-Ethylpentylone, ephylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)	7543	I
α-PHP, alpha-Pyrrolidinohexanophenone	7544	I
α-PVP (alpha-pyrrolidinopentiophenone)	7545	I
α-PBP (alpha-pyrrolidinobutiophenone)	7546	I
PV8, alpha-Pyrrolidinoheptaphenone	7548	I
AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I
Norfentanyl	8366	I
Acetyldihydrocodeine	9051	I
Benzylmorphine	9052	I
Codeine-N-oxide	9053	I
Cyprenorphine	9054	I
Desomorphine	9055	I
Etorphine (except HCl)	9056	I
Codeine methylbromide	9070	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Heroin	9200	I
Hydromorphinol	9301	I
Methyldesorphine	9302	I
Methyldihydromorphine	9304	I
Morphine methylbromide	9305	I
Morphine methylsulfonate	9306	I
Morphine-N-oxide	9307	I
Myrophine	9308	I
Nicocodeine	9309	I
Nicomorphine	9312	I
Normorphine	9313	I
Pholcodine	9314	I
Thebacon	9315	I
Acetorphine	9319	I
Drotebanol	9335	I
U–47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH–7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Benzethidine	9606	I
Betacetylmethadol	9607	I
Betameprodine	9608	I

Controlled substance	Drug code	Schedule
Betamethadol	9609	I
Betaprodine	9611	I
Clonitazene	9612	I
Dextromoramide	9613	I
Diampromide	9615	I
Diethylthiambutene	9616	I
Dimenoxadol	9617	I
Dimepheptanol	9618	I
Dimethylthiambutene	9619	I
Dioxaphetyl butyrate	9621	I
Dipipanone	9622	I
Ethylmethylthiambutene	9623	I
Etonitazene	9624	I
Etoxeridine	9625	I
Furethidine	9626	I
Hydroxypethidine	9627	I
Ketobemidone	9628	I
Levomoramide	9629	I
Levophenacylmorphan	9631	I
Morpheridine	9632	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Norpipanone	9636	I
Phenadoxone	9637	I
Phenampromide	9638	I
Phenoperidine	9641	I
Piritramide	9642	I
Proheptazine	9643	I
Properidine	9644	I
Racemoramide	9645	I
Trimeperidine	9646	I
Phenomorphan	9647	I
Propiram	9649	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	9663	I
Tilidine	9750	I
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-Methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide	9816	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Para-fluorobutyryl fentanyl	9823	I
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I
Para-chloroisobutyryl fentanyl	9826	I
Isobutyryl fentanyl	9827	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I
Thiofentanyl	9835	I
Beta-hydroxythiofentanyl	9836	I
Para-methoxybutyryl fentanyl	9837	I
Ocfentanil	9838	I
Valeryl fentanyl	9840	I
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide)	9843	I
Cyclopropyl Fentanyl	9845	I
Cyclopentyl fentanyl	9847	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration (FDA).	7365	II

Controlled substance	Drug code	Schedule
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Anileridine	9020	II
Cocaine	9041	II
Codeine	9050	II
Etorphine HCl	9059	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Hydrocodone	9193	II
Levomethorphan	9210	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine-intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Metazocine	9240	II
Methadone	9250	II
Methadone intermediate	9254	II
Metopon	9260	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Dihydroetorphine	9334	II
Levo-alphacetylmethadol	9648	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Phenazocine	9715	II
Thiafentanil	9729	II
Piminodine	9730	II
Racemethorphan	9732	II
Racemorphan	9733	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Bezitramide	9800	II
Fentanyl	9801	II
Moramide-intermediate	9802	II

The company plans to import analytical reference standards for distribution to its customers for research and analytics purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09802 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1349]

Bulk Manufacturer of Controlled Substances Application: Research Triangle Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Research Triangle Institute has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 5, 2024. Such persons may also file a written request for a hearing on the application on or before July 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 11, 2024, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Building, Room 106, Research Triangle Park, North Carolina 27709–2194, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ...	7370	I

The company plans to bulk manufacture the listed controlled substance synthetically for distribution to its customers for research and as analytical reference standards. No other activities for this drug code are authorized for this registration.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09783 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1359]

Importer of Controlled Substances Application: Restek Corporation

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Restek Corporation has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 5, 2024. Such persons may also file a written request for a hearing on the application on or before June 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 5, 2024, Restek Corporation, 110 Benner Circle, Bellefonte, Pennsylvania 16823–8433, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amineptine	1219	I
Mesocarb	1227	I
3-Fluoro-N-methylcathinone (3–FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4–FMC)	1238	I
Para-Methoxymethamphetamine (PMMA), 1-(4–1245 I N methoxyphenyl)-N-methylpropan-2-amine	1245	I
Pentedrone (a-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone	1248	I
4-Methyl-N-ethylcathinone (4–MEC)	1249	I
Naphyrone	1258	I
N-Ethylamphetamine	1475	I
Methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2- 1478 I N amine)	1478	I
N,N-Dimethylamphetamine	1480	I
Fenethylline	1503	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
4,4′-Dimethylaminorex	1595	I
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
Mecloqualone	2572	I
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR–18 (Also known as RCS–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I
5-Fluoro-UR–144 and XLR11 [1-(5-Fluoro-pentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I

Controlled substance	Drug code	Schedule
AB–FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
FUB–144 (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone)	7014	I
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	7019	I
MDMB–FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
FUB–AMB, MMB- FUBINACA, AMB–FUBINACA (2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate).	7021	I
AB–PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7023	I
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	7024	I
5F–AB–PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluropentyl)-1H-indazole-3-carboximide)	7025	I
AB–CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7031	I
MAB–CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I
5F–AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I
5F–ADB, 5F–MDMB–PINACA (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7034	I
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
5F–EDMB–PINACA (ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7036	I
5F–MDMB–PICA (methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	7041	I
MDMB–CHMICA, MMB–CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate).	7042	I
4F–MDMB–BINACA (4F–MDMB–BUTINACA or methyl 2- (1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate) 7043 I N.	7043	I
MMB–CHMICA, AMB–CHMICA (methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate)	7044	I
FUB–AKB48, FUB–APINACA, AKB48 N-(4–FLUOROBENZYL) (N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboximide).	7047	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
5F–APINACA, 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7049	I
JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
5F–CUMYL–PINACA, 5GT–25 (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide)	7083	I
5F–CUMYL–P7AICA (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide)	7085	I
4–CN–CUML–BUTINACA, 4-cyano-CUMYL–BUTINACA, 4–CN–CUMYL BINACA, CUMYL–4CN–BINACA, SGT–78 (1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide).	7089	I
SR–19 (Also known as RCS–4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I
JWH–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I
UR–144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
NM2201, CBL2201 (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	7221	I
PB–22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I
5F–PB–22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
4-methyl-alpha-ethylaminopentiophenone (4–MEAP) 7245 I N 4–MEAP	7245	I
N-ethylhexedrone 7246 I N	7246	I
Alpha-ethyltryptamine	7249	I
Ibogaine	7260	I
2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine)	7286	I
CP–47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7297	I
CP–47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol)	7298	I
Lysergic acid diethylamide	7315	I
2C–T–7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine	7348	I
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Parahexyl	7374	I
Mescaline	7381	I
2C–T–2 (2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine)	7385	I
3,4,5-Trimethoxyamphetamine	7390	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
2,5-Dimethoxyamphetamine	7396	I
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
2,5-Dimethoxy-4-ethylamphetamine	7399	I
3,4-Methylenedioxyamphetamine	7400	I
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I
4-Methoxyamphetamine	7411	I
Peyote	7415	I
5-Methoxy-N–N-dimethyltryptamine	7431	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
4-chloro-alpha-pyrrolidinovalerophenone (4-chloro-a-PVP)	7443	I
4′-methyl-alpha-pyrrolidinohexiophenone (MPHP)	7446	I
N-Ethyl-1-phenylcyclohexylamine	7455	I
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	7473	I
N-Ethyl-3-piperidyl benzilate	7482	I
N-Methyl-3-piperidyl benzilate	7484	I
N-Benzylpiperazine	7493	I
4-MePPP (4-Methyl-alphapyrrolidinopropiophenone)	7498	I
2C–D (2-(2,5-Dimethoxy-4-methylphenyl) ethanamine)	7508	I
2C–E (2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine)	7509	I
2C–H 2-(2,5-Dimethoxyphenyl) ethanamine)	7517	I
2C–I 2-(4-iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I
2C–C 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine)	7519	I
2C–N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I
2C–P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I
2C–T–4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine)	7532	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
25B–NBOMe (2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7536	I
25C–NBOMe (2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7537	I
25I–NBOMe (2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7538	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
N-Ethypentylone, ephylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)	7543	I
alpha-pyrrolidinohexanophenone (a-PHP)	7544	I
alpha-pyrrolidinopentiophenone (α-PVP)	7545	I
alpha-pyrrolidinobutiophenone (α-PBP)	7546	I
Ethylone	7547	I
alpha-pyrrolidinoheptaphenone (PV8)	7548	I
AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I
Acetyldihydrocodeine	9051	I
Benzylmorphine	9052	I
Codeine-N-oxide	9053	I
Cyprenorphine	9054	I
Desomorphine	9055	I
Etorphine (except HCl)	9056	I
Codeine methylbromide	9070	I
Brorphine (1-(1-(1-(4-bromophenyl)ethyl)piperidin-4–4l)1,3-dihydro-2H-benzo[d]imidazol-2-one)	9098	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Heroin	9200	I
Hydromorphinol	9301	I
Methyldesorphine	9302	I
Methyldihydromorphine	9304	I
Morphine methylbromide	9305	I
Morphine methylsulfonate	9306	I
Morphine-N-oxide	9307	I
Myrophine	9308	I
Nicocodeine	9309	I
Nicomorphine	9312	I
Normorphine	9313	I
Pholcodine	9314	I
Thebacon	9315	I
Acetorphine	9319	I
Drotebanol	9335	I
U–47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH–7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Benzethidine	9606	I
Betacetylmethadol	9607	I
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I

Controlled substance	Drug code	Schedule
Clonitazene	9612	I
Dextromoramide	9613	I
Isotonotazene (N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine)	9614	I
Diampromide	9615	I
Diethylthiambutene	9616	I
Dimenoxadol	9617	I
Dimepheptanol	9618	I
Dimethylthiambutene	9619	I
Dioxaphetyl butyrate	9621	I
Dipipanone	9622	I
Ethylmethylthiambutene	9623	I
Etonitazene	9624	I
Etoxeridine	9625	I
Furethidine	9626	I
Hydroxypethidine	9627	I
Ketobemidone	9628	I
Levomoramide	9629	I
Levophenacylmorphan	9631	I
Morpheridine	9632	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Norpipanone	9636	I
Phenadoxone	9637	I
Phenampromide	9638	I
Phenoperidine	9641	I
Piritramide	9642	I
Proheptazine	9643	I
Properidine	9644	I
Racemoramide	9645	I
Trimeperidine	9646	I
Phenomorphan	9647	I
Propiram	9649	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	9663	I
Tilidine	9750	I
Butonitazene	9751	I
Lunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro1H-benzimidazol-1-yl)ethan-1- amine)	9756	I
Metonitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-5- nitro-1Hbenzimidazol-1-yl)ethan-1-amine	9757	I
N-pyrrolidino etonitazene; etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)- 1Hbenzimidazole)	9758	I
Protonitazene (N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine)	9759	I
Metodesnitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)- 1H-benzimidazol-1- yl)ethan-1-amine)	9764	I
Etodesnitazene; etazene (2-(2-(4-ethoxybenzyl)- 1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine)	9765	I
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide	9816	I
Para-Methylfentanyl (N-(4-methylphenyl)-N-(1- phenethylpiperidin-4-yl)propionamide; also known as 4- methylfentanyl)	9817	I
4'-Methyl acetyl fentanyl (N-(1-(4- methylphenethyl)piperidin-4-yl)-N-phenylacetamide)	9819	I
Ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2- methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide)	9820	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Para-fluorobutyryl fentanyl	9823	I
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I
Para-chloroisobutyryl fentanyl	9826	I
Isobutyryl fentanyl	9827	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I
Thiofentanyl	9835	I
Beta-hydroxythiofentanyl	9836	I
Para-methoxybutyryl fentanyl	9837	I
Ocfentanil	9838	I
Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylthiophene-2-carboxamide; also known as 2- thiofuranyl fentanyl; thiophene fentanyl).	9839	I
Valeryl fentanyl	9840	I
Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylbenzamide; also known as benzoyl fentanyl)	9841	I
Beta'-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3- diphenylpropanamide; also known as β'-phenyl fentanyl; 3-phenylpropanoyl fentanyl).	9842	I

Controlled substance	Drug code	Schedule
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide	9843	I
Crotonyl fentanyl ((E–N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)	9844	I
Cyclopropyl Fentanyl	9845	I
Cyclopentyl fentanyl	9847	I
Ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1- phenethylpiperidin-4-yl)acetamide; also known as 2- methyl acetylfentanyl).	9848	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
Fentanyl carbamate (ethyl (1-phenethylpiperidin-4- yl)(phenyl)carbamate)	9851	I
Ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)acrylamide)	9852	I
Ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)isobutyramide)	9853	I
Para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)furan-2-carboxamide)	9854	I
2'-Fluoro ortho-fluorofentanyl (N-(1-(2- fluorophenethyl)piperidin-4-yl)-N-(2- fluorophenyl)propionamide; also known as 2'-fluoro 2- fluorofentanyl).	9855	I
Beta-Methyl fentanyl (N-phenyl-N-(1-(2- phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl)	9856	I
Zipeprol	9873	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	7365	II
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Norfentanyl (N-phenyl-N-(piperidin-4-yl) propionamide)	8366	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Anileridine	9020	II
Coca Leaves	9040	II
Cocaine	9041	II
Codeine	9050	II
Etorphine HCl	9059	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Hydrocodone	9193	II
Levomethorphan	9210	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Metazocine	9240	II
Oliceridine (N-[(3-methoxythiophen-2yl)methyl] ({2-[9r)-9-(pyridin-2-yl)-6-oxaspiro[4.5] decan-9-yl] ethyl {time})amine fumarate).	9245	II
Methadone	9250	II
Methadone intermediate	9254	II
Metopon	9260	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Dihydroetorphine	9334	II
Opium, raw	9600	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Levo-alphacetylmethadol	9648	II
Opium poppy	9650	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Poppy Straw Concentrate	9670	II

Controlled substance	Drug code	Schedule
Phenazocine	9715	II
Thiafentanil	9729	II
Piminodine	9730	II
Racemethorphan	9732	II
Racemorphan	9733	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Bezitramide	9800	II
Fentanyl	9801	II
Moramide-intermediate	9802	II

The company plans to import analytical reference standards for distribution to its customers for research and analytics purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized in 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09803 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1361]

Importer of Controlled Substances Application: NSI Lab Solutions, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: NSI Lab Solutions, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 5, 2024. Such persons may also file a written request for a hearing on the application on or before June 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 22, 2024, NSI Lab Solutions, Inc., 7212 ACC Boulevard, Raleigh, North Carolina 27617, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
3-Fluoro-N-methylcathinone (3–FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4–FMC)	1238	I
Pentedrone (α-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4–MEC)	1249	I
Naphyrone	1258	I
3-methylmethcathinone (2-(methylamino)-1-(3- methylphenyl)propan-1-one)	1259	I
N-Ethylamphetamine	1475	I
Methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2- amine)	1478	I
N,N-Dimethylamphetamine	1480	I
Fenethylline	1503	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
4,4′-Dimethylaminorex (4,4′-DMAR; 4,5-dihydro-4- methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5- (4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine).	1595	I

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine	2780	I
Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine)	2785	I
Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2786	I
Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2788	I
Diclazepam (7-chloro-5-(2-chloro-5-(2-chlorophenyl)-1- methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one	2789	I
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR–18 (Also known as RCS–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I
5-Fluoro-UR–144 and XLR11 ([1-(5-Fluoro-pentyl)1H-indol-3-yl] (2,2,3,3-tetramethylcyclopropyl)methanone)	7011	I
AB–FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
(1-(4-Fluorobenzyl)-1H-indol-3-yl)(2,2,3,3- tetramethylcyclopropyl)methanone	7014	I
JWH–019 (1-Hexyl-3-(1-naphthoyl) indole)	7019	I
MDMB–FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
FUB–AMB, MMB–FUBINACA, AMB–FUBINACA (2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate)	7021	I
AB–PINACA (N-(1-amino-3-methyl-	7023	I
1-oxobutan-2-yl)-1-pentyl-1H-indazole-)3-carboxamide		
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-	7024	I
yl](naphthalen-1-yl)methanone)		
5F–AB–PINACA (N-(1-amino-3methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7025	I
ADB–BUTINACA (N-(1-amino-3,3-dimethyl-1-oxobutan2-yl)-1-butyl-1H-indazole-3-carb	7027	I
AB–CHMINACA (N-(1-amino-3-methyl-1-	7031	I
oxobutan-2-yl)-1-(cyclohexylmethyl)-		
1H-indazole-3-carboxamide)		
MAB–CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I
5F–AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)- 3,3-dimethylbutanoate	7041	I
MDMB–CHMICA, MMB–CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate).	7042	I
4F–MDMB–BINACA (4F–MDMB–BUTINACA or methyl 2- (1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate).	7043	I
MMB–CHMICA, AMB–CHMICA (methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate)	7044	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
MDMB–4en-PINACA (methyl 3,3-dimethyl-2-(1-(pent-4- en-1-yl)-1H-indazole-3-carboxamido)butanoate)	7090	I
SR–19 (Also known as RCS–4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I
JWH–018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I
UR–144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone)	7144	I
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
NM2201, CBL2201 (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7221	I
PB–22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I
5F–PB–22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
Alpha-ethyltryptamine	7249	I
Ibogaine	7260	I
Lysergic acid diethylamide	7315	I
Marihuana extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
3,4-Methylenedioxyamphetamine	7400	I
3,4-Methylenedioxymethamphetamine	7405	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
4-chloro-alpha-pyrrolidinovalerophenone (4-chloro-a-PVP)	7443	I
N-Benzylpiperazine	7493	I
2C–I (2-(4-iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I
2C–N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I
2C–P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25C–NBOMe)	7537	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I

Controlled substance	Drug code	Schedule
N-Ethylpentylone, ephylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)	7543	I
α-PVP (alpha-pyrrolidinopentiophenone)	7545	I
α-PBP (alpha-pyrrolidinobutiophenone)	7546	I
Ethylone	7547	
PV8, alpha-Pyrrolidinoheptaphenone	7548	I
Eutylone	7549	I
α-PiHP (4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1- one)	7551	I
AM–694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I
Acetyldihydrocodeine	9051	I
Codeine-N-oxide	9053	I
Desomorphine	9055	I
Brorphine (1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)- 1,3-dihydro-2H-benzo[d]imidazol-2-one)	9098	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Myrophine	9308	I
Nicomorphine	9312	I
Normorphine	9313	I
Pholcodine	9314	I
Thebacon	9315	I
U–47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH–7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I
Isotonitazene (N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1-amine)	9614	I
Dimethylthiambutene	9619	I
Dipipanone	9622	I
Etonitazene	9624	I
Ketobemidone	9628	I
Tilidine	9750	I
Butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1	9751	I
Flunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5-nitro1H-benzimidazol-1-yl)ethan-1-amine)	9756	I
Metonitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1-amine)	9757	I
N-pyrrolidino etonitazene; etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)- 1H-benzimidazole)	9758	I
Metodesnitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)- 1H-benzimidazol-1-yl)ethan-1-amine)	9759	I
Metodesnitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)- 1H-benzimidazol-1-yl)ethan-1-amine)	9764	I
Etodesnitazene; etazene (2-(2-(4-ethoxybenzyl)-1Hbenzimidazol-1-yl)-N,N-diethyleth	9765	I
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-Methylfentanyl	9814	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Para-fluorobutyryl fentanyl	9823	I
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I
Para-chloroisobutyryl fentanyl	9826	I
Isobutyryl fentanyl	9827	I
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I
Thiofentanyl	9835	I
Beta-hydroxythiofentanyl	9836	I
Ocfentanil	9838	I
Valeryl fentanyl	9840	I
Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylbenzamide; also known as benzoyl fentanyl)	9841	I
beta′-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3- diphenylpropanamide; also known as β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl).	9842	I
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide)	9843	I
Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-Nphenylbut-2-enam	9844	I
Cyclopropyl Fentanyl	9845	I
Cyclopentyl fentanyl	9847	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
2′-Fluoro ortho-fluorofentanyl (N-(1-(2- fluorophenethyl)piperidin-4-yl)-N-(2- fluorophenyl)propionamide; also known as 2'-fluoro 2- fluorofentanyl).	9855	I
Amphetamine	1100	II
Methamphetamine	1105	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Norfentanyl (N-phenyl-N-(piperidin-4-yl)propionamide)	8366	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II

Controlled substance	Drug code	Schedule
Hydrocodone	9193	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine-intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Methadone	9250	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium, raw	9600	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Bezitramide	9800	II
Fentanyl	9801	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols) the company plans to import a synthetic cannabidiol and a synthetic tetrahydrocannabinol. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09811 Filed 5–3–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1324]

Importer of Controlled Substances Application: AndersonBrecon dba PCI Pharma Services; Correction

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of correction.

SUMMARY: The Drug Enforcement Administration (DEA) published a document in the **Federal Register** on March 6, 2024, concerning an application for an Importer of Controlled Substances. The document request removal of Dimethyltrytamine.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** on March 6, 2024, in FR Doc No: 89 FR 16029, FR No. 2024–04753, on pages 16029–16030 (2 pages), in the first column, remove the controlled substance Dimethltrytamine from the list to read as follows:

Controlled substance	Drug code	Schedule
Cocaine	9041	II
Methadone	9250	II

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09785 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1357]

Bulk Manufacturer of Controlled Substances Application: Pharmaron Manufacturing Services (US) LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Pharmaron Manufacturing Services (US) LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 5, 2024. Such persons may also file a written request for a hearing on the application on or before July 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for

submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 25, 2024, Pharmaron Manufacturing Services (US) LLC, 498 Washington Street, Coventry, Rhode Island 02816, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Oxymorphone	9652	II
Noroxymorphone	9668	II

The company plans to bulk manufacture the listed controlled substances for the purpose of producing material for clinical trials. No other activities for these drug codes are authorized for this registration.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09805 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1363]

Importer of Controlled Substances Application: AndersonBrecon dba PCI Pharma Services

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AndersonBrecon dba PCI Pharma Services has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 5, 2024. Such persons may also file a written request for a hearing on the application on or before June 5, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 3, 2024, AndersonBrecon dba PCI Pharma Services, 5775 Logistics Parkway, Rockford, Illinois 61109–3608, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I
Cocaine	9041	II
Methadone	9250	II
Thebaine	9333	II

The company plans to import the listed controlled substances for clinical trials. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–09787 Filed 5–3–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB 1140–0008]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application and Permit for Permanent Exportation of Firearms—ATF Form 9 (5320.9)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until June 5, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Melisa Mason, by phone at 304–616–4500, or email at *nfaombcomments@atf.gov.*

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, volume 89 page 15614, on Monday, March 4, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should

address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0008. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Application and Permit for Permanent Exportation of Firearms.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* ATF Form 9 (5320.9).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected Public: Private Sector-for or not for profit institutions.

Abstract: ATF Form 9 (5320.9) is typically used by a Federal firearms licensee who has paid the special (occupational) tax to deal, manufacture or import NFA firearms. The form must be filed (in quadruplicate) for approval to permanently export NFA firearms registered in the National Firearms Registration and Transfer Record. Once authorization has been granted, one copy is retained by ATF and the remaining copies returned to the exporter to establish that the exportation took place. The information collection (IC) OMB 1140–0008 (Application and Permit for Permanent Exportation of Firearms—ATF Form 9 (5320.9) is being revised to change the last sentence in 'Instructions 1a'. This change includes deleting ''to that effect'' and adding ''certifying compliance with 26 U.S. Code § 5854 and 27 CFR 479.33''.

5. *Obligation to Respond:* Required to obtain or retain benefits.

6. *Total Estimated Number of Respondents:* 1,831.

7. *Estimated Time per Respondent:* 18 minutes.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 549 hours.

10. *Total Estimated Annual Other Costs Burden:* $320.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: May 1, 2024.

Darwin Arceo,

Department Clearance Officer for PRA,U.S. Department of Justice.

[FR Doc. 2024–09792 Filed 5–3–24; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0292]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension, With Change, of a Currently Approved Collection; Survey of Sexual Victimization

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until June 5, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Emily Buehler, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Emily.Buehler@usdoj.gov;* telephone: 202–598–1036).

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on February 12, 2024, allowing a 60-day comment period.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number [1121–0292]. This

information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension, with changes, of a currently approved collection.

2. *Title of the Form/Collection:* Survey of Sexual Victimization (SSV).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Summary Forms: SSV–1, SSV–2, SSV–3, SSV–4, SSV–5, SSV–6. Incident Forms: SSV–IA, SSV–IJ. Bureau of Justice Statistics, Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will include the Federal Bureau of Prisons; state prison and juvenile justice systems; private prisons; correctional facilities operated by the U.S. Military and U.S. Immigration and Customs Enforcement; local, private and tribal jails; local and private juvenile justice facilities; and juvenile facilities in Indian country.

5. *Obligation to Respond:* The obligation to respond is required under the Prison Rape Elimination Act of 2003 (Pub. L. 108–79).

6. *Total Estimated Number of Respondents:* 4,492 total responses received (1,492 summary forms and 3,000 incident forms).

7. *Estimated Time per Respondent:* Varies from 30 minutes to 1 hour per summary form; 40 minutes per incident form.

8. *Frequency:* Once a year.

9. *Total Estimated Annual Time Burden:* 3,047 hours.

10. *Total Estimated Annual Other Costs Burden:* PREA requires facilities to track the data collected in SSV. No costs other than the cost of the hour burden exist for this data collection.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: April 30, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–09726 Filed 5–3–24; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Extension Package for Labor Condition Application for H–1B, H–1B1, and E–3 Nonimmigrant Workers and Nonimmigrant Worker Information Form

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice; request for comments.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning the proposed extension of the information collection request (ICR) for the ''Labor Condition Application for Nonimmigrant Workers'' and ''Nonimmigrant Worker Information Form''; and related information collection and retention requirements (OMB Control Number 1205–0310), which covers Form ETA–9035, Form ETA–9035E (electronic), Form ETA–9035 & 9035E, Appendix A, Form ETA–9035CP, General Instructions for the 9035 & 9035E, and Form WH–4. This action seeks an extension of the forms without changes. This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by July 5, 2024.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained for free by contacting Brian Pasternak, Administrator, Office of Foreign Labor Certification, by telephone at 202–693–8200 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *ETA.OFLC.Forms@dol.gov.*

Instructions: Submit written comments about, or requests for a copy of, this ICR by email at *ETA.OFLC.Forms@dol.gov.* To ensure proper consideration, include the OMB control number 1205–0310.

FOR FURTHER INFORMATION CONTACT: Brian Pasternak, Administrator, Office of Foreign Labor Certification, by telephone at 202–693–8200 (this is not a toll-free number) or by email at *ETA.OFLC.Forms@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, in its continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program ensures the public provides all necessary data in the desired format, the reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

This information collection is required under sections 212(n) and (t) and 214(c) of the Immigration and Nationality Act (INA). *See* 8 U.S.C. 1182(n) and (t), and 1184(c). DOL and the Department of Homeland Security have promulgated regulations to implement the INA's requirements at 20 CFR part 655, subparts H and I, and 8 CFR 214.2(h)(4), respectively. The INA mandates that no H–1B, H–1B1 or E–3 temporary nonimmigrant worker may enter the United States (U.S.) to perform work in a specialty occupation or as a fashion model of distinguished merit and ability unless the U.S. employer makes certain attestations to the Secretary of Labor (Secretary). The employer must attest that the working conditions for the nonimmigrant worker will not adversely affect the working conditions of workers similarly employed; that it will offer a wage that is at least the higher of the prevailing wage for the occupational classification in the area of employment or the actual wage paid to all other individuals with similar experience and qualifications for the specific employment in question; that there is no strike or lockout in the course of a labor dispute in the occupational classification at the place of employment; and that it has provided notice of the filing of the LCA. *See* 20 CFR 655.731, 655.732, 655.733, and 655.734. In addition, further attestations are generally required for H–1B dependent employers and willful violators. *See* 20 CFR 655.736, 655.738, and 655.739. The current ICR expires December 31, 2024. DOL seeks to extend, without changes, the validity of

Forms ETA–9035, ETA–9035E, ETA–9035 & 9035E, Appendix A, ETA–9035CP, General Instructions, and WH–4.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection unless OMB, under the PRA, approves it and the collection tool displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments regarding this ICR to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. To help ensure appropriate consideration, comments should mention OMB control number 1205–0310.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Extension Without Changes.

Title of Collection: Labor Condition Application for H–1B, H–1B1, and E–3 Non-immigrants; and Nonimmigrant Worker Information Form.

Forms: ETA–9035, ETA–9035E, ETA–9035 & 9035E, Appendix A, ETA–9035CP, and WH–4.

OMB Control Number: 1205–0310.

Affected Public: Private Sector: Business or other for-profits and not-for-profit institutions; State, Local, and Tribal Governments; Individuals or Households.

Total Estimated Number of Annual Respondents: 138,314.

Annual Frequency: On Occasion.

Total Estimated Number of Annual Responses: 645,353.

Estimated Time per Response: Varies by form.

Total Estimated Annual Burden Hours: 843,989 hours.

Total Estimated Annual Other Costs: $41,140.

Authority: 44 U.S.C. 3506(c)(2)(A).

José Javier Rodríguez,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2024–09735 Filed 5–3–24; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0030]

Ionizing Radiation Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Ionizing Radiation Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by July 5, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *https://www.regulations.gov.* Documents in the docket are listed in the *https://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the websites. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0030) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The Ionizing Radiation Standard specifies a number of collection of information requirements. The basic purpose of the collections of information in the Ionizing Radiation Standard is to document that employers are providing their workers with protection from ionizing radiation exposure. The collections of information contained in the Standard include: monitoring worker exposure to ionizing radiation, posting caution signs at radiation areas, reporting worker overexposure to OSHA, maintaining exposure records, and providing exposure records to current and former workers.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the Ionizing Radiation Standard. The agency is requesting an adjustment increase of 11,479 burden hours from 59,077 to 70,556 hours. This increase is primarily due to increasing the percentage of affected establishments that may be using ionizing radiation in each industry identified as using ionizing radiation. Also, the agency is requesting an adjustment increase in capital cost from $8,892,917 to $11,461,149, a total increase of $2,568,232. The increase is due to increases in both the estimated number employees being monitored and the costs for exposure monitoring badges.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the collection of information requirements.

Type of Review: Extension of a currently approved collection.

Title: Ionizing Radiation Standard.

OMB Control Number: 1218–0103.

Affected Public: Business or other for-profits.

Number of Respondents: 25,631.

Number of Responses: 395,705.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 70,556.

Estimated Cost (Operation and Maintenance): $11,461,149.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; or (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (OSHA–2010–0030). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at *https://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *https://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *https://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link.

Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC, on April 29, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–09737 Filed 5–3–24; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: National Medal for Museum and Library Service Nomination Form

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB review, comment request.

SUMMARY: The Institute of Museum and Library Services announces the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This Notice proposes the clearance of the web-based National Medal for Museum and Library Service Nomination Form.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before June 06, 2024.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this Notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Chief of Staff, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. Maas can be reached by telephone at 202–653–4798, or by email at *nationalmedals@imls.gov.* Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays. Persons who are deaf or hard of hearing (TTY users) can contact IMLS at 202–207–7858 via 711 for TTY-Based Telecommunications Relay Service.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services (IMLS) is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. To learn more, visit *www.imls.gov.*

Current Actions: The purpose of this collection is to administer the IMLS process by which organizations nominated for the National Medal for Museum and Library Service submit administrative information about their organizations, communities, and programs. IMLS uses a standardized electronic form to collect this information from museums and libraries when they submit their nominations. The National Medal for Museum and Library Service is the nation's highest honor for institutions that make significant and exceptional contributions to their communities. Since 1994, IMLS has presented the award to institutions that demonstrate extraordinary and innovative approaches to community service. In addition to the Medal, IMLS may provide a monetary award. This action is to renew the content, form, and instructions for the next three years. The 60-Day Notice was published in the **Federal Register** on March 4, 2024 (89 FR 15617, Document Number 2024–04451). The agency received and responded to one comment in response to this Notice.

Agency: Institute of Museum and Library Services.

Title of Collection: National Medal for Museum and Library Service Nomination Form.

OMB Control Number: 3137–0097.

Agency Number: 3137.

Affected Public: Library and Museum applicants.

Total Estimated Number of Annual Responses: 175.

Frequency of Response: Once per year.

Average Hours per Response: 9.

Total Estimated Number of Annual Burden Hours: 1,575.

Total Annual Cost Burden: $50,225.

Total Annual Federal Costs: $8,024.

Dated: May 1, 2024.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2024–09772 Filed 5–3–24; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: IMLS Library and Museum Reviewer Forms

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB review, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services announces that the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This Notice proposes the clearance of the IMLS Museum and Library Reviewer Forms which are used by library and museum professionals to submit their interest and expertise to be considered for selection as an IMLS peer reviewer. A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before June 6, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this Notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Institute of Museum and Library Services'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, please mail your written comments to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, or call (202) 395–7316.

OMB is particularly interested in comments that help the agency to:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

FOR FURTHER INFORMATION CONTACT: Julie Balutis, Director, Office of Grants Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Ms. Balutis may be reached by telephone at 202–653–4645, or by email at *jbalutis@imls.gov.* Persons who are deaf or hard of hearing (TTY users) may contact IMLS at 202–207–7858 via 711 for TTY-Based Telecommunications Relay Service.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. To learn more, visit *www.imls.gov.*

Current Actions: This Notice proposes the clearance of the content, forms, and instructions for IMLS Library and Museum Reviewer Forms for the next three years.

All proposals submitted for IMLS competitive awards are reviewed by library and museum professionals who know the needs of communities, can share promising practices, and are well versed in the issues and concerns of libraries and museums today. Peer reviewers dedicate their time and expertise to advance the highest professional practices in the field. The IMLS review process is well respected, and the success of our grant programs is largely due to the expertise of our reviewers. These peer reviewer forms, accessed through the IMLS website, allow library and museum professionals to indicate their interest and provide information on their professional expertise to be considered for selection as an IMLS peer reviewer.

The 60-day Notice was published in the **Federal Register** on March 04, 2024 (89 FR 15618) (Document Number: 2024–04411). The agency received no comments in response to this Notice.

Agency: Institute of Museum and Library Services.

Title: IMLS Library and Museum Reviewer Forms.

OMB Control Number: 3137–0099.

Agency Number: 3137.

Respondents/Affected Public: Library and Museum professionals.

Total Number of Respondents: 1,450.

Frequency of Response: Once per year.

Average Minutes per Response: 15.

Total Estimated Annual Burden Hours: 363.

Total Annual Cost Burden: $11,649.

Total Annual Federal Costs: $3,989.

Dated: May 01, 2024.

Suzanne Mbollo,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2024–09775 Filed 5–3–24; 8:45 am]

BILLING CODE 7036–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0189]

Information Collection: Public Records and NRC Forms 507 and 509

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Public Records and NRC Forms 507 and 509.''

DATES: Submit comments by July 5, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0189. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0189 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0189. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2023–0189 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML24022A113, ML24022A114, and ML24022A116. The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML24022A111 and ML24022A112.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0189, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not

want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection:* Public Records and NRC Forms 507 and 509.
2. *OMB approval number:* 3150–0043.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Forms 507 and 509.
5. *How often the collection is required or requested:* On occasion.
6. *Who will be required or asked to respond:* Freedom of Information Act (FOIA) requesters, outside vendors, and licensees who submit an objection to disclosure.
7. *The estimated number of annual responses:* 628.
8. *The estimated number of annual respondents:* 273.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 180.5.
10. *Abstract:* The FOIA, 5 U.S.C. 552, and the implementing regulations, part 9 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Public Records,'' require individuals seeking access to records under the FOIA and Privacy Act of 1974, as amended, 5 U.S.C. 552a, to submit a request in writing and to describe the records sought sufficiently for the NRC to conduct a reasonable search. The Privacy Act of 1974, as amended, 5 U.S.C. 552a, establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by Federal agencies. Specifically, Subpart B (Privacy Act regulations) implements the provisions of the Privacy Act of 1974, as amended, (5 U.S.C. 552a), with respect to the procedures by which individuals may determine the existence of, seek access to, and request correction of NRC records concerning themselves. Requesters can currently submit FOIA and/or Privacy Act requests in writing, fax, email, *https://www.foia.gov* or by using the Public Access Link (*https://foia.nrc-gateway.gov/app/Home.aspx*). NRC Form 509, ''Statement of Estimated Fees for Freedom of Information Act (FOIA) Request'' is used by: (1) the NRC to notify requesters that fees will be assessed for processing their FOIA requests, (2) the requester to notify NRC in writing of their agreement to pay fees, (3) the NRC to notify the requester to submit a written request for a waiver pursuant to 10 CFR 9.41 within 10 working days from the receipt of the notice, and (4) the NRC to notify the requester to provide advanced payment of estimated fees. NRC Form 507, ''Identity Verification and/or Third-Party Authorization for Freedom of Information Act/Privacy Act Requests,'' is used by requesters to provide the identity verification or third-party authorization that is needed by the NRC in order to process their requests. The NRC uses the information provided by requesters to process requests from the public. In addition, outside vendors and licensees can submit an objection to disclosure. The NRC needs this information to properly process FOIA requests that involve confidential information or trade secrets.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: April 30, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–09747 Filed 5–3–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0079]

NUREG: Report to Congress on Abnormal Occurrences: Fiscal Year 2023; Dissemination of Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Final report; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing NUREG–0090, Volume 46, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2023.'' The report describes those events that the NRC or an Agreement State identified as abnormal occurrences (AOs) during fiscal year (FY) 2023, based on the criteria defined by the Commission. The report describes nine events at Agreement State-licensed facilities and two events at NRC-licensed facilities.

DATES: NUREG–0090, Volume 46, is available May 6, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0079 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0079. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The FY 2023 AO report, NUREG–0090, Volume 46, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2023 is available in ADAMS under Accession No. ML24121A231).

FOR FURTHER INFORMATION CONTACT: Rigel Flora, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3890; email: *Rigel.Flora@nrc.gov.*

SUPPLEMENTARY INFORMATION: Section 208 of the Energy Reorganization Act of 1974, as amended (Pub. L. 93–438), defines an ''abnormal occurrence'' as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. The FY 2023 AO report, NUREG–0090, Volume 46, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2023'' describes those events that the NRC identified as AOs during FY 2023.

This report describes nine events involving Agreement State licensees and two events involving NRC licensees. Seven of the AOs occurred at medical facilities, three AOs involved the theft or diversion and recovery of Category 2 radioactive material sources, and the other event involved an overexposure.

The NRC identified no events at NRC-licensed facilities during FY 2023 that met the guidelines for inclusion in Appendix B, ''Other Events of Interest.''

One event met the guidelines for inclusion in Appendix C, ''Updates of Previously Reported Abnormal Occurrences.''

Agreement States are the 39 U.S. States that currently have entered into formal agreements with the NRC pursuant to section 274 of the Atomic Energy Act of 1954, as amended (AEA), to regulate certain quantities of AEA-licensed material at facilities located within their borders.

The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104–68) requires that AOs be reported to Congress annually. The full report, NUREG–0090, Volume 46, ''Report to Congress on Abnormal Occurrences: Fiscal Year 2023,'' is also available electronically at the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff.*

Dated: May 1, 2024.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

[FR Doc. 2024–09790 Filed 5–3–24; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

[Docket ID: OPM–2024–0011]

Submission for Review: Revision and Consolidation of Two Existing Information Collections Related to Health Benefits Election Forms

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) for two forms: SF 2809 Health Benefits Election Form and OPM 2809 Health Benefits Election Form.

DATES: Comments are encouraged and will be accepted until July 5, 2024.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection by one of the following means:

- *Federal Rulemaking Portal: http://www.regulations.gov.*

All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection request, with applicable supporting documentation, may be obtained by contacting Retirement Services, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, Attention: Cyrus Benson. You may also contact (202) 936–0401 or email *RSPublicationsTeam@opm.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act (PRA) (44 U.S.C. chapter 35), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. This notice complies with that requirement, and OPM is soliciting comments for the ICR described below.

The Federal Employees Health Benefits (FEHB) Program, as governed by 5 U.S.C. chapter 89, provides health insurance to employees and annuitants of the Federal Government. Standard Form 2809 Health Benefits Election Form, OMB Control No. 3206–0160, has long been used by OPM and other Federal agencies to collect the information needed for employees to enroll in and to update enrollment information for the FEHB. OPM is proposing that the SF–2809 be categorized as a ''common form.''

The form OPM–2809 Health Benefits Election Form, OMB Control No 3206–0141, is in many respects similar to the SF–2809. The OPM–2809 provides OPM with the information needed for annuitants, survivor annuitants, and former spouses of annuitants in the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS) to enroll in and to update enrollment information for the FEHB.

The SF–2809 and the OPM–2809 forms are generally very similar in terms of the information collected, with only a few different data points to reflect differences between an employee and an annuitant. Nonetheless, the forms were historically managed under two different information collections. OPM is not currently planning to consolidate the forms into a single form because the instructions for annuitants are different than the instructions for an employee. OPM expects that retaining separate forms helps annuitants better understand what information is required.

OPM anticipates that both forms will generally require revisions at the same time and that comments relevant to one form will generally apply equally to the other form. Therefore, because the forms serve the same purpose (for two different populations) and collect virtually identical information, OPM is proposing to combine the two information collections and to manage the two forms under a single information collection, OMB Control No. 3206–0160, going forward.

The Postal Service Reform Act of 2022 (PSRA; Pub. L. 117–108) created a new Postal Service Health Benefits (PSHB) Program within the Federal Employees Health Benefits (FEHB) Program. As part of the regulatory implementation of the PSHB, OPM requested comment on whether OPM should introduce a separate enrollment form for PSHB. One commenter recommended that OPM update the existing 2809 form rather than introducing a new form for PSHB. OPM is publishing a final rule to implement the PSHB Program elsewhere in this issue of the **Federal Register**. OPM agrees with the commenter in that rulemaking and is proposing to add one data element to the existing SF–2809 and OPM–2809 forms. Specifically, the forms will request, only for PSHB retirees and family members, information on eligibility for health

services from the Indian Health Service and enrollment in health care benefits provided by the Veterans Affairs. OPM is requesting this information because it is necessary to determine Program eligibility for these individuals.

In addition, the Forms have been updated to improve clarity and ease of use. OPM consulted with Agency Benefit Officers, Federal benefit electronic enrollment systems, FEHB insurance carriers and conducted several employee focus groups to determine proposed changes. Some changes to instructions for the SF–2809 form have not been made to the OPM–2809 form to accommodate a larger use of paper forms by the annuitant population.

Finally, as part of the release of the new PSHB Program, OPM will be offering the use of a new online enrollment system. The information collected using the system will be identical to the paper and electronic PDF versions of the SF–2809 and OPM–2809 forms; however, users will be able to enter the information using a series of prompts that provide additional instructions and guidance.

The information collection for form SF–2809 (OMB Control Number 3206–0160) is currently approved with an estimated public burden of 9,000 hours for 18,000 responses. The information collection (OMB Control number 3206–0141) associated with that form is currently approved with an estimated public burden of 11,667 hours for 30,000 responses. As OPM is proposing to combine these information collections, the estimated public burden for the revised information collection is 20,667 hours for 48,000 responses.

The Standard Form 2809 and OPM Form 2809 reflect the minimal critical elements collected across the Federal government to begin an application for enrollment under the FEHB Program (including the PSHB Program) under the authority of 5 U.S.C. chapter 89.

We invite comments that:

1. Evaluate the utility of the changes made to the forms;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and

4. Suggest ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

In particular, OPM requests comment on (a) the proposed changes to form SF–2809, (b) the proposed changes to form OPM–2809, (c) OPM's proposal to collect the SF–2809 and OPM–2809 information for PSHB via the new electronic system, and (d) OPM's proposal to combine the two information collections into a single collection.

Analysis

Agency: Office of Personnel Management.

Title: Health Benefits Election Forms.

OMB Number: 3206–0160.

Frequency: Annually.

Affected Public: Eligible individuals who wish to enroll in FEHB (including Postal Service Health Benefits under FEHB) for the first time or to change an existing enrollment.

Number of Respondents: 48,000.

Estimated Time per Respondent: 30 Minutes.

Total Burden Hours: 20,667.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2024–09566 Filed 5–3–24; 8:45 am]

BILLING CODE 6325–64–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–261 and CP2024–267; MC2024–262 and CP2024–268; MC2024–263 and CP2024–269]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 8, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–261 and CP2024–267; *Filing Title:* USPS Request to Add Priority Mail Express Contract 101 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 30, 2024;

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* May 8, 2024.

2. *Docket No(s).:* MC2024–262 and CP2024–268; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 235 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 30, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jana Slovinska; *Comments Due:* May 8, 2024.

3. *Docket No(s).:* MC2024–263 and CP2024–269; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 236 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 30, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jana Slovinska; *Comments Due:* May 8, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–09770 Filed 5–3–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–256 and CP2024–262; MC2024–257 and CP2024–263; MC2024–258 and CP2024–264; MC2024–259 and MC2024–265; MC2024–260 and CP2024–266]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 7, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–256 and CP2024–262; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, USPS Ground Advantage & Parcel Select Contract 5 to Competitive Product List and Notice of filing Materials Under Seal; *Filing Acceptance Date:* April 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* May 7, 2024.

2. *Docket No(s).:* MC2024–257 and CP2024–263; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 231 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* May 7, 2024.

3. *Docket No(s).:* MC2024–258 and CP2024–264; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 232 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 7, 2024.

4. *Docket No(s).:* MC2024–259 and CP2024–265; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 233 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 7, 2024.

5. *Docket No(s).:* MC2024–260 and CP2024–266; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 234 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* April 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 7, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–09736 Filed 5–3–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, May 9, 2024.

PLACE: The meeting will be held via remote means and/or at the

Commission's headquarters, 100 F Street, NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov*.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: May 2, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–09960 Filed 5–2–24; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–428, OMB Control No. 3235–0478]

Submission for OMB Review; Comment Request; Extension: Rule 11a1–1(T)

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 11a1–1(T) (17 CFR 240.11a1–1(T)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

On January 27, 1976, the Commission adopted Rule 11a1–1(T) to exempt certain exempt transactions of exchange members for their own accounts that would otherwise be prohibited under Section 11(a) of the Exchange Act. The Rule provides that a member's proprietary order may be executed on the exchange of which the trader is a member, if, among other things: (1) the member discloses that a bid or offer for its account is for its account to any member with whom such bid or offer is placed or to whom it is communicated; (2) any such member through whom that bid or offer is communicated discloses to others participating in effecting the order that it is for the account of a member; and (3) immediately before executing the order, a member (other than a specialist in such security) presenting any order for the account of a member on the exchange clearly announces or otherwise indicates to the specialist and to other members then present that he is presenting an order for the account of a member.

Without these requirements, it would not be possible for the Commission to monitor its mandate under the Exchange Act to promote fair and orderly markets and ensure that exchange members have, as the principal purpose of their exchange memberships, the conduct of a public securities business.

There are approximately 531 respondents that require an aggregate total of approximately 15 hours per year to comply with this Rule. Each of these approximately 531 respondents makes an estimated 20 annual responses, for an aggregate of 10,620 responses per year. Each response takes approximately 5 seconds to complete. Thus, the total time burden per year is approximately 15 hours (10,620 × 5 seconds/60 seconds per minute/60 minutes per hour = 14.7618 hours rounded up to 15 hours). The approximate internal cost of compliance per hour is approximately $405, resulting in a total internal cost of compliance of approximately $6,075 per year (15 hours @$405).

Compliance with Rule 11a1–1(T) is necessary for exchange members to make transactions for their own accounts under a specific exemption from the general prohibition of such transactions under Section 11(a) of the Exchange Act. Compliance with Rule 11a1–1(T) does not involve the collection of confidential information. Rule 11a1–1(T) does not have a record retention requirement per se. However, responses made pursuant to Rule 11a1–1(T) may be subject to the recordkeeping requirements of Rules 17a–3 and 17a–4.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by June 5, 2024 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: May 1, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09759 Filed 5–3–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20292 and #20293; TEXAS Disaster Number TX–20007]

Administrative Declaration of a Disaster for the State of Texas

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of TEXAS dated 04/30/2024.

Incident: Severe Storms, Flooding, Hail and Straight-line Winds.

Incident Period: 04/08/2024 through 04/26/2024.

DATES: Issued on 04/30/2024.

Physical Loan Application Deadline Date: 07/01/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 01/30/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Jasper

Contiguous Counties: Texas: Angelina, Hardin, Newton, Orange, Sabine, San Augustine, Tyler

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 202926 and for economic injury is 202930.

The State which received an EIDL Declaration is Texas.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2024–09760 Filed 5–3–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12390]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Paris 1874: The Impressionist Moment'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Paris 1874: The Impressionist Moment'' at the National Gallery of Art, Washington, District of Columbia, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section 2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street, NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–09740 Filed 5–3–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 12395]

60-Day Notice of Proposed Information Collection: Four DDTC Information Collections

ACTION: Notice of request for public comments.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collections described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on these collections from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collections to OMB.

DATES: The Department will accept comments from the public up to July 5, 2024.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2024–0016'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: DDTCPublicComments@state.gov.*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Andrea Battista, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522–0112, via phone at 202–992–0973, or via email at *battistaal@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data.
- *OMB Control Number:* 1405–0003.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–5.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.

- *Estimated Number of Respondents:* 1,668.
- *Estimated Number of Responses:* 16,845.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 16,845 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.
- *Title of Information Collection:* Application/License for Temporary Import of Unclassified Defense Articles.
- *OMB Control Number:* 1405–0013.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–61.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 141.
- *Estimated Number of Responses:* 572.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 286 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.
- *Title of Information Collection:* Application/License for Temporary Export of Unclassified Defense Articles.
- *OMB Control Number:* 1405–0023.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–73.
- *Respondents:* Business and Nonprofit Organizations.
- *Estimated Number of Respondents:* 340.
- *Estimated Number of Responses:* 2,029.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 2,029 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.
- *Title of Information Collection:* Application for Amendment to License for Export or Import of Unclassified Defense Articles and Related Unclassified Technical Data.
- *OMB Control Number:* 1405–0092.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–6; DSP–62; DSP–74.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 440.
- *Estimated Number of Responses:* 1,742.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 871 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The export, temporary import, and brokering of defense articles, including technical data, and defense services are authorized by the Department of State, Bureau of Political-Military Affairs, Directorate of Defense Trade Controls (DDTC) in accordance with the International Traffic in Arms Regulations (''ITAR,'' 22 CFR parts 120–130) and section 38 of the Arms Export Control Act (AECA). Any person who engages in the United States in the business of manufacturing, brokering, exporting, or temporarily importing defense articles, including technical data, or furnishing defense services must register with the Department of State. Manufacturers who do not engage in exporting must nevertheless register. Additionally, any person who intends to export or to import temporarily a defense article must obtain the approval from DDTC prior to the export or temporary import, unless the export or temporary import qualifies for an exemption. The applicant must be registered with DDTC prior to submitting an application or using an exemption. Also, registered brokers must submit annual reports regarding all brokering activities that were transacted, and registered manufacturers and exporters must maintain records of defense trade activities for five years.

1405–0003, Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data: In accordance with part 123 of the ITAR, any person who intends to permanently export unclassified defense articles or unclassified technical data must obtain DDTC approval prior to export. The ''Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data'' (Form DSP–5) is the licensing vehicle typically used to obtain permission for the permanent export of unclassified defense articles, including unclassified technical data covered by the U.S. Munitions List (USML). This form is an application that, when approved, signed and dated by an official of DDTC, serves as the applicant's authorization for the permanent export of unclassified USML articles.

1405–0013, Application/License for Temporary Import of Unclassified Defense Articles: In accordance with part 123 of the ITAR, any person who intends to temporarily import unclassified defense articles must obtain DDTC authorization prior to import. The ''Application/License for Temporary Import of Unclassified Defense Articles'' (Form DSP–61) is the licensing vehicle typically used to obtain permission for the temporary import of unclassified defense articles covered by the USML. This form is an application that, when completed and approved by DDTC, it constitutes the official record and authorization for the temporary commercial import of unclassified USML articles, pursuant to the AECA and the ITAR.

1405–0023, Application/License for Temporary Export of Unclassified Defense Articles: In accordance with part 123 of the ITAR, any person who intends to temporarily export unclassified defense articles must obtain authorization from DDTC prior to export. The ''Application/License for Temporary Export of Unclassified Defense Articles'' (Form DSP–73) is the licensing vehicle typically used to obtain permission for the temporary export of unclassified defense articles covered by the USML. This form is an application that, when completed and approved by DDTC, it constitutes the official record and authorization for the temporary commercial export of unclassified USML articles, pursuant to the AECA and the ITAR.

1405–0092, Application for Amendment to License for Export or Import of Unclassified Defense Articles and Related Unclassified Technical Data: In accordance with part 123 of the ITAR, any person who intends to permanently export, temporarily import, or temporarily export unclassified or classified defense articles or related technical data must obtain DDTC authorization. This information collection is used by private industry to make changes in an approved Form DSP–5, Form DSP–61, or Form DSP–73. Upon approval, the amendment form along with the original license constitutes the authority to export or temporarily import.

Methodology

This information collection may be sent to DDTC via the following methods: electronically or by mail.

Michael J. Vaccaro,

Deputy Assistant Secretary for Defense Trade Controls, U.S. Department of State.

[FR Doc. 2024–09784 Filed 5–3–24; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 33 (Sub-No. 350X); Docket No. AB 1338X]

Union Pacific Railroad Company—Abandonment Exemption—in St. Louis County, Mo.; Missouri Eastern Railroad, LLC—Discontinuance of Service Exemption—in St. Louis County, Mo.

Union Pacific Railroad Company (UP) and Missouri Eastern Railroad, LLC (MER) (collectively, Applicants) have jointly filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for UP to abandon, and for MER to discontinue service over, a 0.55-mile portion of the Rock Island Old Passenger Main extending from milepost 11.58 to milepost 11.03, near Olivette, in St. Louis County, Mo. (the Line). The Line traverses U.S. Postal Service Zip Code 63132.

Applicants have certified that: (1) no local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years, and there is therefore no need to reroute any traffic; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment or discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] these exemptions will be effective on June 5, 2024, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/railbanking requests under 49 CFR 1152.29 must be filed by May 16, 2024.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by May 28, 2024.

All pleadings, referring to Docket Nos. AB 33 (Sub-No. 350X) and AB 1338X, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on UP's representative, Christine A. Neuharth, 1400 Douglas Street, MS 1580, Omaha, NE 68179, and MER's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before effective date of the exemptions. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request to stay should be filed as soon as possible so that the Board may take appropriate action before the effective date of the exemptions.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

UP has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by May 10, 2024. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245. Comments on environmental and historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by UP's filing of a notice of consummation by May 6, 2025, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov*.

Decided: May 1, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2024–09778 Filed 5–3–24; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Initiate a Deactivation Request for Tallahassee Commercial (68J), a Privately Owned Airport for Public Use Located in Tallahassee, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice announces that the FAA intends to file a Deactivation request for Tallahassee Commercial Airport (68J), a privately owned for public use airport.

DATES: Comments are due on or before May 10, 2024. Permanent airport closure is applicable after this date.

ADDRESSES: Documents are available for review at the FAA Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819. Written comments on the Sponsor's request must be delivered or mailed to: Jenny Iglesias-Hamann, Community Planner, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819.

FOR FURTHER INFORMATION CONTACT: Jenny Iglesias-Hamann, Community Planner, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819, or by telephone at (407) 487–7234.

SUPPLEMENTARY INFORMATION: The Eastern Service Area (ESA) Air Traffic Safety Action Program (ATSAP) Event Review Committee (ERC) has received reports from Tallahassee Air Traffic Control Tower (TLH) indicating the Tallahassee Commercial Airport (68J) is reported as closed via Notice to Air Missions (NOTAM), however, is still depicted on Visual Flight Rules (VFR) sectional charts. TLH controllers have had several instances where pilots have mistakenly tried to land at 68J airport due to it still being depicted on VFR sectional charts.

The 68J airport has been closed via NOTAM since 2011 when the owner of 68J was forced to close the runway (RWY) due to a large pavement failure. Airport Master Record states RWY 16/34 has surface cracking and shows Airport Status as closed indefinitely. The airport has continued to receive licensing under the presumption that progress was being made to repair the runway. It has been reported that no progress has been made to repair the runway pavement. A certified letter was sent to airport owner requesting corrective actions, with no response or comments received after 30 days.

(Authority: 1 CFR 22.2.)

Rebecca R. Henry,

Acting Manager, Orlando Airports District Office, Southern Region.

[FR Doc. 2024–07887 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Decommissioning and Disposition of the National Historic Landmark Nuclear Ship Savannah; Notice of Public Meeting

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: The Maritime Administration (MARAD) announces a public meeting of the Peer Review Group (PRG). The PRG was established pursuant to the requirements of the National Historic Preservation Act (NHPA) and its implementing regulations to plan for the decommissioning and disposition of the Nuclear Ship Savannah (NSS). PRG membership is comprised of officials from the U.S. Department of Transportation, MARAD, the U.S. Nuclear Regulatory Commission (NRC), the Advisory Council on Historic Preservation (ACHP), and the Maryland State Historic Preservation Officer (SHPO) and other consulting parties. The public meeting affords the public an opportunity to participate in PRG activities, including reviewing and providing comments on draft deliverables. MARAD encourages public participation and provides the PRG meeting information below.

DATES: The meeting will be held on Tuesday, May 21, 2024, from 2:30 p.m. to 4:00 p.m. Eastern Daylight Time (EDT). Requests to attend the meeting must be received by 5:00 p.m. EDT one week before the meeting, Tuesday, May 14, 2024, to facilitate entry or to receive instructions to participate online. Requests for accommodations for a disability must also be received one week before the meeting, Tuesday, May 14, 2024.

ADDRESSES: The meeting will be held onboard the NSS, online, or by phone. The NSS is located at Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21124.

FOR FURTHER INFORMATION CONTACT: Erhard W. Koehler, (202) 680–2066 or via email at *marad.history@dot.gov.* You may send mail to N.S. Savannah/Savannah Technical Staff, Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21224, ATTN: Erhard Koehler.

SUPPLEMENTARY INFORMATION:

I. Background

The decommissioning and disposition of the NSS is an Undertaking under Section 106 of the NHPA. Section 106 requires that federal agencies consider views of the public regarding their Undertakings; therefore, in 2020, MARAD established a Federal docket at *https://www.regulations.gov/docket/MARAD-2020-0133* to provide public notice about the NSS Undertaking. The federal docket was also used in 2021 to solicit public comments on the future uses of the NSS. MARAD is continuing to use this same docket to take in public comment, share information, and post agency actions.

The NHPA Programmatic Agreement (PA) for the Decommissioning and Disposition of the NSS is available on the MARAD docket located at *www.regulations.gov* under docket id ''MARAD–2020–0133.'' The PA stipulates a deliberative process by which MARAD will consider the disposition of the NSS. This process requires MARAD to make an affirmative, good-faith effort to preserve the NSS. The PA also establishes the PRG in Stipulation II. The PRG is the mechanism for continuing consultation during the effective period of the PA and its members consist of the signatories and concurring parties to the PA, as well as other consulting parties. The PRG members will provide individual input and guidance to MARAD regarding the implementation of stipulations in the PA. PRG members and members of the public are invited to provide input by attending bi-monthly meetings and reviewing and commenting on deliverables developed as part of the PA.

II. Agenda

The agenda will include (1) welcome and introductions; (2) program update; (3) status of PA stipulations; (4) other business; and (5) date of next meeting. The agenda topic, titled *PA stipulations,* involves deliverables identified in the PA. MARAD will provide status updates for the following items: the Disposition Alternatives Study; the Notice of Availability/Request for Information; and the License Termination Plan. The agenda will also be posted on MARAD's website at *https://www.maritime.dot.gov/outreach/history/maritime-administration-history-program* and on the MARAD docket located at *www.regulations.gov* under docket id ''MARAD–2020–0133.''

III. Public Participation

The meeting will be open to the public. Members of the public who wish to attend in person or online must RSVP to the person listed in the **FOR FURTHER INFORMATION CONTACT** section with your name and affiliation. Members of the public may also call-in using the following number: 312–600–3163 and conference ID: 930 866 814#.

Special services. The NSS is not compliant with the Americans with Disabilities Act (ADA). The ship has some capability to accommodate persons with impaired mobility. If you require accommodations to attend PRG meetings in-person, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The U.S. Department of Transportation is committed to providing all participants

equal access to this meeting. If you need alternative formats or services such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

(Authority: 49 CFR 1.81 and 1.93; 36 CFR part 800; 5 U.S.C. 552b.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–09769 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2023–0026]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Examining Distraction and Driver Monitoring Systems To Improve Driver Safety

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval of a new information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) summarized below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This document describes a new collection of information for which NHTSA intends to seek OMB approval titled Examining Distraction and Driver Monitoring Systems to Improve Driver Safety. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on July 14, 2023. Four comments were received during the comment period. This 30-day notice includes a summary of those comments, responses to the comments (no changes to the study are expected as a result of the comments), and an update to the estimated burden hours from the 60-day notice.

DATES: Comments must be submitted on or before June 5, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact: Thomas Fincannon, Office of Vehicle Safety Research, Human Factors/Engineering Integration Division NSR–310, West Building, W46–447, 1200 New Jersey Ave. SE, Washington, DC 20590; *thomas.fincannon@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

Title: Examining Distraction and Driver Monitoring Systems to Improve Driver Safety.

OMB Control Number: New.

Form Numbers: NHTSA Form 1718 Online Eligibility Questionnaire, NHTSA Form 1719 Karolinska Sleepiness Scale, NHTSA Form 1799 Appointment Reminder Confirmation Process, NHTSA Form 1720 Sleep and Food Intake, NHTSA Form 1721 End of Visit Release Agreement, NHTSA Form 1730 Track A Consent Form, and NHTSA Form 1731 Track B Consent Form Track B.

Type of Request: New information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years from date of approval.

Summary of the Collection of Information

NHTSA proposes to collect information from the public as part of a study to improve NHTSA's understanding of the differences in approaches to driver state detection and the potential safety impacts of driver monitoring systems (DMS). DMS refers to in-vehicle technology that can detect driver state and interact with the driver through the human-machine interface (the user interface that connects the driver to the vehicle). For example, a DMS that detects drowsiness may display an icon on the dashboard, such as a coffee cup, accompanied by a sound to alert the driver that drowsiness is present.

This study contains two tracks to assess DMS, and subjects may participate in Track A, Track B, or both. This allows for a balance between understanding how driver state detection changes within a diverse testing sample and within an individual across driver states. The overall sample will contain 80 data sets. Each track will have 40 completed data sets. Thus, the total sample size is anticipated to be 68 subjects and will include subjects that completed Track A only (n = 28), Track B only (n = 28), and those that completed both tracks (n = 12). Track A will evaluate the ability of the DMS to assess distraction and Track B will evaluate the ability of the DMS to assess both drowsiness alone and distraction while drowsy.

NHTSA proposes to collect information from licensed drivers about their age, sex, driver license status, sleep and driving habits, and general health history to determine eligibility for the study. Those interested in participating will be asked about their ability to adhere to various requirements of the protocol (*e.g.,* abstain from caffeine) and availability for a study appointment. Those who participate in the study will come to the University of Iowa Driving Safety Research Institute (DSRI), home of the National Advanced Driving Simulator (NADS). Both tracks involve a consent process, breath alcohol measurement, facial shape measurement, standing and seated height measurement, training presentation, a familiarization drive in the driving simulator, and sleepiness ratings before and after each study drive as well as approximately every 30 minutes during a waiting period. Both tracks also involve taking a digital image of the face so that researchers can obtain RGB values to assess skin tone variability. Track A only involves one study drive that occurs while the subject is alert and distracted. In Track B, subjects will be asked about their sleep and food intake (to confirm they have not consumed caffeine since 1:00 p.m., that they were awake by 7:00 a.m., and that they have consumed no other substances that could influence driving) prior to an overnight driving session that involves three study drives. The first drive occurs while alert. The next two drives are counterbalanced and will occur while drowsy (at least 14 hours awake and having sleepiness ratings indicating drowsiness) and while drowsy and distracted. Simulator data will be used to evaluate the ability of the DMS to assess driver state.

Respondents will volunteer for the study by responding to an internet ad or via solicitation for volunteers from the

DSRI subject registry. Only potential subjects in the registry meeting inclusion criteria will be contacted. Respondents will be asked a series of questions to determine eligibility to participate in the study. The questionnaire covers both Track A and Track B so respondents don't have to complete the questionnaire more than once and so researchers can ensure a subset of respondents meet criteria for both tracks. Criteria for both studies are largely the same; differences are related to ability to attend visits of a specified length, willingness to adhere to different protocol elements, and sleep habits (needed only for Track B). A research team member will answer all questions the respondent may have and schedule eligible respondents who wish to participate for a session at the DSRI.

Description of the Need for the Information and Proposed Use of the Information

NHTSA was established by the Highway Safety Act of 1970 (Pub. L. 91–605, 202(a), 84 Stat. 1713, 1739–40). Its mission is to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on our nation's highways. To further this mission, NHTSA conducts research as a foundation for the development of traffic safety programs.

In 2013, NHTSA published the final version of the Visual-Manual NHTSA Driver Distraction Guidelines for In-Vehicle Electronic Devices. In the decade since, vehicle technologies and interfaces have evolved and a substantial amount of new research on the topic of driver distraction has been conducted. As a result, NHTSA requires a rigorous and thorough review to update the current state of knowledge on driver distraction, attention management, and distraction/risk assessment. Driver monitoring systems (DMS) are currently deployed in many production vehicles. Current production systems use different data sources, including driver-facing cameras, vehicle inputs (*e.g.,* steering wheel torque), driving performance (*e.g.,* lane departures), and other measures (*e.g.,* time on task). Future production systems are also likely to use physiological sensors (*e.g.,* heart rate) as tools to identify driver state more accurately. DMS could play a variety of roles in vehicles, including detecting and alerting drivers to distraction, drowsiness, or impairment, and then adjusting the vehicle technology to meet the needs of the driver or providing support in particular situations. It is important for NHTSA to be able to discern the differences in approaches to state detection to understand the potential safety impacts of DMS. This requires a comparison of various sensor approaches to driver state monitoring and the development of a test protocol for different DMS methodologies. The overall objective is to develop and deliver a methodology that will assess the ability of DMS to accurately determine driver state by collecting data to support a full assessment of the factors associated with DMS and modeling driver state based on sensor data in a driving simulator.

60-Day Notice

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on July 14, 2023 (88 FR 45269). Four comments and one email were received in response to that notice. During the public comment period for the 60-day notice, NHTSA received four comments and one email. The first comment requested collection of data regarding circadian effects as related to school start times. This would involve subjects under the age of 18 and are not related to driver monitoring systems and is out of scope of the planned research project. The second comment expressed a dislike for driver monitoring systems as expressed the opinion that DMS are a disciplinary tool rather than a safety tool. NHTSA respectfully disagrees with this opinion and believes DMS may be able to improve motor vehicle safety.

One email from Alliance for Automotive Innovation asked if the research was in response to Sec. 24209 of the Infrastructure Investment and Jobs Act, 2021 (H.R. 3684; Pub. L. 117–58, enacted on November 15, 202 and commonly referred to as the Bipartisan Infrastructure Law or BIL). NHTSA responded by email to the Alliance for Automotive Innovation and noted that this project does include elements that were funded by the IIJA/BIL legislation. The email response also encouraged submission of comments to *regulations.gov* and noted that NHTSA would provide responses to comments in a 30-day notice published in the **Federal Register** (this document).

Two of the comments received were relevant to the burden and design of the study. The following summarizes the points brought up in those comments and NHTSA's response.

The American Academy of Sleep Medicine (AASM) commended NHTSA for planning the current information collection. They found the assessment of both drowsiness and distraction while drowsy to be a progressive and necessary step in determining the utility of DMS as a tool for road safety.

The AASM commented that self-reported sleepiness may not always reflect an individual's true level of sleepiness and recommended the inclusion of other objective measures of alertness, such as electroencephalography (EEG) or the psychomotor vigilance task (PVT) to strengthen the accuracy of collected drowsiness data. *Response:* The research team has used both EEG [1] and PVT [2] as part of prior drowsy driving research. We included the review of this data as part of preliminary steps in this research study. Specifically, we found a strong relationship between the Observer Rating of Drowsiness (ORD) and the Karolinska Sleepiness Scale (KSS) ($r = 0.682$, $p < 0.001$) and weak relationships between ORD and Psychomotor Vigilance Task (PVT) prior to the drive ($r = 0.150$, $p < 0.001$) and after the drive ($r = 0.244$, $p < 0.001$). Based on our prior published research, the inherent value of adding EEG is limited, but there are substantial increases to the burden (*e.g.,* application/cleanup & driver distraction) that do not outweigh this benefit. Depending on the EEG system, applying the EEG to the participant's scalp can range from 45 minutes to 120 minutes. The EEG may also interfere with the driver and cause additional distraction, discomfort, or prevent them from becoming immersed in the driving scenario, further reducing ecological validity. Recently, other researchers have investigated the associations between KSS, ORD, vehicle-based measures, and metrics from electrooculogram (EOG) and EEG.[3] KSS

[1] Brown, T., Johnson, R., & Milavetz, G. (2013). Identifying Periods of Drowsy Driving Using EEG. Annals of Advances in Automotive Medicine, 57, 99. *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3861841/;* Brown, T., Lee, J., Schwarz, C., Fiorentino, D., McDonald, A., Traube, E., & Nadler, E. (2013). Detection of Driver Impairment from Drowsiness. 23rd International Technical Conference on the Enhanced Safety of Vehicles, Seoul, South Korea.; Brown, T., Lee, J., Schwarz, C., Fiorentino, D., & McDonald, A. (2014). Assessing the Feasibility of Vehicle-Based Sensors to Detect Drowsy Driving. (DOT HS 811 886). Washington, DC: National Highway Traffic Safety Administration Retrieved from *http://www.nhtsa.gov/DOT/NHTSA/NVS/Crash%20Avoidance/Technical%20Publications/2014/811886-Assess_veh-based_sensors_4_drowsy-driving_detection.pdf.*

[2] McDonald, A.D., Lee, J.D., Schwarz, C., & Brown, T.L. (2018). A Contextual and Temporal Algorithm for Driver Drowsiness Detection. Accident Analysis & Prevention.

[3] Uchiyama, Y., Sawai, S., Omi, T., Yamauchi, K., Tamura, K., Sakata, T., Nakajima, K., & Sakai, H. (2023). Convergent validity of video-based observer rating of drowsiness, against subjective, behavioral, and physiological measures. PLoS one, 18(5), e0285557.

was associated with ORD, standard deviation of lateral position (SDLP), percentage of eyelid closure over the pupil over time (PERCLOS), EEG alpha power, EEG theta power, and percentage of time with slow eye movement. Interestingly, measures from the physiological sensors (*i.e.,* EEG and EOG) displayed only weak and moderate associations. Given these considerations, we maintain that the KSS will produce sufficiently accurate data to support the goals of the data collection while minimizing participant burden. The KSS will be used to determine when drivers have achieved a certain level of drowsiness and thus, they will begin the drowsy drive. We anticipated participants will complete the KSS nine times prior to the drive. Drowsiness will be defined based on a combination of the participant being awake for a minimum of 14 hours and the KSS. The KSS will not be administered during the drive as this may influence driver's levels of drowsiness. Drowsiness during the drive will be captured by measures derived from eye closures over the course of the drive (*e.g.,* PERCLOS). Given that each approach to measuring drowsiness comes with inherent flaws, we are using a combination of measures to infer drowsiness based on a sleepiness scale to bookend drowsiness during the drive and use of eye measures (*i.e.,* PERCLOS) to elucidate changes in drowsiness levels during the drive.

The AASM recommended that the information collection include an assessment of possible sleep disorders during the online eligibility questionnaire and advised excluding individuals with untreated sleep disorders from the study. Additionally, AASM recommended that the data collection include a measure of participant sleep quality in order to quantify contributing factors to drowsiness and driving performance; they suggested use of a participant sleep log and/or a three-day reporting of bedtimes, waketimes, estimate of the amount of time to fall asleep, number of awakenings, estimate of the amount of time awake during the awakenings, and daytime sleeping times and duration. *Response:* The proposed study procedures will capture wake and sleep time for the day preceding the study visit. We are not aware of any validated sleep log, and as additional measures would increase burden to participants, we have proposed to only ask targeted items that are known to influence drowsiness (*i.e.,* wake time and sleep time) and can be used to provide measures for the analysis (*i.e.,* hours of sleep and continuous time awake). The items that we ask participants are extracted from sleep logs and are variables that we could include in our statistical models. Since the sleep logs are not validated, we selected specific items, rather than using the entire log, as this reduces participant burden. Given that the focus of this research is on the manifestation of drowsiness (*i.e.,* for the purpose of determining validity of DMS assessment) while driving in the general driving population, we did not propose collecting subjective evaluation of sleep quality in subjects which might be better addressed by NIH funded research, nor do we plan to exclude participation based on sleep disorders given that an estimated 9 to 15% of individuals have ongoing sleep disorders. A DMS will need to detect distraction and drowsiness, regardless of individual health conditions, and exclusion of these drivers could hinder the external validity of findings from this research. The presence of daytime drowsiness regardless of source will be collected using self-reported sleepiness via the KSS.

The AASM also requested clarification on how the data obtained from the study would be protected, particularly as it related to prevention of consequences for participants who are distracted while driving. The AASM also asked whether a certificate of confidentiality would be provided. *Response:* The study has received approval from the University of Iowa Institutional Review Board, which requires us to protect the participants' anonymity. Respondents' performance in the driving simulator will be deidentified and separated from any personally identifiable information. Certificates of confidentiality are generally not sought unless we are collecting data that would put the participants at legal risk, which is not the case in this study.

The National Association of Mutual Insurance Companies (NAMIC) commented that the use of the Fitzpatrick Skin Type Scale in the online eligibility questionnaire, which requires participants to self-rate, negates the uniformity of the scale. Further, NAMIC questions why the study intends to oversample participants who are rated higher on the scale (*e.g.,* darker skin types). *Response:* The proposed self-rating of an applicant on the Fitzpatrick Skin Type Scale will be used to inform our study stratification and data collection logistics. The scale will be used to objectively quantify their skin pigmentation upon consenting and enrolling our study by a single rater. Additionally, the RGB values for skin tone will be captured during the visit via visual processing to provide an objective metric with greater gradation.

NAMIC also requested additional clarification on which driver monitoring system(s) will be used in the study. Response: The team will implement a sensor suite to provide the same types of signals available to a variety of types of DMS including vehicle and driver data. DSRI has existing relationships with technology suppliers that will be leveraged to provide necessary data. We do not propose to evaluate the algorithms from any technology suppliers, but instead focus on the utility of the underlying signals in detection.

Both AASM and NAMIC commented on the importance of recruiting participants from a large audience to ensure a sample that is representative and generalizable to a larger driving population. NAMIC noted their concerns related to the limited location (noting a 30-mile radius around Iowa City, IA), number of participants, and participant selection process. Response: A power analysis was conducted to estimate the sample size needed for the study. We agree that generalizability is important and must be balanced with the experimental aims of the research. Given that the research method utilizes a one-of-a-kind driving simulator, recruitment must be focused in the geographic area where it is housed. The plan is to maximize diversity of the sample within the limits of the proposed sample size through robust recruitment utilizing the existing registry which includes thousands of potential participants that includes the Cedar Rapids-Iowa City, IA CSA; Davenport-Moline, IA-IL CSA; Waterloo-Cedar Falls, IA MSA; Dubuque, IA MSA; Ottumwa, IA USA; Fort Madison-Keokuk, IA-IL-MO USA; Burlington, IA-IL USA; and Marshalltown, IA USA in addition to the surrounding rural areas. To expand the diversity of the overall sample, areas outside of Iowa City are being included in the recruitment approach. Additionally, participants who are not in the registry are not excluded from participating. No participants are excluded due to location so long as they are able to arrange safe transportation to/from the facility for the overnight visit. Prior research has shown that this can be done effectively, particularly when the study includes within-subject comparisons, which is one reason why we are including a subset of the sample in both tracks. As Iowa is less ethnically diverse than the US population overall, targeted recruitment will be performed

to promote a more balanced sample based on the Fitzpatrick Skin Type Scale, which is also a crucial variable to include when assessing the capabilities of DMSs. The proposed self-rating of an applicant on the Fitzpatrick Skin Type Scale will be used to inform our study stratification and data collection logistics.

Affected Public

Individuals aged 18+ from Eastern Iowa and the surrounding areas who have volunteered to take part in driving studies will be contacted for participation. They will be randomized evenly by sex, though some imbalance will be permitted to be inclusive of individuals who do not identify on the binary. Efforts will be made to enroll a diverse age sample that broadly represents the age of the driving population and includes those at greater risk of crashing (*e.g.,* less than 25 years of age and greater than 65 years of age). Additional efforts will be made to enroll individuals with diverse skin tones, oversampling those who rate themselves higher on the Fitzpatrick Skin Type Scale.

Estimated Number of Respondents: Varies by individual information collection. See Table 1 below.

Frequency: Varies by individual information collection. See Table 1 below.

Annual Number of Responses: 626.

Estimated Annual Burden Hours: 175 hours.

The estimated annual burden for the study is 175 hours. Table 1 provides estimates for the burden calculation across the study.

TABLE 1—ANNUAL BURDEN ESTIMATES

Study component	Annual number of respondents	Frequency of response	Annual responses	Time per response	Cost per response ($32.36/hour)	Annual estimated burden (rounded) (hrs)	Annual opportunity costs (rounded)
Online Eligibility Questionnaire (Form 1718)	200	1	200	10 min	$5.39	33	$1,078
Appointment Reminder Confirmation Process (Form 1799)	35	1.15	40	5	2.70	3	108
Breathalyzer Measurement	28	1.16	32	3	1.62	2	52
Facial Shape and Height Measurement	27	1.15	31	7	3.78	4	117
Karolinska Sleepiness Scale (Form 1719)	27	8.43	228	1	0.54	4	123
Track A Informed Consent (Form 1730)	16	1	16	15	8.09	4	129
Track A Study Drive (includes Training Presentation, Familiarization Drive and Study Drive)	16	1	16	81.25	43.82	22	22
Track B Informed Consent (Form 1731)	16	1	16	15	8.09	4	129
Sleep & Food Intake (Form 1720)	16	1	16	5	2.70	1	43
Track B Study Drive (includes Training Presentation, Familiarization Drive, Wait Time, Study Drives)	45	1	45	388.38	209.47	97	3,142
End of Visit Release Agreement (Form 1721)	16	1	16	2	1.08	1	17
Total Burden			626			175	5,159

Estimated Total Annual Burden Cost: $0.

The respondents are not expected to incur any reporting or recordkeeping cost from the information collection. The only costs associated with any of the information collections is the cost for travel to and from DSRI, which is associated with each of the study drives. We estimate that 83 respondents will travel to DSRI for each of the two tracks, though 13 respondents will travel for both tracks resulting in 96 round trips. We expect most subjects to be traveling locally, within 30 miles from the test facility. Maximally, we estimate a round trip distance from subjects' starting destination to DSRI to be 60 miles. The standard mileage rate for business-related driving in 2023 is 65.5 cents per mile driven, or $39.30 for 60 miles driven. Therefore, we estimate the maximum travel costs associated with Track A Study Drive to be $1,886 (48 respondents × $39.30 = $1,886.40). We estimate that the total transportation costs will be higher for subjects in Track B, who will not be permitted to walk, bike, or drive when leaving the test facility. Previous overnight studies conducted at DSRI have shown that $70 compensation for transportation expenses was sufficient to limit subject attrition and offset costs of third-party transportation. Accordingly, we estimate the travel costs associated with Track B Study Drive to be $3,360 (48 respondents × $70 = $3,360). The total costs for this ICR are estimated to be $5,246 ($1,886 + $3,360). These transportation costs are offset by subject compensation. For subjects in Track B, who will not be permitted to walk, bike, or drive when leaving the test facility, an additional $70 will be provided to offset the costs of finding alternative transportation. Table 1 provides an estimate for the opportunity cost of the collection; however, there is no direct cost to the respondents for this collection.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29A.

Cem Hatipoglu,

Associate Administrator, Vehicle Safety Research.

[FR Doc. 2024–09776 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No: PHMSA–2022–0085]

Pipeline Safety: Information Collection Activities: Mitigation of Ruptures on Onshore Gas Transmission and Gathering, Hazardous Liquid, and Carbon Dioxide Pipeline Segments Using Rupture-Mitigation Valves or Alternative Equivalent Technologies and Blending of Hydrogen Gas and Natural Gas within Gas Pipelines

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice and extension of comment period.

SUMMARY: On March 25, 2024, PHMSA published a notice in the **Federal Register** inviting public comments on its intent to request the Office of Management and Budget's (OMB) approval of changes to PHMSA forms to collect data on the use of rupture mitigation valves, or alternative equivalent technologies, and the blending of hydrogen gas with other natural gases within gas pipelines. In response to a petition, PHMSA is extending the deadline to submit comments.

DATES: The comment submission deadline for the notice published March 25, 2024 at 89 FR 20751 is extended from May 24, 2024, to June 24, 2024.

FOR FURTHER INFORMATION CONTACT: Angela Hill by phone at 202–366–1246 or by email at *Angela.Hill@dot.gov.*

SUPPLEMENTARY INFORMATION: On March 25, 2024, PHMSA published a notice in the **Federal Register** (89 FR 20751) inviting public comments on its intent to request the Office of Management and Budget's (OMB) approval of changes to existing information collections under OMB control numbers 2137–0627 (National Registry of Pipeline and LNG Operators), 2137–0635 (Pipeline Operators), 2137–0635 (Incident Reports for Natural Gas Pipeline Operators), 2137–0629 (Annual Report for Gas Distribution Operators), 2137–0522 (Annual Reports for Gas Pipeline Operators), 2137–0614 (Hazardous Liquid Pipeline Operator Annual Reports), and 2137–0596 (National Pipeline Mapping Program). The proposed information collection changes would provide data necessary to demonstrate an alternative approach to the implementation of Recommendation P–11–11 made by the National Transportation Safety Board and allow PHMSA to identify trends related to the blending of hydrogen gas and natural gas within gas pipelines from operator-submitted data. Comments on the proposed data collection are due on May 24, 2024.

On April 1, 2024, the Interstate Natural Gas Association of America, the American Fuel and Petrochemical Manufacturers, the American Gas Association, the American Petroleum Institute, the American Public Gas Association, and the GPA Midstream Association (the Associations) requested PHMSA extend the May 24, 2024, deadline to submit comments. Specifically, the Associations requested an additional 119 days to provide comments on the information collection proposal.

PHMSA believes the allotted time is sufficient to provide comments on the proposed changes, however, PHMSA acknowledges the Associations request for additional time due to them also providing comments on pending rulemaking actions. PHMSA will extend the comment submission deadline from May 24, 2024, to June 24, 2024. Consistent with 49 CFR 190.323, PHMSA will consider late-filed comments to the extent practicable.

Issued in Washington, DC, on April 30, 2024, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2024–09742 Filed 5–3–24; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons and vessels that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons, including the identified vessels, are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

A. On November 16, 2023, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below:

Entities

1. GALLION NAVIGATION INCORPORATED, 80 Broad Street, Monrovia, Liberia; Unit 27610–001, Building A1, IFZA Business Park, Dubai Silicon Oasis, Dubai, United Arab Emirates; Identification Number IMO 4112088 [RUSSIA–EO14024].

Designated pursuant to section 1(a)(i) of Executive Order 14024 of April 15, 2021, ''Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation,'' 86 FR 20249, 3 CFR, 2021 Comp., p. 542 (Apr. 15, 2021) (E.O. 14024) for operating or having operated in the marine sector of the Russian Federation economy.

2. KAZAN SHIPPING INCORPORATED, Office OT 17–32, 17th Floor, Office Tower, Central Park Towers, Dubai, United Arab Emirates; Unit 27610–001, Building A1, IFZA Business Park, DDP, Dubai Silicon Oasis, Dubai, United Arab Emirates; Identification Number IMO 1142781 [RUSSIA–EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

3. PROGRESS SHIPPING COMPANY LIMITED, 80 Broad Street, Monrovia, Liberia; Unit 27610–001, Building A1, IFZA Business Park, Dubai Silicon Oasis, Dubai, United Arab Emirates; Identification Number IMO 4075276 [RUSSIA–EO14024].

Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the marine sector of the Russian Federation economy.

On November 16, 2023, OFAC also identified the following vessels as property in which a blocked person has an interest, under the relevant sanctions authority listed below:

Vessels

1. NS CENTURY (A8IJ8) Crude Oil Tanker Liberia flag; Vessel Registration Identification

IMO 9306782; MMSI 636012853 (vessel) [RUSSIA–EO14024] (Linked To: GALLION NAVIGATION INCORPORATED).

Identified as property in which Gallion Navigation Incorporated, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

2. KAZAN (A8CE6) Crude Oil Tanker Liberia flag; Vessel Registration Identification IMO 9258002; MMSI 636011916 (vessel) [RUSSIA–EO14024] (Linked To: KAZAN SHIPPING INCORPORATED).

Identified as property in which Kazan Shipping Incorporated, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

3. LIGOVSKY PROSPECT (A8AP5) Crude Oil Tanker Liberia flag; Vessel Registration Identification IMO 9256066; MMSI 636011641 (vessel) [RUSSIA–EO14024] (Linked To: PROGRESS SHIPPING COMPANY LIMITED).

Identified as property in which Progress Shipping Company Limited, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

Dated: May 1, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–09788 Filed 5–3–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0188]

Agency Information Collection Activity Under OMB Review: Applications for Motor Vehicle Adaptive Equipment and HISA Services

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0188.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Avenue NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0188'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–3521.

Title: Applications for Motor Vehicle Adaptive Equipment and HISA Services.

OMB Control Number: 2900–0188.

Type of Review: Reinstatement, with revisions, of a previously approved collection.

Abstract: The Department of Veterans Affairs (VA), through its Veterans Health Administration (VHA), administers medical services established by law. Title 38 U.S.C. 1701(6) includes prosthetic items within the scope of medical services. Title 38 U.S.C. 3901, 3902, 3903, 3904, and 1162 authorize the Secretary to provide each person eligible for a motor vehicle grant the adaptive equipment deemed necessary to ensure that the person will be able to operate the vehicle safely, in a manner consistent with the safety of others and to satisfy the applicable standards of licensure established by the state of residency. VA also provides assistance to Veterans applying for Home Improvements and Structural Alterations (HISA) grants. The Prosthetic Service determines eligibility, entitlement, and payment of individual claims for home improvements and structural alterations to accommodate a Veteran's needs.

VA Form 10–1394 will be used to collect necessary information from eligible Veterans applying for motor vehicle adaptive equipment. VA Form 10–0103 will be used to collect necessary information from eligible Veterans applying for HISA grants.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 40 on February 28, 2024, pages 14740 and 14741.

Total Annual Burden: 2,750 hours.

Total Annual Responses: 21,000.

Affected Public: Individuals or households.

Estimated Annual Burden:

10–1394–1,500 hours.

10–0103–1,250 hours.

Estimated Average Burden per Respondent:

10–1394–15 minutes.

10–0103–5 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents:

10–1394–6,000.

10–0103–15,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09771 Filed 5–3–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0067]

Agency Information Collection Activity: Application for Automobile or Other Conveyance and Adaptive Equipment (Under 38 U.S.C. 3901–3904)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 5, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0067'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise

and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0067'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3901–3904, 38 CFR 3.808.

Title: Application for Automobile or Other Conveyance and Adaptive Equipment (Under 38 U.S.C. 3901–3904) (VA Form 21–4502).

OMB Control Number: 2900–0067.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–4502 is used by veterans and servicepersons to apply for automobile or other conveyance and adaptive equipment benefits. Without the information solicited by this form, VA would be unable to determine eligibility, and benefits would not be properly paid.

No changes have been made to this form. The respondent burden has increased due to the estimated number of receivables averaged over the past year.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,197 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 12,786 per year.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09728 Filed 5–3–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0545]

Agency Information Collection Activity Under OMB Review: Report of Medical, Legal, and Other Expenses Incident to Recovery for Injury or Death

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0545''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0545'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 1503, 28 CFR 3.262, § 3.271, and § 3.272.

Title: Report of Medical, Legal, and Other Expenses Incident to Recovery for Injury or Death.

OMB Control Number: 2900–0545.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21P–8416b is used to gather information about certain expenses related to securing compensation based on personal injury or death. The form is used by claimants for VA income-based benefits to determine the amount of countable income. Without this information, the VA would be unable to properly determine entitlement to income-based benefits and the rate payable.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 14154 on Friday, February 26, 2024, page 14154.

Affected Public: Individuals or Households.

Estimated Annual Burden: 75 hours.

Estimated Average Burden per Respondent: 45 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 100.

By direction of the Secretary:

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09721 Filed 5–3–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Monday,
No. 88 May 6, 2024

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 809

Medical Devices; Laboratory Developed Tests; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2023–N–2177]

RIN 0910–AI85

Medical Devices; Laboratory Developed Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is issuing a final rule to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, the Food and Drug Administration is phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

DATES: This rule is effective July 5, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6512, *LDTFinalRule@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. This amendment reflects that the device definition in the FD&C Act does not differentiate between entities manufacturing the device. In connection with amending the regulation, FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs (*i.e.,* FDA's expectations for compliance will generally be the same). This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs [1] and LDTs for unmet needs. For purposes of this document, we use ''manufacture'' and related terms as a shorthand for the various activities that constitute manufacturing as described in FDA regulations (*e.g.,* design, preparation, propagation, assembly, and processing).

In 1976, the Medical Device Amendments of 1976 (the MDA) amended the FD&C Act to create a comprehensive system for the regulation of devices intended for human use. In implementing the MDA, FDA has exercised enforcement discretion such that it generally has not enforced applicable requirements with respect to most LDTs. Enforcement discretion for LDTs developed as a matter of practice. However, the risks associated with LDTs are much greater today than they were at the time of enactment of the MDA. As discussed more fully in the notice of proposed rulemaking (NPRM) (88 FR 68006, October 3, 2023) and this preamble, today's LDTs are, among other things, used more widely, by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions. In this regard, today's LDTs are similar to other IVDs that have not come within FDA's general enforcement discretion approach.

Given these changes, and for the additional reasons discussed in the NPRM and this preamble, FDA is phasing out the general enforcement discretion approach for LDTs. By phasing out this approach, FDA intends to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

B. Summary of Select Provisions of the Final Rule

FDA is amending the definition of ''in vitro diagnostic products'' in its regulations to state that IVDs are devices

[1] As discussed in section V.A.1, FDA uses the phrase ''IVDs offered as LDTs'' throughout this preamble to refer to IVDs that are manufactured and offered as LDTs by laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and that meet the regulatory requirements under CLIA to perform high complexity testing, and used within such laboratories, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory.

under the FD&C Act ''including when the manufacturer of these products is a laboratory.''

In conjunction with this amendment, FDA is phasing out the general enforcement discretion approach for LDTs. As discussed further in this preamble, however, FDA is adopting targeted enforcement discretion policies for several categories of IVDs manufactured by a laboratory in certain circumstances. As with any enforcement discretion policy, FDA may update any of these enforcement discretion policies as circumstances warrant or if the circumstances that inform these policies change, consistent with FDA's good guidance practices (21 U.S.C. 371(h), § 10.115 (21 CFR 10.115)).

Additional details regarding the phaseout policy are discussed further in section V of this preamble.

C. Legal Authority

FDA is issuing this rule under the Agency's general rulemaking authorities and statutory authorities relating to devices. These authorities include sections 201(h)(1), 301, 501, 502, 510, 513, 514, 515, 518, 519, 520, 701, 702, 704, and 801 of the FD&C Act (21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, and 381) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262).

D. Costs and Benefits

We quantify benefits to patients from averted health losses due to problematic IVDs offered as LDTs. We focus mainly on certain broad disease categories associated with the majority of misdiagnosis-related harms in the United States. Additional benefits include averted non-health losses from reduced spending on problematic IVDs offered as LDTs and unquantified reduction in costs from lawsuits. We quantify costs to affected laboratories for complying with statutory and regulatory requirements. Additional costs include costs to FDA, which we include in our estimates. We estimate that the annualized benefits over 20 years range from $0.99 billion to $11.1 billion at a 7 percent discount rate, with a primary estimate of $3.51 billion, and from $1.24 billion to $13.62 billion at a 3 percent discount rate, with a primary estimate of $4.34 billion. The annualized costs range from $566 million to $3.56 billion at a 7 percent discount rate, with a primary estimate of $1.29 billion, and from $603 million to $3.79 billion at a 3 percent discount rate, with a primary estimate of $1.37 billion.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
3P510k Review Organization	Third Party Review Organization Accredited Under FDA's Third Party Review Program
510(k)	Premarket Notification.
AABB	Association for the Advancement of Blood and Biotherapies.
ACGME	Accreditation Council for Graduate Medical Education.
ACLA	American Clinical Laboratory Association.
ADLT	Advanced Diagnostic Laboratory Test.
ACHC	Accreditation Commission for Health Care.
AMC	Academic Medical Center.
AML	Acute Myeloid Leukemia.
AMP	Association for Molecular Pathology.
ANI	Average Nucleotide Identity.
APA	Administrative Procedure Act.
ASHI	American Society for Histocompatibility and Immunogenetics.
ASR	Analyte Specific Reagent.
AST	Antimicrobial Susceptibility Test.
BLA	Biologics License Application.
CAP	College of American Pathologists.
CAPA	Corrective and Preventive Action.
CBRN	Chemical, Biological, Radiological, or Nuclear.
CDER	Center for Drug Evaluation and Research.
CDRH	Center for Devices and Radiological Health.
CDC	Centers for Disease Control and Prevention.
CDx	Companion Diagnostic.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
CGT	Cell and Gene Therapy.
CLIA	Clinical Laboratory Improvement Amendments of 1988.
CLIAC	Clinical Laboratory Improvement Advisory Committee.
CLSI	Clinical and Laboratory Standards Institute.
CMS	Centers for Medicare & Medicaid Services.
COLA	Commission on Office Laboratory Accreditation.
CRO	Clinical Research Organization.
Cures Act	21st Century Cures Act.
DNA	Deoxyribonucleic Acid.
DoD	Department of Defense.
EGFR	Epidermal Growth Factor Receptor.
EMR	Electronic Medical Record.
EO	Executive Order.
EUA	Emergency Use Authorization.
EUCAST	European Committee on Antimicrobial Susceptibility Testing.
FACT	Foundation for the Accreditation of Cellular Therapy.
FCC	Federal Communications Commission.
FDA	Food and Drug Administration.
FDAAA	Food and Drug Administration Amendments Act.
FDAMA	Food and Drug Administration Modernization Act.
FDA–ARGOS	FDA dAtabase for Reference Grade MicrObial Sequences.
FD&C Act	Federal Food, Drug, and Cosmetic Act.

Abbreviation/acronym	What it means
FRIA	Final Regulatory Impact Analysis.
GAO	Government Accountability Office.
HCFA	Health Care Financing Administration.
HCT/Ps	Human Cells, Tissues, and Cellular and Tissue-Based Products.
HDE	Humanitarian Device Exemption.
HHS	Department of Health & Human Services.
HIV	Human Immunodeficiency Virus.
HLA	Human Leukocyte Antigen.
HUD	Humanitarian Use Device.
ICCS	International Clinical Cytometry Society.
IDE	Investigational Device Exemption.
IND	Investigational New Drug Application.
ISO	International Organization for Standardization.
IVD	In Vitro Diagnostic Product.
IVDR	In Vitro Diagnostic Medical Device Regulation.
LDT	Laboratory Developed Test.
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, and Asexual.
LoQ	Limit of Quantitation.
MAF	Master File.
MDA	Medical Device Amendments of 1976.
MDAC	Medical Devices Advisory Committee.
MDR	Medical Device Report.
MDUFA	Medical Device User Fee Amendments.
MolDx	Molecular Diagnostic Services.
NCBI	National Center for Biotechnology Information.
NDA	New Drug Application.
NGS	Next Generation Sequencing.
NIFLA	National Institute of Family and Life Advocates.
NIH	National Institutes of Health.
NIPS	Non-Invasive Prenatal Screening.
NLRB	National Labor Relations Board.
NMDP	National Marrow Donor Program.
NOTA	National Organ Transplant Act.
NPRM	Notice of Proposed Rulemaking.
NSQAP	Newborn Screening Laboratory Quality Assurance Program.
NYS CLEP	New York State Department of Health's Clinical Laboratory Evaluation Program.
OED	Oxford English Dictionary.
OHT7	Office of Health Technology 7.
OIRA	Office of Information and Regulatory Affairs.
OMB	Office of Management and Budget.
OPTN	Organ Procurement and Transplant Network.
OTC	Over-the-Counter.
PAMA	Protecting Access to Medicare Act of 2014.
PCCP	Predetermined Change Control Plan.
PHS Act	Public Health Service Act.
PMA	Premarket Approval Application.
PrEP	Pre-Exposure Prophylaxis.
PRIA	Preliminary Regulatory Impact Analysis.
QS	Quality System.
QSR	Quality System Regulation.
RBC	Red Blood Cell.
RNA	Ribonucleic Acid.
RUO	Research Use Only.
SAMHSA	Substance Abuse and Mental Health Services Administration.
SDO	Standards Development Organization.
Secretary	Secretary of HHS.
STI	Sexually Transmitted Infection.
STIC	Susceptibility Test Interpretive Criteria.
TMB	Tumor Mutational Burden.
UDI	Unique Device Identification.
UMRA	Unfunded Mandates Reform Act of 1995.
USG	United States Government.
VALID Act	Verifying Accurate, Leading-Edge IVCT Development Act of 2023.
VHA	Veterans Health Administration.

III. Background

FDA's regulations define IVDs as reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae, and intended for use in the collection, preparation, and examination of specimens taken from the human body. IVDs include test systems (also referred to in this preamble as ''tests'') that are intended for use in the collection, preparation, and examination of samples taken from the human body, such as blood or tissue, for the purpose of detecting diseases or other conditions, monitoring

a person's overall health, identifying patients who are likely to benefit from specific therapies, or otherwise helping to diagnose, cure, mitigate, treat, or prevent disease or its sequelae. Some IVDs are manufactured by conventional medical device manufacturers for use by other entities such as laboratories, healthcare providers, or, in some cases, patients. Such IVDs may include ''test kits,'' containing packaged sets of components that are part of or comprise a test system. Other IVDs are manufactured by laboratories for use by the same or other laboratories. Such IVDs include LDTs. FDA has generally considered an LDT to be an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high complexity testing.[2]

However, in implementing the MDA since 1976, FDA has exercised enforcement discretion such that it generally has not enforced applicable legal requirements with respect to most LDTs. This means that, for most LDTs, FDA generally has not enforced requirements related to registration and listing, reporting adverse events to FDA, current good manufacturing practices (CGMPs), or premarket review of an IVD by FDA prior to use of the LDT in patient care, among other requirements. The rationale for this approach was that, at the time of passage of the MDA, LDTs were mostly manufactured in small volumes by laboratories that served their local communities. They were typically intended for use in diagnosing rare diseases or for other uses to meet the needs of a local patient population, or were generally similar to well-characterized, standard IVDs (Refs. 2 and 3). They also tended to employ manual techniques (and did not use automation) and were performed by laboratory personnel with specialized expertise; to be used and interpreted by physicians or pathologists in a single institution responsible for the patient (and who were actively involved in patient care); and to be manufactured using components legally marketed for clinical use, such as general purpose reagents or immunohistochemical stains marketed in compliance with FDA requirements. Due to these and other factors, FDA exercised enforcement discretion such that it generally has not enforced applicable requirements for most LDTs.[3]

However, the LDT landscape has evolved significantly since 1976. Today, many LDTs increasingly rely on high-tech or complex instrumentation and software to generate results and clinical interpretations (Refs. 2 and 3). They are often used in laboratories outside of the patient's healthcare setting and are often run in high volume for large and diverse populations. Many LDTs are manufactured by laboratory corporations that market the IVDs nationwide, as they accept specimens from patients across the country and run their LDTs in very large volumes in a single laboratory. Today's LDTs are also more commonly manufactured with instruments or other components not legally marketed for clinical use and are more often used to inform or direct critical treatment decisions, to widely screen for common diseases, to predict personal risk of developing certain diseases, and to diagnose serious medical conditions such as cancer and heart disease.[4] The risks associated with most LDTs today are therefore much greater than they were at the time FDA began implementing the MDA, and most LDTs today are similar to other IVDs that have not been under FDA's general enforcement discretion approach. In addition, FDA is concerned that firms are offering IVDs as ''LDTs'' even when they are not LDTs as defined on FDA's website, because they are not actually designed, manufactured, and used within a single laboratory (see, *e.g.,* Refs. 5 and 6).

As LDTs increasingly rely on high-tech instrumentation and software, the potential for cybersecurity vulnerabilities is growing. Many LDTs are connected to Laboratory Information Management Systems and other IT infrastructure, making them a potential conduit for those looking to access information in such systems. This may include patient genetic information, among other things, which could have national security implications. Further, it has been demonstrated that hackers can modify medical test results (Ref. 7). Through premarket review, FDA works with manufacturers to ensure cybersecurity is appropriately considered, mitigating the potential for future problems. Through medical device reporting (MDR) and correction and removal reporting requirements, FDA helps to ensure that any problems are appropriately addressed. In fact, FDA has seen cybersecurity problems with certain instruments and issued two safety communications where laboratories may not have otherwise been aware that the research use only (RUO) versions of the instruments used as part of their LDTs had the same vulnerabilities (Refs. 8 and 9).

As a result of these evolutions in the testing landscape, FDA has long recognized the need for a change in the Agency's general enforcement discretion approach for LDTs. The history of FDA's efforts with respect to LDTs is described more fully in the NPRM. Over the past few years, FDA has accumulated even more information supporting the need for a change, as noted in the NPRM and discussed below. In light of these developments, FDA is amending FDA's regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer is a laboratory.[5] FDA is also issuing a policy (see section V) under which FDA is: (1) phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs and (2) adopting targeted enforcement discretion policies for specific categories of IVDs manufactured by a laboratory. As reflected in FDA's Final Regulatory Impact Analysis (FRIA), FDA estimates that the benefits of the phaseout policy outweigh the costs (see Ref. 10).

A. FDA's Current Regulatory Framework

A comprehensive system for the regulation of devices is included in the FD&C Act, as amended by the MDA. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three categories (classes) of devices depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of

[2] Such laboratories may include those operating under State licensure programs deemed exempt from CLIA. *See* CMS, ''Exempt States Under the Clinical Laboratory Improvement Amendments'' (Ref. 1).

[3] FDA's general enforcement discretion approach has not applied to LDTs in all contexts; for example, it has not applied to, among other LDTs, those used for declared emergencies/potential emergencies/material threats under section 564 of the FD&C Act (21 U.S.C. 360bbb–3).

[4] *See, e.g.,* Refs. 2–4. These observations are also informed by FDA's own experience, including the review of submissions and site visits, and staff with prior experience in the laboratory industry manufacturing and performing LDTs.

[5] FDA is also amending the statutory citation for the device definition included in § 809.3 (21 CFR 809.3) to reflect that it is now codified at section 201(h)(1) of the FD&C Act.

such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

General controls include, but are not limited to, provisions that relate to establishment registration and device listing; premarket notification; prohibitions against adulteration and misbranding (*e.g.,* labeling that fails to bear adequate directions for use); recordkeeping and reporting, including adverse event reporting and reporting of corrections and removals initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health; investigational device exemption (IDE) requirements; [6] and CGMP requirements. These controls apply to all devices unless an exemption applies.

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d)(1) of the FD&C Act, devices that were introduced or delivered for introduction into interstate commerce for commercial distribution before the enactment of the MDA on May 28, 1976 (generally referred to as ''preamendments devices'') are classified after FDA: (1) receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation, along with a proposed regulation classifying the device, and provides an opportunity for interested persons to submit comments; and (3) publishes a final regulation classifying the device. A preamendments device for which a classification regulation has not been promulgated is known as an ''unclassified device.'' Until an unclassified device type has been formally classified by regulation, the marketing of new devices within the device type requires FDA premarket review through a premarket notification (510(k)) under section 510(k) of the FD&C Act.

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices'') are classified automatically by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require approval of a premarket approval application (PMA), unless and until: (1) FDA classifies or reclassifies the device into class I or II under section 513(f)(2) or (3) of the FD&C Act, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of the regulations (21 CFR part 807).

Failure to comply with applicable requirements of the FD&C Act and FDA regulations may render the device adulterated and misbranded under sections 501 and 502 of the FD&C Act and may constitute a prohibited act under section 301 of the FD&C Act (21 U.S.C. 331). For a further discussion of these regulatory measures, and specifically how they help to ensure device safety and effectiveness, see section III.B.1 of this preamble.

IVDs, as defined in § 809.3 (21 CFR 809.3), are devices intended for human use and are subject to the FD&C Act. They include class I, class II, and class III devices, as well as both preamendments and postamendments devices. Like other devices, IVDs are subject to general controls, and other applicable requirements under the FD&C Act and FDA's regulations. IVDs are also subject to specific labeling requirements in part 809 of the regulations (21 CFR part 809).

For additional discussion of how FDA's legal authorities apply to LDTs, see the ''Legal Basis for the Amendment'' section (section V.B) of the NPRM (88 FR 68006 at 68017) and sections VI.D and VI.E of this preamble.

B. Need for the Rule

This final rule is the culmination of years of study and deliberation by FDA and represents a significant step forward for public health. By phasing out the general enforcement discretion approach for LDTs, FDA is correcting the imbalance in its oversight between non-laboratory and laboratory IVD manufacturers—an imbalance that harms American patients. As a result of the final phaseout policy, the public will benefit from laboratory manufacturer compliance with basic FDA requirements that protect and promote public health, such as adverse event reporting, establishment registration and device listing, labeling standards, investigational use requirements and, as new IVDs enter the market or are significantly modified, CGMPs and premarket review. Compliance with these time-tested regulatory measures will put patients in a better position to understand and have confidence in IVDs regardless of where they are manufactured. FDA believes that the benefits of this rulemaking will become more and more pronounced over time, as new IVDs come on the market and as the circumstances in which we exercise enforcement discretion narrow correspondingly (as discussed in section V.B of this preamble).

FDA has considered a wide array of input on this topic. In light of that input, we have adapted our thinking and adjusted the phaseout policy in a manner that we believe best serves the public health. The final phaseout policy, as set forth in section V of this preamble, fulfills the core goal of greater oversight of laboratory-manufactured IVDs while also accounting for other key public health interests, such as helping to maintain access to those beneficial IVDs on which patients currently rely and access to certain IVDs for which

[6] Under section 520(g) of the FD&C Act and part 812 of FDA's regulations (21 CFR part 812), a clinical investigation to determine the safety and effectiveness of certain devices must be the subject of an approved IDE before such investigation may commence. If an IDE has been granted, a failure to comply with a requirement under which the device was exempted for investigational use renders the device adulterated (see section 501(i) of the FD&C Act).

there is little financial incentive for development. This final phaseout policy reflects a careful balancing of relevant factors and, overall, will substantially promote and protect public health, both now and in the future.

1. The Device Regulatory Scheme Advances Public Health, Including as Applied to Laboratory Manufacturers

Since Congress first enacted the FD&C Act, over time and across a wide range of product areas, Congress has empowered FDA with a standard set of tools to manage the risks (and, as applicable, help assure the effectiveness) of regulated products. *See* 21 U.S.C. 393(b). These tools—such as adverse-event reporting, establishment registration and product listing, labeling standards, investigational controls, CGMPs, and premarket review—routinely appear in FDA statutory schemes because they effectively serve the public. See section IV for a more complete description of these authorities. As applied to devices, these regulatory measures help ensure product safety and effectiveness and facilitate greater information production and sharing, among other things.[7] FDA anticipates that compliance with these regulatory measures will have equal benefit in the context of laboratory-manufactured IVDs.[8]

For example, FDA expects that laboratory compliance with MDR requirements will yield significant public health benefits. Today, clinical laboratories comply with CLIA, which means that complaints are investigated and monitored generally only on a laboratory-by-laboratory basis. That approach makes sense in light of CLIA's focus on individual laboratory operations. However, FDA is focused on identifying problems with an IVD itself—such as design or other manufacturing problems—so FDA looks for different types of errors and applies a different analysis to the MDRs it receives. Among other things, FDA aggregates MDR information across IVD types for tracking and trending, enabling the detection of issues that a single laboratory may never see. FDA has identified and helped resolve a wide range of IVD issues using this type of information (see the response to comment 165 for additional information). For example, using MDRs submitted by multiple manufacturers, FDA discovered that high dose biotin supplements were interfering with certain immunoassays (biotin is commonly used in the design of these assays), which caused inaccurate results among those tests. FDA's investigation of the issue—an issue that could apply equally to laboratory-manufactured tests—led to the redesign of multiple tests on the market (see also comment response 122). In order to maximize the value of medical device reporting, FDA's Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics, within the Office of Product Evaluation and Quality in FDA's Center for Devices and Radiological Health (CDRH), employs trained staff dedicated to the review of MDRs for each IVD product code. These efforts help ensure that FDA catches and addresses potentially problematic IVDs to better protect the public.

Compliance with registration and listing requirements will also have substantial public health value. The collection of this information provides FDA with the location of device establishments and all devices manufactured at those establishments. Knowledge of the location where devices are manufactured allows for effective planning, coordinating, and scheduling of inspections, ensuring that FDA has visibility into the operations and practices at different manufacturing facilities. Through inspections, FDA has been able to determine when manufacturers have deficient processes, such as failure to investigate complaints and adverse events (which can signal larger problems, as just described). Although CLIA inspections occur for laboratories, such inspections do not have the same focus on design issues, for example, such as design changes that fundamentally alter the IVD's safety or effectiveness and present novel risks to patients. In addition, compliance with listing requirements will give FDA better information about the universe of IVDs on the market. With respect to the biotin interference issue discussed earlier, for example, FDA's investigation led to the redesign of affected tests in FDA's listing database, but FDA did not have insight into laboratory developed tests on the market that might have the same issue because they were not in the database. It is possible that laboratories today are *still* manufacturing and offering tests with inaccurate results due to biotin interference. With greater listing information, FDA can better protect the public through more comprehensive remediation efforts, among other things. FDA's publicly accessible registration and listing database also gives the public greater knowledge of IVD manufacturers and the range of IVDs on the market, which will benefit patients and providers who seek to better understand the different testing options that are available and the source and location of those testing options. Right now, as noted in the FRIA, there is no reliable inventory of IVDs on the market. More comprehensive information will do a great service to the public and improve patient care.

Laboratory compliance with FDA labeling requirements will also materially advance public health, because it will provide for the availability of a consistent set of information critical to understanding the IVD, whether the IVD is manufactured by a laboratory or another manufacturer. The labeling requirements in § 809.10 (21 CFR 809.10) require IVD manufacturers to disclose basic facts about an IVD that can inform a doctor or patient's selection decisions, such as the intended use, limitations, and performance characteristics of the test. Today, ordering physicians do not necessarily have access to this standardized set of information for IVDs offered as LDTs, and therefore may lack the information needed to understand the use and performance of tests for their intended uses, make decisions in the context of an individual patient's needs, and pass on relevant information to their patients. Laboratory compliance with labeling requirements will mean that laboratories both compile and provide access to this type of information, which will facilitate knowledge transfer and, consequently, more informed healthcare decisions. Labeling also provides a frame of

[7] *See, e.g.,* Ref. 11 (finding, for stents, that the testing required under U.S. device premarket review standards improves consumer welfare and reflects ''optimal policy in terms of trading off testing versus access to innovation''—while also noting that post-market surveillance or learning could theoretically yield the same benefits as pre-market review at lower cost); Ref. 12 (noting that one benefit of ''approval regulation'' is the collection of ''information useful to 'downstream' product users,'' such as physicians, who then ''exhibit higher consumption and will more readily switch to superior products''); Ref. 13 (''The FDA is a critical component to the industries' success because it (1) provides appropriate reviews for safety and effectiveness, and (2) helps provide consumers with confidence that these technologies are safe and effective.'').

[8] *See, e.g.,* Ref. 14 (''Negative consequences of poorly understood or weakly applied regulatory oversight processes for laboratory developed tests have been vividly demonstrated . . . . Failure to insist on good clinical and laboratory practices, apply rigorous standards for the design, conduct, and analysis of biomedical research, and implement safeguards to address conflicts of interest poses threats to the integrity of biomedical research and exposes patients to potential harms.''); Ref. 15 (''Increasing regulatory responsibilities and requirements could encourage laboratories seeking to introduce LDTs . . . to prioritize tests with the greatest potential to positively affect patient care, which could reduce the clutter of available assays with limited utility.'').

reference for evaluating a manufacturer's promotional claims, helping FDA determine, for example, whether manufacturers may be misleading the public about the safety or effectiveness of their IVDs. Based on the various lawsuits cited in the NPRM (88 FR 68006 at 68012), FDA is aware that such promotion may be taking place and should be addressed.

FDA is also aware that, today, laboratories are conducting IVD clinical investigations without complying with FDA requirements, including the requirement to submit an IDE application for FDA review before beginning studies involving ''significant risk'' IVDs. When this occurs, subjects may be enrolled in studies that lack key human subject protections. Among other things, such investigations may lack an appropriate evaluation of whether, for example, the informed consent documents that are provided to potential subjects contain adequate information about the reasonably foreseeable risks or potential benefits of participation in the study. Such investigations of significant risk IVDs may also lack review by FDA to evaluate whether there are sufficient data to justify use of a significant risk IVD in the proposed study population. As explained in an FDA memorandum to file that was part of the record for this rulemaking, FDA is aware of circumstances in which laboratories have failed to conduct appropriate analytical validation studies to support the use of tests in clinical investigations (Ref. 16). In these instances, in the absence of FDA review of these investigations, subjects may have been enrolled in studies that exposed them to safety risks with little potential for benefit or for generating useful information.

Laboratory compliance with CGMP requirements will benefit the public as well. The Quality System Regulation (QSR) requires manufacturers to establish procedures for the consistent, quality manufacturing of devices. FDA recently issued comprehensive amendments to harmonize the QSR with international quality management system requirements (89 FR 7496, February 2, 2024). Under FDA's quality system (QS) requirements, design controls are a key area of focus, and an area that is distinct from CLIA (see the response to comment 188 for further information). Design controls require manufacturers to have procedures for generating IVD specifications, making sure their IVDs actually meet those specifications, and confirming that those specifications conform with user needs and intended use(s). By establishing and following a set system of documentation, manufacturers approach device design and modifications systemically, ensuring that the original design and any changes have been properly evaluated and do not have unintended consequences. In 1990, Congress specifically granted FDA authority to issue design control requirements after the Agency found that 44 percent of the quality problems that had led to voluntary recall actions between 1983 and 1989 were due to design errors or deficiencies, and the Agency promulgated corresponding QS regulations in 1996 (61 FR 52602, October 7, 1996). Design controls play such a key role because, as FDA explained when it issued those regulations, ''[t]he intrinsic quality of devices, including their safety and effectiveness, is established during the design phase'' (61 FR 52602 at 52615). Other QS requirements help ensure effective and appropriate design, such as acceptance activities, corrective and preventive actions, and records requirements. Although FDA recognizes that compliance with the QS requirements is associated with relatively higher costs for laboratories, and has taken that fact into account in crafting the phaseout policy, FDA believes laboratory compliance with the requirements generally will advance public health.

Finally, premarket review is one of FDA's most important tools for protecting and promoting public health. Through premarket review, the Agency evaluates the scientific information supporting the analytical validity, clinical validity, and safety of high- and moderate-risk IVDs, which helps ensure the IVD's safety and effectiveness before it reaches a patient. In FDA's experience, premarket review serves an important gatekeeping function regardless of whether an IVD is manufactured by a laboratory or another manufacturer. For example, FDA has received submissions for IVDs offered as LDTs showing that laboratories do not always properly validate tests or have sound clinical data to support a test's intended use (Ref. 16). If marketed as originally presented to FDA, many of these tests could have led to missed diagnoses or misdiagnoses, improper patient management decisions, or missed opportunities for beneficial treatment. Through premarket review, FDA works with applicants to obtain adequate data, determine whether a device works as intended, and refine labeling to reflect the intended use and limitations of an IVD. This process motivates the development of robust scientific data on safety and effectiveness [9] and gives patients confidence that an independent, expert third party has determined that patients can rely on these IVDs. FDA has recognized circumstances in the final phaseout policy in which the benefits of laboratory compliance with premarket review requirements are outweighed by other public-health considerations. The Agency will exercise enforcement discretion in those circumstances, as described below. Apart from these circumstances, FDA expects that laboratory compliance with premarket review requirements will have a significant positive impact on public health.

2. The Oversight Approach Set Forth in This Preamble Will Advance Public Health

Those who object to this rulemaking appear to argue that the IVDs manufactured by laboratories are so fundamentally different from, or better than, other IVDs that these IVDs should not fall under the oversight scheme outlined above. But these commenters are not able to point to differences that logically sustain that position. Many laboratory-manufactured tests use the same materials and technology, are based on the same scientific principles, are intended for the same or similar purposes, are developed by those with similar expertise, require the same level of training to perform, and are marketed for the same patients as tests from other manufacturers. Although some activities of these laboratories are also subject to CLIA, CLIA is not a substitute for FDA oversight, as detailed throughout this preamble and as the Centers for Medicare & Medicaid Services (CMS) has explained.

Furthermore, a review of the evidence does not bear out the suggestion that laboratory-manufactured IVDs have higher quality or perform better than other IVDs. FDA's memorandum to file describing submissions for IVDs offered as LDTs detailed the many defects FDA has seen with laboratory validation, among other things, and described the submissions as raising ''significant concerns'' in some cases (Ref. 16). During the COVID–19 emergency, FDA's conversations with laboratory manufacturers revealed that many were unfamiliar with what constitutes appropriate analytical and clinical validation for an IVD generally (see comment response 37 and Ref. 18). FDA's experience is corroborated by new information in the record from New York State. New York State submitted

[9] See Ref. 17.

data indicating that more than half of original applications from laboratories could not be approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP) based on deficiencies such as ''design flaws, inadequate validation data, and process problems that call into question the reliability of the results'' (Ref. 19). And in one of the only true head-to-head comparisons between IVDs offered as LDTs and the parallel FDA-authorized IVD,[10] the IVDs offered as LDTs were less accurate than the FDA-authorized IVD (Ref. 20). Although some commenters suggested that a reanalysis of that data supports a different conclusion, even under the reanalysis, the laboratory tests had worse performance, with only 8 of 19 laboratories correctly reporting all variants (compared to 7 in the original analysis). For additional information about the analysis and reanalysis, see comment responses 34 and 38.[11]

In short, based on the information before us, we do not believe that the general enforcement discretion approach for LDTs should continue. Today, IVDs offered as LDTs do not have appropriate assurances of safety and effectiveness. At least one survey suggests that the public agrees.[12] Therefore, FDA is phasing out the general enforcement discretion approach for LDTs, as explained in more detail in section V.

However, FDA also recognizes the effect that its longstanding enforcement discretion approach has had on the market, the role that laboratory-manufactured tests play in modern healthcare, and the presence of other expert regulatory bodies. Many comments emphasized these considerations. FDA agrees with certain comments' concern, for example, that expecting compliance with full QS and premarket review requirements for all currently marketed IVDs offered as LDTs could lead to the loss of access to safe and effective IVDs on which patients currently rely, and we are issuing an enforcement discretion policy to address that issue (see section V.B.3). FDA also agrees with the concern that, for certain LDTs for unmet needs, expecting full compliance with FDA requirements could lead to loss of access to tests for unmet needs for which laboratories cannot recoup the costs of compliance; we are issuing an enforcement discretion policy to address that issue in circumstances in which certain risk mitigations apply (see section V.B.3). FDA has also incorporated enforcement discretion policies recognizing the regulatory role that other Federal and State entities play (see sections V.B.1 and 2). In these and other ways, FDA has crafted a tailored phaseout policy that balances the important public health considerations at issue in this rule.

We anticipate that the final phaseout policy will provide significant benefits to the public. As indicated in the FRIA, the anticipated benefits significantly outweigh the anticipated costs. Through this Agency action, patients will have greater assurance that the IVDs used in their care are safe and effective, a significant step forward for public health. In addition, by applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs, FDA will reduce regulatory uncertainty, which will give stakeholders more stability, clarity, and confidence, and facilitate investment in the development of innovative IVDs (Ref. 22). FDA oversight will help to support coverage and reimbursement determinations for IVDs offered as LDTs, which we anticipate will make certain IVDs offered as LDTs for which there is a reasonable assurance of safety and effectiveness more affordable for patients. And with increased oversight, FDA will be able to help promote adequate representation in validation studies, and transparency regarding potential differential performance and unknown performance in certain patient populations, which will ultimately help advance health equity (see comment response 221 for additional information).

FDA expects the benefits of the phaseout policy to become more and more pronounced over time, as new tests come on the market and as the circumstances in which we exercise enforcement discretion narrow correspondingly. Diagnostic testing is increasingly important; for example, as time goes on, more novel treatments will require use of a specialized test to identify patients likely to benefit from those treatments.[13] Furthermore, IVDs offered as LDTs are a growing sector of the diagnostic testing market (Ref. 4). FDA anticipates that IVDs will continue to become more complex and play a greater role in modern healthcare (Ref. 3). The U.S. LDT market size is anticipated to grow 6 percent from 2023 to 2030 due to varying factors including increased use in personalized medicine and rising prevalence of chronic diseases. (*Id.*) FDA is therefore taking steps to help ensure that IVDs are safe and effective regardless of where they are manufactured, so that both now and in the future, patients can have confidence about the tests used in their care.

C. Summary of Comments on the Notice of Proposed Rulemaking

In the **Federal Register** of October 3, 2023, FDA published a rule proposing an amendment to its regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer is a laboratory, and proposing a policy under which FDA would phase out its general enforcement discretion approach for LDTs. The comment period for the NPRM closed on December 4, 2023. FDA received more than 6,500 comments on the NPRM from a variety of entities including medical device associations, members of the medical device and pharmaceutical industries, medical and healthcare professional associations, hospitals and academic medical centers (AMCs), accreditation organizations, other advocacy organizations, government agencies, and individuals.

Comments supporting FDA's proposal pointed to problems with LDTs, concerns about the significant impact of problematic LDTs on patients and the treatment decisions of healthcare providers, and the need for increased oversight of LDTs by FDA. Some comments also emphasized the importance of creating a ''level playing field'' between laboratory and non-laboratory manufacturers of IVDs, and described how phasing out the general enforcement discretion approach for LDTs would incentivize innovation by non-laboratory IVD manufacturers.

Some comments raised concerns or requested clarification regarding the following:

- the evidence related to the safety or effectiveness of IVDs offered as LDTs,
- the sufficiency of regulation by CMS and other non-FDA entities,
- FDA's legal authority to regulate LDTs,
- the impact of the phaseout policy on access to and the pricing of IVDs offered as LDTs,

[10] For purposes of this preamble, ''FDA-authorized'' refers to FDA permitting the marketing of a device via the premarket approval, 510(k), De Novo classification, Biologics License Application (BLA), or Humanitarian Device Exemption (HDE) pathway and to devices that are exempt from premarket notification. This term does not include devices authorized for emergency use under section 564 of the FD&C Act.

[11] For additional discussion of evidence relevant to IVDs offered as LDTs, see section III.B.2 of the NPRM (88 FR 68006 at 68010–12).

[12] Ref. 21 (''When presented with information on the differences between FDA regulation and CMS oversight, most participants supported FDA having oversight over all diagnostic tests.'').

[13] *See, e.g.,* Ref. 23 (''Demand is increasing in the CDx market, due to the paradigm shift to precision medicine.'').

- the impact of the phaseout policy on test innovation,
- the impact of the phaseout policy on small laboratories,
- the impact of the phaseout policy on specific patient populations, including underrepresented and underserved populations,
- the details of the phaseout policy,
- the types of IVDs offered as LDTs for which FDA intends to continue the general enforcement discretion approach and generally not enforce some or all applicable requirements, and
- FDA's implementation of the phaseout policy and the resources needed for such implementation.

D. General Overview of the Final Amendment to the Definition of In Vitro Diagnostic Products

FDA is amending its regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. This amendment reflects that the device definition in the FD&C Act does not differentiate between entities manufacturing the device, and provides further clarity, including for stakeholders affected by the accompanying changes to FDA's general enforcement discretion approach for LDTs.

FDA is also amending the statutory citation for the device definition included in § 809.3 to reflect amendments to section 201(h) of the FD&C Act as a result of the enactment of the Safeguarding Therapeutics Act (Pub. L. 116–304). For many years, the definition of ''device'' had been codified at section 201(h) of the FD&C Act. Upon enactment of the Safeguarding Therapeutics Act, the definition of ''device'' was redesignated as paragraph (h)(1) and a new definition of ''counterfeit device'' was codified at paragraph (h)(2).

FDA considered comments received on the NPRM, as discussed in more detail throughout this preamble, and has made no changes to the amendment.

E. General Overview of the Final Phaseout Policy

FDA has had a general enforcement discretion approach for most LDTs.[14] FDA is phasing out this general enforcement discretion approach so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. The phaseout is intended to help assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

Following a 4-year phaseout period, FDA will no longer have a general enforcement discretion approach for LDTs. The phaseout policy includes the following five stages for IVDs offered as LDTs (a term discussed further in section V.A.1):

- *Stage 1:* beginning 1 year after the publication date of this final rule, FDA will expect compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (21 CFR 820.198) (complaint files);
- *Stage 2:* beginning 2 years after the publication date of this final rule, FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements;
- *Stage 3:* beginning 3 years after the publication date of this final rule, FDA will expect compliance with QS requirements under part 820 (21 CFR part 820) (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1);
- *Stage 4:* beginning 3½ years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs (IVDs that may be classified into class III or that are subject to licensure under section 351 of the Public Health Service Act), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review; and
- *Stage 5:* beginning 4 years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.

The phaseout policy includes targeted enforcement discretion policies for certain categories of IVDs manufactured by a laboratory, as explained in more detail in sections V.B. and V.C. For example, as proposed in the NPRM, FDA generally does not intend to enforce requirements under the FD&C Act and FDA's regulations for ''1976-Type LDTs'' (as described in section V.B.1); Human Leukocyte Antigen (HLA) tests that are designed, manufactured, and used within a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and ''virtual'' HLA crossmatch tests; and tests intended solely for forensic (law enforcement) purposes (88 FR 68006 at 68022).

In addition, FDA considered comments received on the proposed phaseout policy and, based in part on those comments, made various changes to the phaseout policy, which include the addition of the following enforcement discretion policies:

- FDA intends to exercise enforcement discretion and generally not enforce requirements for LDTs manufactured and performed within the Veterans Health Administration (VHA) or the Department of Defense (DoD);
- FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP; [15]
- FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records))[16] [17] for LDTs manufactured and performed by a

[14] As discussed further in section V.A.2, FDA's general enforcement discretion approach has not applied to certain categories of LDTs. For these categories of LDTs, FDA has generally expected applicable requirements to be met, and in the NPRM we proposed that this approach be maintained (88 FR 68006 at 68021). After considering comments received on this topic we are not changing that approach for these categories with the phaseout policy described in this preamble.

[15] For purposes of this preamble, FDA uses the phrase ''LDTs approved by NYS CLEP'' to refer to LDTs that are approved, conditionally approved, or within an approved exemption from full technical documentation, under NYS CLEP. These three categories of LDTs are discussed further below in section V.B.2. Other LDTs, including ''LDTs used in Clinical Trials'' and ''Tests Not Subject to Evaluation'' which are described on NYS CLEP's website (Ref. 24), are not considered ''LDTs approved by NYS CLEP'' and are not within the enforcement discretion policy with respect to premarket review requirements described in section V.B.2. For additional discussion of the NYS CLEP premarket review program, see section V.B.2.

[16] When the final rule to amend part 820 takes effect in February 2026, the comparable requirements can be found in International Organization for Standardization (ISO) 13485 subclause 4.2 as modified by part 820.

[17] FDA recognizes that part 820, subpart M (Records) includes cross-references to §§ 820.20, 820.22, 820.40, and 820.50 (21 CFR 820.20, 820.22, 820.40, and 820.50). For the categories of IVDs discussed in section V.B.3 of this preamble, FDA generally expects compliance with requirements under subpart M but not §§ 820.20, 820.22, 820.40, and 820.50, or comparable provisions of ISO 13485 in accordance with the amendments to part 820 once that rule takes effect in February 2026.

laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system;

- FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in certain limited ways as described in section V.B.3; and
- FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for non-molecular antisera LDTs for rare red blood cell (RBC) antigens where such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories and where there is no alternative available to meet the patient's need for a compatible blood transfusion.

These enforcement policies do not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

IV. Legal Authority

FDA is issuing this final rule under the Agency's general rulemaking authorities and statutory authorities relating to devices. These authorities include sections 201(h)(1), 301, 501, 502, 510, 513, 514, 515, 518, 519, 520, 701, 702, 704, and 801 of the FD&C Act and section 351 of the PHS Act. In particular:

- Under section 201(h)(1) of the FD&C Act, a device is defined as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.''
- Section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

For additional descriptions of some of the authorities referenced above, see section III.A of this preamble. For additional discussion of how these legal authorities apply to LDTs, see the ''Legal Basis for the Amendment'' section (section V.B) of the NPRM (88 FR 68006 at 68017) and sections VI.D and VI.E of this preamble.

V. Phaseout Policy

Based on the considerations set forth in the NPRM and this preamble, including the public comments discussed in section VI.F below, FDA is phasing out the general enforcement discretion approach for LDTs in stages, as described in more detail below. FDA's intent is that following a 4-year phaseout period, IVDs offered as LDTs generally will be expected to meet applicable requirements, with several enforcement discretion policies for certain categories of IVDs manufactured by a laboratory as discussed further below.

We note that these policies may not be the only enforcement discretion policies applicable to these IVDs, and other enforcement discretion policies not addressed in this phaseout policy may apply to certain IVDs. As discussed in the NPRM, FDA has adopted and intends to continue adopting enforcement discretion policies for certain types of IVDs in certain circumstances, as appropriate (88 FR 68006 at 68021). For example, FDA issued final guidance documents with enforcement discretion policies for certain COVID–19 and mpox tests at the beginning of each declared emergency and, concurrent with this final rule, is issuing a draft guidance document with an enforcement policy for certain IVDs for immediate response to a chemical, biological, radiological, or nuclear (CBRN) agent in the absence of a declaration under section 564 of the FD&C Act (21 U.S.C. 360bbb–3).

Although FDA is phasing out its current general enforcement discretion approach over a period of years, the phaseout policy does not in any way alter the fact that it is illegal to offer IVDs without complying with applicable requirements. Regardless of the phaseout timeline and enforcement discretion policies for certain IVDs discussed below, FDA retains discretion to pursue enforcement action for violations of the FD&C Act at any time, and intends to do so when appropriate.

The details of FDA's final phaseout policy, including the scope, subsidiary enforcement discretion policies, and stages, are set forth below.

A. Scope

1. IVDs Within the Scope of the Phaseout Policy

While FDA's general enforcement discretion approach has been focused on LDTs,[18] FDA has determined to apply a broader scope for the phaseout policy, consistent with FDA's proposal in the NPRM (88 FR 68006 at 68021).[19] Specifically, the phaseout policy applies to IVDs that are *manufactured and offered* as LDTs by laboratories that are certified under CLIA and that meet the regulatory requirements under CLIA to perform high complexity testing, and used within such laboratories,[20] even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory. Throughout this preamble, these IVDs are referred to as ''IVDs offered as LDTs.'' [21] FDA is adopting this scope because it recognizes that not all laboratories have understood the limited nature of FDA's general enforcement discretion approach and have been offering IVDs based on the approach even when those IVDs do not fit what FDA generally considers to be an LDT. FDA has determined that this

[18] As discussed elsewhere in this preamble, FDA has generally considered the term ''laboratory developed test (LDT)'' to mean an IVD that is intended for clinical use and that is designed, manufactured, and used within a single CLIA-certified laboratory that meets the regulatory requirements under CLIA to perform high complexity testing.

[19] However, certain enforcement discretion policies described in sections V.B and V.C apply only to LDTs.

[20] Other laboratories would be out of compliance with CLIA regulations if they were developing and performing tests that are not FDA authorized. Such tests have never fallen within FDA's general enforcement discretion approach (see, *e.g.,* Refs. 25–27).

[21] We note that ''IVDs offered as LDTs'' does not include IVDs manufactured or used *outside* of a laboratory, including collection devices. FDA's statements and actions have shown that the Agency has expected compliance where, for example, CLIA is inapplicable (*e.g.,* manufacturing outside of a laboratory and collection devices). *See, e.g.,* 61 FR 10484 (''*in-house* developed tests have not been actively regulated by the Agency'') (emphasis added); Ref. 23 (describing an LDT as an IVD that is ''designed, manufactured, and *used* within a single laboratory'') (emphasis added); *United States* v. *Undetermined No. of Unlabeled Cases,* 21 F.3d 1026 (10th Cir. 1994) (FDA enforcement action against a laboratory that ''purchased specimen containers, repackaged them into kits which included instruction sheets, and forwarded them along with consent forms to insurers to collect specimens''); Ref. 28 (compliance action regarding a blood lead testing system manufactured outside of a laboratory but for use by a laboratory); Ref. 29 (compliance action involving a laboratory and a sample collection kit).

approach will help facilitate uniform compliance going forward.

2. IVDs Outside the Scope of the Phaseout Policy

Although FDA is adopting a broader scope for the phaseout policy, it does not intend to sweep in certain IVDs that were excluded from the general enforcement discretion approach, as reflected in compliance patterns, multiple public FDA actions and communications, or both. In particular, the general enforcement discretion approach has never applied to the following tests:

a. Tests that are intended as blood donor screening or human cells, tissues, and cellular and tissue-based products (HCT/P) donor screening tests required for infectious disease testing under § 610.40 (21 CFR 610.40) and § 1271.80(c) (21 CFR 1271.80(c)), respectively, or required for determination of blood group and Rh factors under § 640.5 (21 CFR 640.5). Under the cited regulations, a blood or HCT/P establishment must not use a test for the purposes listed here unless the test is authorized by FDA for such use. Blood and HCT/P establishments must register with FDA and are subject to FDA inspection (see parts 207, 607, 807, and 1271 (21 CFR parts 207, 607, 807, and 1271)). FDA's general enforcement discretion approach for LDTs has never applied to these tests because these tests are a critical part of the overall process of ensuring the safety of blood and blood components and HCT/Ps by preventing infectious disease transmission and incompatible blood transfusions which can have life-threatening consequences (see, *e.g.,* Refs. 30 and 31). Based on FDA experience, establishments have been generally complying with the requirements to use authorized tests under §§ 1271.80(c), 610.40, and 640.5. FDA addresses comments related, in part, to this category of tests in sections VI.L.14 and VI.L.15.

b. Tests intended for emergencies, potential emergencies, or material threats declared under section 564 of the FD&C Act. After all previous declarations under section 564(b), FDA has generally expected LDTs to comply with applicable requirements in the FD&C Act and FDA regulations. FDA's general enforcement discretion approach has not applied to these tests because of the significant risk posed by the disease (as signified by the unusual step of issuing a declaration) and because false results can have serious implications for disease progression and public health decision-making, in addition to the individual patient's care. As it has done in other areas, FDA has adopted (and may continue to adopt) specific enforcement discretion policies for such tests (see, *e.g.,* Refs. 32 and 33). In addition, consistent with the Government Accountability Office (GAO)'s 2022 recommendation that ''FDA should develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies'' (Ref. 34), FDA is issuing a draft guidance document, concurrent with this final rule, on factors to consider in adopting such enforcement discretion policies. FDA has communicated its expectations regarding tests for emergency use in final guidance and elsewhere, including ''It has come to our attention'' letters posted on FDA's website and other public communications (see, *e.g.,* Refs. 27, 32 to 37). FDA addresses comments related, in part, to this category of tests in section VI.L.10.

c. Direct-to-consumer tests. FDA's general enforcement discretion approach has not applied to tests intended for consumer use (without meaningful involvement by a licensed healthcare professional), given the greater risks to patients presented by these tests (see, *e.g.,* Refs. 28 and 39 to 44). FDA's enforcement discretion approach for LDTs was originally premised, in part, on the participation of medical professionals to help determine whether a particular test was appropriate, counsel patients on the significance and limitations of a test, assist in interpreting results, assess how the results fit in the overall clinical picture, and consider next steps. When patients order tests, receive results, or make decisions (such as a decision to stop medication) without this expert intermediary, there is a heightened need for FDA oversight. FDA addresses comments related, in part, to this category of tests in section VI.L.1.

For these categories of tests, FDA has generally expected applicable requirements to be met, and we are not changing that approach with the phaseout policy. FDA intends to continue to enforce all applicable requirements for these categories of tests. Neither the phaseout policy nor any subsidiary enforcement discretion policies described in sections V.B and V.C apply to these tests.

Finally, as further discussed in the NPRM, tests manufactured and offered for use exclusively for public health surveillance are distinct from other tests where: (1) they are intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control and (2) test results are not reported to patients or their healthcare providers (88 FR 68006 at 68023). The results of these tests are generally used for trending on a population basis or public health outbreaks, where the test results are not intended for clinical decision making. FDA received several comments on these tests (see section VI.L.6), and for the reasons discussed in the NPRM (88 FR 68006 at 68023) and in our responses to those comments, we continue to believe that these tests should not be affected by the phaseout policy.[22]

B. Enforcement Discretion Policies

FDA is phasing out the general enforcement discretion approach for LDTs so that IVDs manufactured by laboratories will generally fall under the same enforcement approach as other IVDs. For certain IVDs, however, FDA intends to exercise enforcement discretion and generally not enforce all or some applicable requirements, for the reasons discussed further below. Specifically, and as described further in section V.B.1, FDA intends to exercise enforcement discretion and generally not enforce all applicable requirements for 1976-Type LDTs, certain HLA tests, tests intended solely for forensic (law enforcement) purposes, and LDTs manufactured and performed within DoD or VHA. As described further in section V.B.2, FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs that are approved by NYS CLEP. In addition, and as described further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system, currently marketed IVDs offered as LDTs, and certain non-molecular antisera LDTs for rare RBC antigens.

As noted above, these policies do not apply to the tests described in section V.A.2. Moreover, in an emergent situation (see additional discussion of this time period below), these policies do not apply to tests that are: (1) intended to detect or diagnose a serious or life-threatening disease or condition that may be attributed to a newly identified, previously unknown, or

[22] Surveillance tests are not used for individual decision-making. Screening tests are distinct from public health surveillance tests and do fall within the phaseout policy.

unusual CBRN agent or agents; or a known agent or agents that results in a newly identified or unusual clinical presentation of such a disease or condition; and (2) needed for immediate response to a potential case or cases of such disease or condition for which there is no adequate, authorized, and available alternative. FDA is proposing a separate enforcement policy for some such tests in a concurrently issued draft guidance entitled ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' As discussed in that draft guidance, that proposed enforcement policy would be for tests that are intended to help ensure the government's coordinated and effective public health response and so is limited to certain tests and certain laboratories, such as those that are U.S. Government (USG) laboratories, State or local public health laboratories, or other laboratories that have agreements with the USG.[23] FDA believes that the proposed policy in that draft guidance (and not the enforcement discretion policies described in section V.B of this preamble) would be appropriate for such tests during the limited time period described in the draft guidance—specifically, during an emergent situation.[24] We note that prior to an emergent situation and after an emergent situation has been resolved, when there is not a critical need for a coordinated and immediate public health response and where the implications of false results may not have as serious implications for public health decision-making, such tests may fall within the enforcement discretion policies described in section V.B of this preamble.

As with any enforcement discretion policy, FDA may update any of these policies as circumstances warrant or if the circumstances that inform these policies change, consistent with FDA's good guidance practices (21 U.S.C. 371(h), § 10.115). Notably, these enforcement discretion policies do not confer lawful marketing status on any IVD being marketed as described in the policies. These policies do not in any way alter the fact that it is illegal to market an IVD that lacks required premarket authorization or is otherwise in violation of the FD&C Act, the PHS Act, or FDA regulations. These policies set forth FDA's general priorities and, consistent with FDA's public health mission, FDA intends to take action to enforce applicable requirements for IVDs (including IVDs described in these policies) as appropriate, taking into account any public health concerns as evaluated on a case-by-case basis.[25] For example, if FDA receives reports, or otherwise learns of information, that raise safety or effectiveness concerns with an IVD that falls within an enforcement discretion policy, FDA generally intends to take action with respect to requirements applicable to that specific IVD.

1. Enforcement Discretion Policies With Respect to All FDA Requirements

For several categories of tests, FDA intends to continue the general enforcement discretion approach and generally not enforce any applicable requirement because tests in these categories are, in our experience, unlikely to pose significant risks or are conducted in circumstances that themselves will mitigate the risks. One such category of tests is referred to in this preamble as ''1976-Type LDTs.'' Such tests have the following characteristics common among LDTs offered in 1976: (1) use of manual techniques (without automation) performed by laboratory personnel with specialized expertise; (2) use of components legally marketed for clinical use; and (3) design, manufacture, and use within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing. The characteristics associated with LDTs offered in 1976 resulted in the emergence of FDA's general enforcement discretion approach for LDTs, and the specific characteristics listed above provide the greatest risk mitigation among the characteristics that were commonly associated with LDTs offered in 1976 (discussed in section III). Based on changes to the LDT landscape since 1976, the risks associated with most modern LDTs are generally much greater today than they were in 1976; however, for tests that share the characteristics listed above, FDA has determined that the risks are sufficiently low such that FDA's general enforcement discretion approach for LDTs should continue to apply (see section VI.L.3 for a discussion of the comments on this topic and FDA's responses to those comments). These tests might include, for example, immunohistochemistry tests that involve no automated preparation or interpretation, but would not include, for example, lateral flow tests, as they do not generally rely on laboratory personnel expertise. This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B. FDA intends to consider whether guidance containing additional discussion and examples of tests that may fall within this category would be helpful, and would issue any such guidance in accordance with good guidance practices (see § 10.115).

Another category of such tests is HLA tests that are designed, manufactured, and used within a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and ''virtual'' HLA crossmatch tests (hereinafter ''HLA tests for transplantation''). Physicians must often make prompt decisions about transplantation based on medical judgment regarding their patient's condition and degree of mismatch between the donor and patient should an organ, stem cells, or tissue become available. Because new alleles are continuously identified, and the need for assessing degree of crossmatch is generally urgent, modifications to HLA tests for transplantation are often made rapidly in response to urgent situations. Further, these tests are often individualized within each medical facility; for example, they include reagents that reflect local HLA polymorphisms and patient demographics.

In addition, oversight under certain Federal programs helps to mitigate the risks of harm from inaccurate and unreliable HLA tests for transplantation. For example, the National Organ Transplant Act (NOTA) of 1984 created the Organ Procurement and Transplant Network (OPTN). NOTA, as amended (42 U.S.C. 273 *et seq.*), and the OPTN

[23] For tests that meet the description included at the beginning of this paragraph but that would not otherwise fall within the proposed policy described in the draft guidance because, for example, they are manufactured by entities that fall outside the scope of the draft guidance, FDA is not proposing an enforcement discretion policy in the draft guidance. For such tests, FDA generally will expect compliance with applicable FDA requirements in line with the phaseout policy during an emergent situation, and outside of an emergent situation, these tests could potentially fall within an enforcement discretion policy described in section V.B. of this preamble.

[24] Prior to finalization of that draft guidance, FDA intends to act consistent with the relevant policies for LDTs included in this final rule and will consider whether to update any policies herein as a result of any changes to the proposed enforcement policy described in the draft guidance, when finalized.

[25] *See Heckler* v. *Chaney,* 470 U.S. 821, 835 (1985) (providing that the FD&C Act's enforcement provisions commit broad discretion to the Secretary to decide how and when they should be exercised).

Final Rule, 42 CFR part 121, establish a comprehensive system for the safe and equitable allocation, distribution, and transplantation of donated organs. The OPTN Final Rule and OPTN bylaws and policies govern operation of all member transplant hospitals, organ procurement organizations, and histocompatibility laboratories in the United States. The Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129), as amended, authorizes a national registry (''Be the Match Registry'') to support patients in need of bone marrow or umbilical cord blood transplants, which is operated under Federal contracts by the National Marrow Donor Program® (NMDP) (Ref. 45). NMDP sets forth minimum requirements for organizations working through the NMDP to facilitate stem cell transplants (Refs. 46 and 47).

OPTN has requirements for performance of HLA typing, antibody screening, and crossmatching tests, and NMDP requires HLA typing for donors and potential recipients for stem cell transplants facilitated by the Be the Match Registry, as well as reporting of test results to NMDP (Refs. 47 and 48). Both OPTN and NMDP have procedures in place for identifying, investigating, and reporting discrepant tests results (Refs. 48 and 49).

In addition to these safeguards designed to identify and resolve potentially inaccurate results, each OPTN member histocompatibility laboratory must, among other things, meet specified American Society for Histocompatibility and Immunogenetics (ASHI) and/or College of American Pathologists (CAP) standards as a condition of OPTN membership (Ref. 50). NMDP similarly requires histocompatibility laboratories used by U.S. transplant centers and donor centers to be accredited by CAP and/or ASHI (Refs. 46, 51 and 52). Both ASHI and CAP standards have provisions that specifically address OPTN and/or NMDP requirements for histocompatibility laboratories that perform tests for those programs. Importantly, as discussed below, FDA does not believe that a CAP or ASHI accreditation of a laboratory, on its own, is sufficient to mitigate risk and provide assurance of the safety and effectiveness for all IVDs offered as LDTs by the accredited laboratory. However, we consider the fact that OPTN and NMDP require adherence to CAP and/or ASHI standards, including provisions specific to OPTN and NMDP requirements, to be one factor that helps mitigate risk of inaccurate results or unreliable HLA tests for transplantation. After considering this factor in combination with the protections provided through the programs described above and the urgent circumstances in which HLA tests for transplantation may be modified and performed, as well as the comments received on our proposed approach to HLA tests for transplantation, FDA intends to continue the general enforcement discretion approach for these tests. We note that this enforcement discretion policy does not apply to HLA tests used for blood transfusion, which are highly standardized across institutions, nor does it apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

An additional category of such tests is tests intended solely for forensic (law enforcement) purposes. FDA has had an enforcement discretion approach for such tests for over 20 years and that approach applies to such tests regardless of whether they are offered as an LDT. *See, e.g.,* 65 FR 18230, April 7, 2000. Tests used in the law enforcement setting are subject to protections and requirements associated with the judicial process that mitigate risk related to test accuracy and sample collection and that generally are not available in the home, workplace, insurance, and sports settings. These protections include the use of rules of evidence in judicial proceedings and legal representation of the accused (*i.e.,* the person being tested) through the judicial process during which the accuracy of the test may be raised during the adjudication. This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

A final category of such tests is LDTs [26] manufactured and performed within DoD or VHA. This policy applies only to LDTs used for patients that are being tested and treated within the DoD or VHA. In the NPRM, FDA sought comment on whether it would be appropriate to continue the general enforcement discretion approach, such that FDA generally would not enforce any applicable device requirements, ''where outside programs can be leveraged'' (88 FR 68006 at 68024). FDA mentioned programs within VHA as an example, and we received several comments stating that FDA should continue the general enforcement discretion approach for LDTs manufactured and performed by VHA, generally on the grounds that it would avoid ''duplicating regulatory oversight regimes'' and promote the efficient use of resources. Two comments suggested that FDA should not continue the general enforcement discretion approach for LDTs manufactured and performed by VHA because VHA's program is not in alignment with FDA regulation (though one of these comments supported ''leveraging'' outside programs ''in principle''). FDA received one comment, submitted by DoD, which stated that FDA should maintain an enforcement discretion approach for LDTs ''utilized by DoD for our service members.'' Among other things, DoD emphasized ''the importance of LDTs to DoD's operational readiness and mission success,'' and referenced DoD's internal programs, including ''the authority, oversight, and responsibilities vested in the Assistant Secretary of Defense (Health Affairs).''

FDA recognizes that DoD and VHA have statutory mandates under 10 U.S.C. chapter 55 and 38 U.S.C. chapter 73 to provide for the care of specific populations in their systems and have existing oversight and enforcement groups within their respective systems. Based on consultation with DoD and VHA, FDA understands that both departments use and will continue to use FDA-authorized IVDs wherever available. However, to meet the needs of their patient populations (*i.e.,* military personnel, veterans, and their families) and fulfill their mandates, DoD and VHA often manufacture unique LDTs, such as tests for diseases or chemicals to which their patients may be exposed while serving abroad but which do not exist at home. DoD and VHA have developed expertise for evaluating these unique tests, and are taking steps in consultation with FDA to track all LDTs in their systems and to ensure the analytical and clinical validity of their LDTs, the quality manufacturing of their LDTs, and the central reporting of adverse events.[27] Additional oversight by FDA would not be an efficient use of government resources in these circumstances.

This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

[26] Consistent with what FDA has generally considered to be an LDT (as discussed elsewhere in this preamble), this enforcement discretion policy applies only to tests that are designed, manufactured, and used within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing.

[27] To the extent that VHA and DoD anticipate the need for additional resources, FDA understands that such matters will be addressed through the management of those departments.

2. Enforcement Discretion Policies With Respect to Premarket Review Requirements

FDA also generally intends to exercise enforcement discretion with respect to premarket review requirements for LDTs [28] that are approved by NYS CLEP.[29] For these LDTs, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements given certain risk mitigations under NYS CLEP as discussed further below. This policy applies only to the approved version of the test (FDA is aware that some laboratories may offer different versions of an LDT depending on whether a patient specimen comes from NYS or from elsewhere). This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

FDA intends to phase out the general enforcement discretion approach with respect to other applicable requirements for these tests consistent with the stages described in section V.C below. In brief, for these tests, FDA intends at stage 1 to phase out the general enforcement discretion approach with respect to MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files) 1 year after publication of this final rule; at stage 2 to phase out the general enforcement discretion approach with respect to requirements not addressed in the other stages (these requirements include, *e.g.,* registration and listing requirements and labeling requirements) 2 years after publication of this final rule; and at stage 3 to phase out the general enforcement discretion approach with respect to certain QS requirements (see below for further discussion) 3 years after publication of this final rule. See section V.C for further information.

As noted above, in the NPRM, FDA sought comment on whether it would be appropriate to continue the general enforcement discretion approach with respect to LDTs that are under NYS CLEP or certain other programs (88 FR 68006 at 68024), and we received several comments in response (see discussion in section VI.F.5 of this preamble). This policy reflects consideration of those comments. Should experience with this policy indicate that changes are warranted, FDA would consider appropriate policy changes through guidance in accordance with good guidance practices (see § 10.115).

FDA believes that NYS CLEP has a program that provides for certain mitigations that help reduce the risk of harm from inaccurate and unreliable LDTs. Specifically, as discussed further below, NYS CLEP has a program under which high risk and moderate risk LDTs generally are evaluated for analytical and clinical validity. Based on the available information, FDA believes that generally NYS CLEP's review of analytical and clinical validity of LDTs helps to mitigate the risk of harm from inaccurate and unreliable LDTs and that, rather than enforcing premarket review requirements by FDA, it would be more efficient and effective to use our resources for other oversight activities regarding IVDs offered as LDTs.

Under NYS CLEP's program, high risk LDTs require full technical review and approval prior to testing on specimens from NYS (Ref. 53). Moderate risk LDTs require full technical review but may receive conditional approval if the laboratory holds a permit in the appropriate category (Ref. 53). For classification as a moderate risk LDT under NYS CLEP, certain criteria must be met, *e.g.,* the LDT uses well-established methodology (as defined by NYS CLEP, this includes, among other things, the laboratory having demonstrated competence for development of LDTs of the same or similar technology through multiple prior high-quality submissions) (Ref. 53). Upon notification of a moderate risk classification and conditional approval, the laboratory may offer the test (Ref. 53). Once the full technical review has been completed, the moderate risk LDT may receive approval (Ref. 53). For additional information, see NYS CLEP's Tiered Evaluation of Laboratory Developed Tests Policy (Ref. 53).

In its enforcement discretion policy with respect to premarket review requirements, FDA is including not just those moderate risk LDTs that receive full approval by NYS CLEP but also those that receive conditional approval by that agency. For LDTs receiving conditional approval, full technical review is pending and these tests may receive approval by NYS CLEP once their review has been completed. FDA does not intend to use its resources to enforce premarket review requirements for these LDTs that are under review by NYS CLEP and may eventually receive approval. However, if an LDT has its conditional approval withdrawn by NYS (*e.g.,* because approval is denied after NYS CLEP completes the full technical review), the LDT would no longer be under this enforcement discretion policy as it would neither have conditional approval nor full approval.[30]

For purposes of full technical review (as mentioned above, this applies to high risk and moderate risk LDTs), NYS CLEP requires the submission of detailed information as specified in the applicable checklist (either the general checklist or test-specific checklist) (Ref. 24). For example, under the general checklist, laboratories must submit, among other things, a description of the test target, data supporting analytical validity, data supporting clinical validity, sample test reports, standard operating procedures, and other information regarding the subject test (Ref. 54). Additionally, laboratories must submit a ''Risk Attestation Form for Laboratory Developed Tests'' containing additional information about the test, including a summary of intended use (including target population, methodology and technology, specimen types, and whether the intend use makes claims or direct reference to recognized diseases/conditions), whether the laboratory has full approval of other LDTs using the same test method that is used for the proposed new test, whether the methodology is well-established in the laboratory and generally accepted by the field, evidence of clinical validity, and information regarding the potential impact of an inaccurate test result (Ref. 55).

NYS CLEP also has a process for laboratories to request an exemption from full technical documentation. As described on NYS CLEP's website, ''[o]nce acceptable method validation performance has been demonstrated by the NYS approval of a representative sampling of tests that utilize a

[28] Consistent with what FDA has generally considered to be an LDT (as discussed elsewhere in this preamble), this enforcement discretion policy applies only to tests that are designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing.

[29] As noted elsewhere in this preamble, for purposes of this preamble FDA uses the phrase ''LDTs approved by NYS CLEP'' to refer to LDTs that are approved, conditionally approved, or within an approved exemption from full technical documentation, under NYS CLEP. These three categories of LDTs are discussed further below in this section (section V.B.2). Other LDTs, including ''LDTs used in Clinical Trials'' and ''Tests Not Subject to Evaluation'' which are described on NYS CLEP's website (Ref. 24), are not considered ''LDTs approved by NYS CLEP'' and are not within the enforcement discretion policy with respect to premarket review requirements described in this section.

[30] Although not relevant to our decision-making with respect to our policy regarding LDTs approved by NYS CLEP, it is our understanding, based on consultation with NYS CLEP, that withdrawal of conditional approval due to approval being denied after NYS CLEP completes the full technical review is a rare occurrence.

methodology that is common across many analytes/targets, the laboratory may request an exemption from the requirement to submit full method validation documentation for future test/assays that utilize the same methodology'' (Ref. 24). An application for an exemption from full technical documentation must include: a written request for an exemption that identifies ''the previously submitted tests to be used as the predicate submissions for the exemption''; ''a standardized protocol for method validation to include a description of the laboratory's principles and practices for assay development and initial validation''; and ''laboratory-specific protocols for on-going validation, including quality control procedures and quality assurance indicators'' (Ref. 24). If an exemption is approved, then a streamlined process applies to new LDTs with the same methodology under the exemption. For such new LDTs, certain information must be provided, including data on analytical and clinical validity, but this can be provided in summary form (see the Add Under Exemption Form available on NYS CLEP's website, Ref. 24). The summary of the validation studies performed must address how analytical and clinical performance characteristics were established (see the Add Under Exemption Form available on NYS CLEP's website, Ref. 24). Additionally, for such new LDTs, laboratories must submit sample reports for all applicable findings (see the Add Under Exemption Form available on NYS CLEP's website, Ref. 24), a ''Risk Attestation Form for Laboratory Developed Tests'' containing additional information about the test, including information regarding the potential impact of an inaccurate test result (Ref. 55), and certain other information if applicable (Ref. 24). Although specific approval of new LDTs added under an approved exemption is not required, it is our understanding that NYS CLEP reviews the information submitted for these LDTs. Further, NYS CLEP reserves the right to rescind an exemption at any time (Ref. 24). Because NYS CLEP reviews the analytical and clinical validity of LDTs that are added under an approved exemption and may rescind an exemption at any time, FDA is including such LDTs within the enforcement discretion policy with respect to LDTs approved by NYS CLEP.

Based on the available information as discussed above, FDA believes that generally NYS CLEP's review of analytical and clinical validity of LDTs helps to mitigate the risk of harm from inaccurate and unreliable LDTs. First, NYS CLEP reviews much of the same information that FDA reviews in assessing analytical and clinical validity (*e.g.,* data supporting analytical validity, data supporting clinical validity, sample test reports, and standard operating procedures). For example, in comments submitted to the docket for this rulemaking, NYS CLEP explained, ''Applications must include validation data throughout the reportable range, particularly at or near the limit of detection, and for intended specimen types, specimen stability range, clinical indications, and target populations (pediatric vs adult, symptomatic vs asymptomatic, varied ethnicities, etc.).'' Second, NYS CLEP is identifying many of the same types of issues that FDA has identified with LDTs. In their comments, NYS CLEP provided a detailed description of the issues they have identified when reviewing LDT applications. For example, NYS CLEP noted that more than half of the LDTs submitted for their review cannot be approved based on the original application. For such applications, NYS CLEP requests additional information, sometimes multiple times, to address a range of issues, including ''design flaws, inadequate validation data, and process problems that call into the question the reliability of the results.'' These are the same types of issues FDA has observed in the review of emergency use authorization (EUA) requests from laboratories for molecular tests for COVID–19 (see Ref. 18) and in other premarket submissions for LDTs (see Ref. 16). Additionally, FDA collaborated with NYS CLEP in the review of the first authorized tumor profiling test and found substantial alignment in FDA's and NYS CLEP's assessments of the analytical and clinical validity of this LDT for tumor profiling. FDA has also accredited NYS CLEP as a Third Party Review Organization accredited under FDA's Third Party review program (3P510K Review Organization) qualified to conduct reviews of 510(k)s for certain IVDs. Accreditation of 3P510K Review Organizations is based on many factors, including qualification of staff in the scientific disciplines relevant to the review of the specific device types that the 3P510K Review Organization intends to review (Ref. 56). In the case of IVDs, the 3P510K Review Organization must be qualified to assess the analytical and clinical validity of tests which NYS CLEP was able to demonstrate.

Exercising enforcement discretion with respect to the premarket review requirements for LDTs approved by NYS CLEP will facilitate more efficient use of FDA resources. The resources that FDA would otherwise spend on premarket review of such LDTs can instead be focused on premarket review of other IVDs offered as LDTs and enforcement of other applicable requirements. FDA estimates that 12.1 percent of IVDs offered as LDTs would not experience new costs associated with submission preparation and review as a result of the enforcement discretion policy with respect to LDTs approved by NYS CLEP, as discussed in appendix A of the FRIA (Ref. 10).

As mentioned above, FDA intends to phase out the general enforcement discretion approach with respect to other applicable requirements for LDTs approved by NYS CLEP, consistent with the stages described below in section V.C. Enforcement of other requirements will help to protect and promote the public health, *e.g.,* by providing FDA and the public with important information about these tests. For example, compliance with registration and listing requirements will provide FDA and the public with basic information on these LDTs, and compliance with MDR requirements will provide FDA and the public with adverse event information about these LDTs. Further, under § 807.26(e) (21 CFR 807.26(e)) (additional device listing information), FDA intends to request the labeling for these LDTs, which will provide information on test performance and a summary of the supporting validation, among other things.[31] Additionally, compliance with labeling requirements, including those in § 809.10(b)(12), will help to ensure that healthcare providers and patients have information on test performance, among other things, and thus enable more informed decision making. The labeling information and adverse event reports will help FDA identify LDTs that raise concerns, *e.g.,* concerns regarding insufficient validation or inaccurate

[31] Devices licensed under section 351 of the PHS Act register and list pursuant to part 607 (21 CFR 607.1 and 807.20(e)), which does not contain a provision identical to 21 CFR 807.26(e). Most licensed IVDs are tests intended for use as blood donor screening tests or HCT/P donor screening tests subject to § 610.40 and 1271.80(c), respectively, or tests for determination of blood group and Rh factors subject to § 640.5. As explained in the NPRM (88 FR 68006 at 68021), FDA's general enforcement discretion approach for LDTs has never applied to such tests. Therefore, we anticipate that there would be a limited number of IVDs subject to the registration and listing requirements in part 607 that would fall within this policy or other policies for which FDA intends to request laboratories to provide labeling information in connection with listing the device. Should FDA receive listing information under part 607 for an IVD that is not licensed, we will consider if any additional action is appropriate, including with respect to information regarding IVD performance.

results. Compliance with the QS requirements that FDA intends to enforce for these LDTs will help provide for quality manufacturing of these tests. As discussed in section V.C, for LDTs, FDA generally will expect compliance at the 3-year mark with some, but not all, of the QS requirements (specifically, design controls, purchasing controls, acceptance activities, corrective and preventive actions (CAPA), and records requirements). This includes for LDTs approved by NYS CLEP. However, it is our understanding, based on consultation with NYS CLEP, that compliance with NYS CLEP's clinical laboratory standards (which exceed CLIA requirements in certain respects) and its premarket review requirements collectively could generally satisfy these subparts of the QSR except as to certain aspects of design control documentation. Therefore, although not relevant to our decision-making with respect to our policy regarding LDTs approved by NYS CLEP, FDA does not anticipate significant additional burden with respect to compliance with these QS requirements for laboratories offering LDTs approved by NYS CLEP.

Finally, as noted elsewhere in this preamble, regardless of this or any other enforcement discretion policy, FDA retains discretion to pursue enforcement action at any time against violative IVDs when appropriate. We intend to carefully monitor tests falling within this policy and to take action when appropriate to protect the public health.

3. Enforcement Discretion Policies With Respect to Premarket Review and Certain QS Requirements

FDA also intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for three categories of IVDs. These enforcement discretion policies have been added to the final phaseout policy after consideration of comments received on the NPRM.

First, for the reasons discussed further below, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) [32] for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

In the NPRM, FDA discussed LDTs for unmet needs, stating that a specific enforcement discretion policy for such LDTs was not included in the proposed phaseout policy because we anticipated that programs currently in place (*e.g.,* the Humanitarian Use Devices (HUD)/HDE program and the Breakthrough Devices program) may facilitate the development and premarket authorization of IVDs for unmet needs.[33] *See* 88 FR 68006 at 68026. We received over 100 comments addressing whether FDA should adopt a specific enforcement discretion policy for LDTs for unmet needs (see section VI.L.5). In particular, we received numerous comments that asserted that the perceived burden of premarket review and QS requirements would lead laboratories to stop developing such LDTs, leaving patients without access to the LDTs they need. For this reason, many comments recommended that FDA adopt an enforcement discretion policy for LDTs for unmet needs. Two public interest groups recommended against adopting a separate policy for LDTs for unmet needs for various reasons, including so that LDTs for patients with unmet needs would have the same assurances of safety and effectiveness as LDTs for other patients. Stakeholders further commented that the existing HUD/HDE and Breakthrough Devices programs are insufficient to mitigate the perceived burden that laboratories face with respect to development of LDTs for unmet needs. Specifically, commenters noted the numerical limit of 8,000 tests nationwide per year is too restrictive, the requirements for use of tests under HDE (*e.g.,* institutional review board approval) dissuade physicians from using them, and the program has only been used for 6 IVDs despite existing for over 30 years. We also received information in comments indicating that laboratories integrated within healthcare systems, including AMCs, often make tests to meet the unique needs of their patients, and that patients may be referred to those systems because of their ability to meet patient needs that cannot be met elsewhere. The comments stated that this is often the case for patients with rare diseases for which the market is so small that there is no financial incentive for non-laboratory manufacturers to meet their needs and for which collecting data to validate a test is particularly challenging due to small patient populations (for example, rare immunohematology problems, Huntington disease, Prader-Willi/Angelman syndrome, and genetic tests for certain cancers).

With respect to AMCs in particular, the Agency sought comment in the NPRM on whether FDA should have a different enforcement policy for tests manufactured by AMC laboratories. *See* 88 FR 68006 at 68023–24. We asked about various aspects of such a policy, including whether any continued enforcement discretion policy should take into account ''whether an FDA cleared or approved test is available for the same intended use as the test manufactured by an AMC laboratory,'' and the public health rationale for how integration of a laboratory into patient care might support a different approach for tests manufactured by AMC laboratories. *Id.* at 68024. We received over 100 comments addressing whether FDA should adopt a specific enforcement discretion policy for tests offered by AMC laboratories and/or other laboratories integrated within healthcare systems (see section VI.F.4 of this preamble). Many of the comments we received addressing whether FDA should adopt a specific enforcement discretion policy for LDTs for unmet needs addressed LDTs for unmet needs manufactured by AMC laboratories/other laboratories integrated within healthcare systems. These comments were from patients, healthcare providers, AMCs, other healthcare systems, and various entities representing such groups.

The majority of comments recommended that FDA adopt an enforcement discretion policy specific to tests manufactured by AMC laboratories given risk mitigations provided by the integration of the laboratory within the AMC that is providing care to the patient. Many comments stated that because other laboratories are similarly integrated within healthcare systems, any such enforcement discretion policy should not be limited to AMC laboratories. Many of these comments emphasized the built-in communication mechanisms between the laboratory and AMC/other healthcare system within which the laboratory is integrated. For example:

- ''[T]he close connection between the clinical pathologists developing the tests and the care providers at AMCs

[32] As noted in footnote 17, for the categories of IVDs discussed in section V.B.3, FDA generally expects compliance with requirements under part 820, subpart M (Records) but not §§ 820.20, 820.22, 820.40, and 820.50 (which are cross-referenced in subpart M), or comparable provisions of ISO 13485 in accordance with the amendments to part 820 once that rule takes effect in February 2026.

[33] As described in the NPRM, FDA considered a possible premarket-review approach specific to LDTs for unmet needs in the ''Discussion Paper on Laboratory Developed Tests (LDTs)'' issued by the Agency on January 13, 2017 (2017 Discussion Paper) (Ref. 57) (88 FR 68006 at 68026).

further validates the alignment between diagnostic results and clinical presentation and helps to provide real-time feedback to the LDT developers on test performance and outcomes.''

- ''As hospital-based labs, we are integrated into patient care within the healthcare system. Treating clinicians will contact us directly when tests don't make sense and we adjust our testing strategies if needed. I personally get around 3–10 questions per week from clinicians as a laboratory medical director. At AMCs, while we implement LDTs we seek information and feedback from our clinical colleagues . . . . This direct connection and information flow allows for quality control and real-time communication if a test is not performing as expected.''
- ''As a CLIA director of a hospital-based lab, I occasionally see patients with specimens that were sent to our laboratory as well as an off-site, disconnected reference lab for the same test at nearly the same time. The results are often not consistent. I am able to investigate further by getting a new specimen and communicating with the clinician about the patients' signs, symptoms, and radiology results. I review our other test results, including some of our other LDTs. The reference labs are often not aware of the issues because they do not have the same line of communication and access to the electronic health record. They continue to offer the same test with no knowledge of the problem.''
- ''There is a direct connection or ability to directly connect between the laboratory provider/director and the treating clinician, and laboratory professionals have access to patient electronic medical records, details of which often inform the nuance of laboratory testing that is managed locally. This direct connection and information flow allows for quality control that cannot be engendered by an off-site, disconnected reference lab model for testing and allows for issues associated with any particular testing modality to be identified; thus it provides quality control at both the patient and assay level.''

Several comments recommended against a separate enforcement discretion policy for tests manufactured by AMC laboratories, including because they argued that AMC laboratory tests have the same problems as other IVDs (which FDA acknowledged in the context of the COVID–19 pandemic) and having the same enforcement policies for these tests as for other tests will level the playing field and promote the development of new and improved tests.

As an initial matter, we understand that laboratories that develop LDTs for unmet needs, often laboratories integrated within a healthcare system, may be more likely to stop developing many of these LDTs for unmet needs if the proposed phaseout policy were finalized. The cost of compliance with premarket review and QS requirements may be deemed too high given the limited market for many of these LDTs for unmet needs, and so laboratories may not have financial incentives to develop these types of LDTs in particular (for example, FDA's primary estimates anticipate the cost per premarket submission to range from approximately $250,000 to $4.5 million depending on the type of submission required, in addition to costs associated with QS requirements, annual reporting requirements (for PMAs) and applicable user fees, as described in sections II.F.3, II.F.4 and II.H of the FRIA (Ref. 10)). In their comments, various laboratories noted challenges and limitations associated with the HDE pathway that would dissuade them from seeking HDE approval for their LDTs. Specifically, commenters noted the numerical limit of 8,000 tests nationwide per year is too restrictive in that it applies to the cumulative testing volume of all patients who would be tested with a diagnostic device annually, and the requirements for use of tests under HDE (*e.g.,* administration of the test in a facility having oversight by an institutional review board, monitoring whether the national testing volume exceeds 8,000 patients per year, and limitations on profit, etc.) dissuade laboratories from developing such tests and submitting them for HDE approval. Although we think that the HDE pathway could help to facilitate the manufacture and premarket authorization of certain LDTs for unmet needs, based on these comments, we are concerned that many laboratories would stop manufacturing LDTs for unmet needs altogether, instead of seeking HDE approval for the LDTs, in light of the perceived financial costs of premarket review and QS requirements. Moreover, although we think that the Breakthrough Devices program would help to facilitate the premarket review process for LDTs for unmet needs, again based on the comments, we are concerned many laboratories would stop manufacturing LDTs for unmet needs altogether if they are expected to comply with premarket review and QS requirements.

As such, and upon further consideration, FDA has determined that a targeted enforcement discretion policy is appropriate to help avoid patients being deprived of critically needed LDTs where certain risk mitigations exist. Specifically, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA intends to phase out the general enforcement discretion approach for these LDTs with respect to all other applicable requirements consistent with the stages described in section V.C. Should experience with this policy indicate that changes are warranted, FDA would consider appropriate policy changes through guidance in accordance with good guidance practices (see § 10.115).

This policy is limited to LDTs for patients who are receiving care within the healthcare system within which the laboratory offering the LDT is integrated. FDA does not consider this to include patients that are being treated at an affiliated hospital with different corporate ownership than the laboratory. Where the laboratory and the treating physicians are in the same corporate entity, there is shared responsibility and potential liability for patient outcomes, which helps mitigate risk. Moreover, the policy is limited to LDTs that are ordered by a healthcare practitioner on the staff or with credentials and privileges at a facility owned and operated by the same healthcare system employing the laboratory director and performing the LDT. In these circumstances, FDA believes that the risk mitigations present help to address some of the concerns raised regarding problematic IVDs offered as LDTs discussed in the NPRM and this preamble.

For LDTs manufactured and performed by laboratories integrated within healthcare systems, FDA generally has greater confidence that ordering physicians will communicate any questions about LDTs or concerns regarding the safety and effectiveness of the LDT (*e.g.,* when the patient's symptoms point to another diagnosis; when subsequent test results contradict the original test result) to a laboratory given the built-in communication mechanisms present. Moreover, FDA generally has greater confidence that laboratories will communicate any limitations of the LDT or other relevant information to the ordering physician given these mechanisms. We think this is particularly likely to happen in the context of LDTs for unmet needs, which

are likely to be a focus of attention and communication between laboratorians and providers given the uncommon nature of the issues presented.

Communication from ordering physicians to laboratories may help laboratories to identify any problems with their LDT and make necessary adjustments, improvements, and other changes to the LDT. Although we acknowledge that any identification and subsequent modification of the LDT would happen postmarket, and thus would not prevent potentially problematic LDTs from ever being used, subsequent modification would benefit future patients and providers who are relying on the LDT. In addition, communication from laboratories to ordering physicians may help to underscore to the ordering physicians any limitations with the LDT and provide other relevant information to ordering physicians, for example that is specific to the unique needs of their patient, which in turn should help inform appropriate use and interpretation of the LDT.[34]

We believe that generally these features associated with integration of a laboratory within the healthcare system, along with enforcement of other applicable regulatory requirements as described in the phaseout policy (see section V.C), help to mitigate the risk of harm from inaccurate and unreliable LDTs. While we recognize that these features do not mitigate all risk and there may still be some uncertainty about the performance of LDTs that fall within this policy, we believe that these features support an enforcement discretion policy for premarket review and most QS requirements in the specific context of LDTs for unmet needs.

This policy is limited to LDTs for unmet needs. FDA considers an LDT to be for an unmet need where there is no available FDA-authorized IVD that meets the patient's needs. This may be because: (1) there is no FDA-authorized IVD for the disease or condition (for example, because it is for a rare disease or condition); (2) there is an FDA-authorized IVD for the disease or condition but it is not indicated for use on the patient, or a unique attribute needs to be added to the LDT to meet the patient's needs; or (3) there is an FDA-authorized IVD but it is not available to the patient. Examples of LDTs for unmet needs are:

- An LDT that is intended for cytogenetic analysis of certain genes and chromosomes associated with rare diseases or conditions, certain metals testing, viral load monitoring for some transplant-associated viruses, or diagnosis of certain mosquito- and tick-borne-diseases, where there is no FDA-authorized IVD for the disease/condition (*rare disease or condition*);
- An LDT to accommodate an alternative specimen type that is infrequently tested when the specimen type required for the FDA-authorized IVD is not and cannot be made available (*variation from the indications for use of an FDA-authorized IVD*);
- An LDT for use on pediatric patients when FDA-authorized IVDs are indicated for use on adults only (*variation from the indications for use of an FDA-authorized IVD*);
- An LDT that generates results in a significantly shorter period (*e.g.,* hours versus days) than an FDA-authorized IVD with the same indication where, due to the circumstances of the patient, the shorter time period to get results is critical for the clinical decision being made (*unique attribute needed to be added to an FDA-authorized IVD*);
- An LDT for the same indication as an FDA-authorized IVD that is offered only in another healthcare system that is not accessible to the patient and the developing laboratory will not make the IVD available outside its system (*FDA-authorized IVD is not available*); and
- An LDT for an emerging pathogen for which there is no FDA-authorized IVD and for which FDA has not identified an emergent situation (*no FDA-authorized IVD*).

In contrast, FDA does not consider an LDT to be for an unmet need when there is an available FDA-authorized IVD that would sufficiently meet the needs of the patient. For example, potential improvements in performance or lower cost in comparison to an FDA-authorized IVD that meets the patient's needs does not fall within this policy.

FDA intends this policy to be targeted. It is not intended to serve as an alternative ''pathway'' to market for LDTs for unmet needs. FDA intends to provide additional guidance on this enforcement discretion policy, which would be issued in accordance with good guidance practices (see § 10.115).

We note that if there is no longer an unmet need for an LDT because, for example, FDA authorizes an IVD that meets the needs of the patient, then the LDT would no longer fall within this enforcement discretion policy. This will encourage manufacturers, including the manufacturers of LDTs falling within this policy, to seek premarket authorization, without delaying patient access to the LDT. It also will provide patients and providers with greater confidence that once an IVD has been authorized by FDA, all similar devices, regardless of who makes them, should have appropriate assurance of safety and effectiveness because all such devices should comply with premarket review and QS requirements. Moreover, such a limitation helps to ensure that the enforcement discretion policy will ultimately target only those LDTs where there is insufficient financial incentive to seek authorization for the LDTs (in such cases, there is unlikely to ever be an available FDA-authorized IVD).

Notably, this unmet needs LDT policy applies only to LDTs that are validated. We acknowledge that validation may vary depending on many factors, including the accessibility of specimens and the number of affected patients. FDA intends to consider whether issuing additional guidance regarding validation of tests, including those for rare diseases that takes into consideration the challenges in obtaining a robust number of samples for validation, would be helpful.

In developing this policy, FDA took into consideration various factors that mitigate the risk that LDTs offered as described in this policy may not have appropriate assurance of safety and effectiveness. As an initial matter, the phaseout of the general enforcement discretion approach for all other applicable requirements will provide greater assurances regarding these LDTs than the Agency, healthcare providers, and patients currently have. Compliance with registration and listing requirements, for example, will provide FDA and the public with insight into what LDTs for unmet needs are being offered by laboratories integrated within healthcare systems. Moreover, compliance with labeling requirements, including those in § 809.10(b)(12), will help to ensure that healthcare providers and patients have information on the performance of the LDT and thus will help to enable more informed decision making. In addition, FDA generally intends to request that laboratories that offer LDTs as described in this policy submit labeling information to FDA in

[34] *See* Ref. 58 (''more aggressive laboratory involvement in [the interpretation and reporting] step may be necessary to ensure a more nearly perfect hit rate on proper interpretation and action after reporting of laboratory results''); *see also* Ref. 59. Shaw and Miller compared hospital laboratories and hospital-independent reference laboratories, and highlighted the following advantages, among others, of the former over the latter: (1) tracking problems (hospital laboratories ''[c]an easily work with medical and nursing services to coordinate patient care efforts'' whereas hospital-independent reference laboratories ''[c]an only track internal problems effectively'') and (2) physician consultation (this is ''[r]eadily available'' for hospital laboratories whereas it is ''[n]ot as readily available'' for hospital-independent reference laboratories).

connection with the listing of the device as provided in § 807.26(e) (this regulation is discussed above). This labeling will facilitate FDA surveillance for potentially poor performing LDTs that should otherwise be addressed.

Finally, as noted elsewhere in this preamble, regardless of this or any other enforcement discretion policy, FDA retains discretion to pursue enforcement action at any time against violative IVDs when appropriate. We intend to carefully monitor LDTs falling within this policy and intend to take action regarding such LDTs as appropriate taking into account any public health concerns as evaluated on a case-by-case basis.

We considered various alternative policies proposed in comments regarding LDTs for unmet needs and LDTs manufactured by AMC laboratories or laboratories integrated within other healthcare systems, but we believe this policy best serves FDA's public health mission by helping to assure the safety and effectiveness of LDTs while also accounting for patient access. For example, an enforcement discretion policy whereby FDA generally does not enforce premarket review and most QS requirements for *any* LDT manufactured by AMC laboratories and laboratories integrated within other healthcare systems would appear to be overly broad, including because it would encompass LDTs for which there are FDA-authorized alternatives that we know have appropriate assurances of safety and effectiveness. Similarly, an enforcement discretion policy whereby FDA generally does not enforce premarket review and most QS requirements for *all* LDTs for unmet needs would also appear to be overly broad, as there are not the same risk mitigations present for all such LDTs that would help address and avoid the use of problematic LDTs. We also considered several narrower enforcement discretion policies, such as an enforcement discretion policy where a premarket submission would be expected *after* an LDT is offered for use and where the LDT is offered until FDA makes a final decision on the LDT (see, *e.g.,* the 2017 Discussion Paper (Ref. 57)) or a longer phaseout policy for QS requirements. We do not think such policies would make sense here because many laboratories would likely be dissuaded from developing LDTs in this space if compliance with premarket review and QS requirements is routinely expected at any point in time due to the lack of financial incentives and perceived costs associated with premarket review and QS requirements.

Second, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) [35] for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule (hereinafter, ''currently marketed IVDs offered as LDTs''). FDA intends for this policy to apply to currently marketed IVDs offered as LDTs as long as they are not modified following the issuance of this final rule, or are modified but only in certain limited ways that are described below. This enforcement discretion policy does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

As part of this policy, FDA intends to request submission of the labeling for currently marketed IVDs offered as LDTs under § 807.26(e) and to use this information, along with information obtained through laboratory compliance with other relevant requirements (such as adverse event reporting), to identify and address those currently marketed IVDs offered as LDTs that specifically raise concerns. We recognize that patients, the healthcare community, and the laboratory industry have likely made decisions in reliance on access to, or the continued manufacturing of, many currently marketed IVDs offered as LDTs, and that loss of beneficial currently marketed IVDs offered as LDTs could cause harm and undermine those reliance interests. We believe this policy appropriately balances the various competing interests at issue to best serve public health because it helps facilitate continued access to those IVDs offered as LDTs that are beneficial while incorporating targeted use of available tools to identify and act against currently marketed IVDs offered as LDTs that are problematic. As IVDs evolve, compliance with premarket review and QS requirements will be phased in according to the natural lifecycle of test development and use.

FDA is adopting this policy after a review of the comments, which leads us to conclude that an expectation of compliance with premarket review and QS requirements for currently marketed IVDs offered as LDTs may be more harmful than helpful to the public because, for example, it will prompt many laboratories to stop offering tests even if they are safe and effective. One commenter stated that ''[i]f the rule is implemented, it is likely that we would consider no longer offer [*sic*] [IVDs offered as LDTs] due to the administrative and financial burdens of the regulations.'' Another commenter stated that ''the most prominent reason [the proposed rule should not move forward] is that patient care will suffer as most small laboratories will be forced to close because of increased cost and need to reduce their test menu.'' These comments corresponded to data in FDA's Preliminary Regulatory Impact Analysis (PRIA) suggesting a potentially high burden on laboratories associated with compliance for currently marketed IVDs offered as LDTs—a burden that could potentially cause some laboratories (particularly small laboratories) to close (Ref. 60). As reflected in section II.F of the FRIA (Ref. 10), a significant fraction of the estimated overall costs of compliance with applicable requirements under the FD&C Act and FDA's regulations is attributable to premarket review (where applicable) and QS requirements. Specifically, out of the total estimated discounted costs to industry of $1.17 billion, the average estimated costs of compliance with stages 1 and 2 of the phaseout policy (as described in section V.C below) are approximately $9,522 per test ($74,783 per laboratory) and the average estimated costs of compliance with premarket review and QS requirements are approximately $3.02 million per test ($1.26 million per laboratory).

In the NPRM and this preamble, FDA explained that relevant evidence points to a high degree of variability in the performance of IVDs offered as LDTs today, but FDA does not take the view that all laboratory-manufactured IVDs are problematic (see, *e.g.,* 88 FR 68006 at 68010–68012 and responses to comments 28, 32–33). We believe that an appreciable proportion of IVDs currently offered as LDTs likely help patients and are important to patient care (see section II.E.1 of the FRIA (Ref. 10)), and as noted above, we understand that patients, the healthcare community, and the laboratory industry have likely made decisions in reliance on access to, or the continued manufacturing of, such IVDs. The loss of such IVDs could cause harm and undermine those reliance interests.

FDA is aware, for instance, that certain patients may have embarked on a course of treatment in reliance on regular testing to help monitor their treatment or condition, and the loss of that testing could pose serious risks and

[35] As noted in footnote 17, for the categories of IVDs discussed in section V.B.3, FDA generally expects compliance with requirements under part 820, subpart M (Records) but not §§ 820.20, 820.22, 820.40, and 820.50 (which are cross-referenced in subpart M), or comparable provisions of ISO 13485 in accordance with the amendments to part 820 once that rule takes effect in February 2026.

complications for that patient. For example, consistent access to tests that are already being used to measure plazomicin to aid in the management of patients with complicated urinary tract infection receiving plazomicin therapy and tests to measure levels of immunosuppressants—such as cyclosporine, tacrolimus, everolimus, and sirolimus—in transplant patients are important for treating physicians to make well-informed treatment decisions for those patients. In the context of patients receiving tests that are not well-standardized to monitor their diseases or conditions, consistent access to the same test at the same laboratory over time is also important for treating physicians to make accurate diagnostic and treatment decisions. Examples of such tests include thyroid hormone tests that are used to monitor thyroid disease, adrenal function tests that are used to monitor adrenal disorders, and flow-cytometry-based minimal residual disease tests that are used to monitor patients with cancer that have undergone treatment to determine if they are at risk for relapse.

FDA also recognizes that healthcare professionals may have made significant financial investments in reliance on access to certain tests (*e.g.,* contracts for certain tests that they need for long-term patient monitoring, where such monitoring must continue with the same test because test results are compared over time and results from a different test are not interchangeable), and that the loss of access could harm their practice and, ultimately, the patients they serve. In addition, laboratories may have made financial investments and other decisions based on a past assumption about the presence of the general enforcement discretion approach.

In light of these reliance considerations and, in particular, the risk that laboratories may stop offering safe and effective tests on which patients and the healthcare community currently rely, we do not think it is appropriate to expect compliance with premarket review and most QS requirements for all currently marketed IVDs offered as LDTs. Instead, we have determined it is in the best interest of the public health to expect compliance with premarket review and QS requirements in a more targeted fashion—*i.e.,* for those currently marketed IVDs offered as LDTs that specifically raise concerns. As new IVDs come on the market following issuance of this rule, they will be expected to comply with premarket review and QS requirements—in accordance with the phaseout policy—gradually phasing in those requirements for the overall market. In the meantime, compliance with other applicable requirements will help enable FDA to identify and address safety and effectiveness problems that may arise.

In deciding on this policy, FDA considered alternatives to address the concerns identified above, including the risk of market exit, such as: (1) extending the phaseout timeline to give more time for currently marketed IVDs offered as LDTs to come into compliance with premarket review and QS requirements and (2) expecting compliance with premarket review and QS requirements only for high-risk currently marketed IVDs offered as LDTs. However, based on FDA's economic projections, neither of these alternatives resolves the concern about market exit resulting in loss of access to beneficial IVDs on which patients and others currently rely because neither substantially changes the economic burden on laboratories. For example, under Alternative 3 in section II.J of the PRIA, FDA evaluated the reduction in burden of an extended phaseout policy, and based on the calculations there, we doubt that the reduction would be sufficient to prevent the outcomes described above (see Ref. 60). In addition, the PRIA shows that the greatest costs in the phaseout policy are those associated with high-risk IVDs, so a policy that involves compliance for currently marketed high-risk IVDs offered as LDTs also would not resolve the concern about market exit. Given this information, and given the information we received in comments, FDA has concluded that the best course is to adopt the policy for currently marketed IVDs offered as LDTs outlined above. (This policy is keyed to the date of this final rule, rather than the proposed rule, because patients and the healthcare community may have begun relying on IVDs during the period between publication of the proposed and final rule.)

Based on FDA's understanding of the current IVD industry, we expect IVDs offered as LDTs to continue to advance to meet new patient needs, accommodate new technologies, and incorporate the latest scientific findings. Under this policy for currently marketed IVDs offered as LDTs, when such IVDs are modified in certain significant ways that would, under FDA requirements, generally prompt the need for premarket review relative to the original currently marketed IVD, FDA expects laboratories to comply with premarket review and QS requirements for that modified IVD. This policy is intended to preserve access to beneficial IVDs on which patients and the healthcare community currently rely, including versions of that IVD with minor changes. However, we expect compliance with premarket review and QS requirements once the IVD is changed in certain, more significant ways that could affect its basic safety and effectiveness profile. In particular, under this policy, FDA generally expects compliance with premarket review and QS requirements for currently marketed IVDs offered as LDTs when a laboratory's modifications (individually or in aggregate):

- change the indications for use of the IVD;
- alter the operating principle of the IVD (*e.g.,* changes in critical reaction components);
- include significantly different technology in the IVD (*e.g.,* addition of artificial intelligence or machine learning to the test algorithm, a change from targeted sequencing to whole genome sequencing, a change from immunoassay to mass spectrometry, or a change from manual to automated procedures); or
- adversely change the performance or safety specifications of the IVD.[36]

FDA believes this approach appropriately limits the scope of this policy and reduces the risk for patients.

As noted above, FDA also intends to take targeted steps to address currently marketed IVDs offered as LDTs that are problematic. In particular, we intend to use available tools to identify and act against currently marketed IVDs offered as LDTs that specifically raise concerns, such as IVDs that are potentially inaccurate or poorly validated. In this way, FDA can work to assure the safety and effectiveness of currently marketed IVDs offered as LDTs without creating the risk of widespread market exit. FDA has a range of tools to assist in this effort.

First, FDA intends to request that laboratories offering currently marketed IVDs offered as LDTs submit labeling to FDA as provided in § 807.26(e). Labeling includes IVD performance information and a summary of supporting validation, as applicable. This information will help FDA more closely monitor currently marketed IVDs offered as LDTs and identify those that may lack analytical validity, clinical validity, or safety. As part of its review of labeling, FDA also intends to

[36] Under FDA regulations, the listed modifications to an IVD would generally require a new submission, such as a new 510(k), PMA, BLA, or De Novo, or certain types of PMA or BLA supplements. *See, e.g.,* 21 CFR 601.2, 601.12, 807.81(a)(3), 814.39, and 860.200; see also ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (Ref. 61).

look closely at claims of superior performance and whether those claims are adequately substantiated.[37] Such claims are of particular public health concern because, in FDA's experience, they have led to escalating claims from competitors that can ultimately mislead the public. FDA generally intends to take action where the labeling of a currently marketed IVD offered as an LDT is false or misleading, and/or the IVD offered as an LDT lacks the appropriate assurance of safety and effectiveness for its intended uses as a result of any such claims that are not adequately substantiated.

Second, FDA intends to enforce records requirements in part 820, subpart M, for manufacturing activities related to a currently marketed IVD offered as an LDT that occur after the date of issuance of this final rule. Compliance with these requirements will facilitate FDA's review of these IVDs during inspections, enabling FDA to understand the validation bases and processes underlying these IVDs, and will support appropriate adverse event reporting (MDRs).

Third, under the policy, FDA expects laboratories to comply with applicable requirements other than premarket review and most QS requirements, including MDR requirements, corrections and removals reporting requirements, registration and listing requirements, and labeling requirements. Compliance with these requirements will provide FDA with additional important information regarding currently marketed IVDs offered as LDTs, such as information enabling FDA to track adverse-event trends.

Finally, based on our experience with other devices, we anticipate that laboratory manufacturers will alert us to potential problems with their competitors' IVDs once IVD performance information is transparent, which will help direct FDA's attention to problematic tests.

FDA emphasizes that these tools are not a substitute for premarket review or full QS compliance. FDA continues to believe that premarket review and full QS compliance are important tools to help assure the safety and effectiveness of IVDs going forward. However, there are sufficient countervailing reasons to take a more targeted approach for currently marketed IVDs offered as LDTs, including the risk of market exit and the potentially significant reliance on currently marketed IVDs offered as LDTs. Thus, FDA has determined that the enforcement discretion policy outlined above best serves public health.

The third category of tests for which FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records))[38] is non-molecular antisera LDTs[39] for rare RBC antigens when such tests are manufactured and performed by blood establishments, including transfusion services and immunohematology laboratories[40] and when there is no alternative IVD available to meet the patient's need for a compatible blood transfusion. This policy does not apply to molecular tests used for genotyping RBC antigens. This policy also does not apply to any IVDs identified in section V.A.2 as falling outside the scope of the phaseout policy or as discussed in section V.B.

Some individuals develop antibodies to certain antigens that they lack on their own RBCs following exposure to foreign RBC antigens through blood transfusion or pregnancy. These may be clinically significant, causing a hemolytic transfusion reaction if the patient receives a transfusion of RBCs that have the corresponding antigen(s). As of July 2023, there are currently 45 recognized blood group systems containing 360 RBC antigens (Ref. 63). FDA understands that there are occasions where licensed antisera IVDs are not available for rare RBC antigens but testing for such rare antigens is necessary to help ensure that patients receive a compatible blood transfusion[41] and avoid potentially life-threatening reactions. Although FDA has also approved molecular tests for use in genotyping RBC antigens, there may not be an available, approved molecular test to use as an alternative for all rare antigens.

FDA is adopting this policy after consideration of comments that requested that FDA continue to exercise enforcement discretion with respect to antisera LDTs for rare RBC antigens and/or molecular tests for genotyping rare RBC antigens. This included comments pointing to FDA's existing 2018 final guidance (Ref. 64), which, among other things, recognized that blood establishments sometimes use unlicensed antisera tests or unapproved molecular tests for RBC antigen typing in circumstances where a licensed reagent for a rare antigen is not available.

The non-molecular antisera LDTs within the scope of this policy share certain characteristics with ''1976-Type LDTs,'' as they use manual techniques performed by laboratory personnel with specialized expertise. For such LDTs, in instances where there is no available alternative to ensure that a patient receives a compatible transfusion, FDA has determined it is in the best interest of public health to adopt this enforcement discretion policy. However, this policy does not apply to molecular tests for genotyping RBC antigens. Compared to serologic tests, molecular RBC typing is a relatively new and complex technique for detection of RBC antigens. Some limitations of molecular RBC typing tests include that the genotype does not always correlate with the phenotype due to samples with rare null phenotypes, and the assay may not be designed to detect all rare or new variants of an antigen. As such, FDA has greater concern regarding risk of error with molecular tests for genotyping RBC antigens that do not comply with applicable FDA requirements.

For LDTs offered as described in this policy, FDA expects the LDT to be validated. As discussed previously, we acknowledge that such expectations may vary depending on many factors, including the accessibility of specimens and the number of affected patients.

In addition, this enforcement policy applies only to premarket review and QS requirements (except for

[37] *See, e.g.,* FDA, Final Guidance for Industry: Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers at 18 (June 2018) (''[P]romotional material is misleading'' when ''it makes a claim of superior effectiveness for Drug A versus Drug B based on a study that was not designed to establish superiority of Drug A to Drug B.''). *See* Ref. 62.

[38] As noted in footnote 17, for the categories of IVDs discussed in section V.B.3, FDA generally expects compliance with requirements under part 820, subpart M (Records) but not §§ 820.20, 820.22, 820.40, and 820.50 (which are cross-referenced in subpart M), or comparable provisions of ISO 13485 in accordance with the amendments to part 820 once that rule takes effect in February 2026.

[39] Consistent with what FDA has generally considered to be an LDT (as discussed elsewhere in this preamble), this enforcement discretion policy applies only to tests that are designed, manufactured, and used within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing.

[40] In our experience, establishments that perform compatibility tests for blood transfusion include establishments, such as reference laboratories, that are not integrated within a healthcare system. Therefore, the non-molecular antisera LDTs at issue may not fall within the policy described above for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

[41] Such tests are not subject to the requirements in § 640.5. As noted elsewhere in this document, FDA's general enforcement discretion approach for LDTs has not applied to tests for determination of blood group and Rh factors that are subject to § 640.5.

requirements under part 820, subpart M (Records)). FDA expects compliance with records requirements in part 820, subpart M, for non-molecular antisera LDTs that fall within this policy. Compliance with these requirements will facilitate FDA's review of these LDTs during inspections and will support appropriate adverse event reporting. The phaseout of the general enforcement discretion approach for other applicable requirements will provide greater assurances regarding tests that fall within this policy than the Agency, healthcare providers, and patients currently have.

Finally, as noted elsewhere in this preamble, regardless of this or any other enforcement discretion policy, FDA retains discretion to pursue enforcement action at any time against violative IVDs. We intend to carefully monitor LDTs falling within this policy and intend to take action regarding such LDTs as appropriate, taking into account any public health concerns as evaluated on a case-by-case basis.

C. Stages

As previously discussed, FDA has determined to gradually phase out its current general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. In particular, FDA has structured the phaseout policy to contain five key stages:

- *Stage 1:* beginning 1 year after the publication date of this final rule, FDA will expect compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files).
- *Stage 2:* beginning 2 years after the publication date of this final rule, FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.
- *Stage 3:* beginning 3 years after the publication date of this final rule, FDA will expect compliance with QS requirements under part 820 (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1).
- *Stage 4:* beginning 3½ years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs, unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.
- *Stage 5:* beginning 4 years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.

These stages, along with certain narrower enforcement discretion policies specific to certain stages, are discussed in further detail below.

We note that FDA generally does not intend to enforce requirements to include certain information (*e.g.,* registration numbers, premarket submission numbers) in reports or other submissions to the Agency until the information is addressed in a later stage of the phaseout policy.

We received several comments on the structure, sequencing, and timing of the proposed phaseout policy described in the NPRM (see section VI.F.6 of this preamble). Some indicated that the proposed timing for all phases was appropriate while others recommended it be shortened or lengthened. Some also proposed different approaches for organizing or implementing the phaseout.

FDA carefully considered these comments, and also considered the impact of other policies included in the final phaseout policy on the considerations noted in these comments. For the reasons discussed below and in section VI.F.6, FDA has determined that it should retain the general structure, sequencing, and timelines proposed in the NPRM (88 FR 68006 at 68021) for the phaseout policy in this final rule.

FDA encourages laboratory manufacturers to begin early and work toward compliance with requirements sooner than the end of the timeframes specified for each stage of the phaseout policy, as described below. FDA also intends to consider providing more targeted guidance and/or making additional resources available on specific topics, such as compliance with applicable labeling requirements, over the course of the phaseout period, as discussed in section VI.P.

1. Stage 1: Beginning 1 Year After the Publication Date of This Final Rule, FDA Will Expect Compliance With MDR Requirements, Correction and Removal Reporting Requirements, and QS Requirements Under § 820.198 (Complaint Files)

As detailed elsewhere in this preamble, FDA is concerned that some IVDs offered as LDTs may be posing risks to patients; therefore, FDA seeks to obtain information about potentially harmful IVDs offered as LDTs as soon as feasible. In light of that objective, and after reviewing the comments, FDA continues to believe that 1 year is an appropriate time for laboratory manufacturers to come into compliance with MDR and correction and removal reporting requirements. Among other things, this timeline is reasonable in light of the estimates in the FRIA, and under CLIA, laboratories should already have some processes in place for detecting problems with their IVDs. In addition, the new enforcement discretion policies set forth in section V.B (particularly the policy for currently marketed IVDs offered as LDTs) may help laboratories with limited resources focus on compliance with requirements at stage 1. Therefore, FDA is retaining the 1-year period for the phaseout of the general enforcement discretion approach with respect to MDR and correction and removal reporting requirements, in order to prioritize the phaseout of the general enforcement discretion approach for requirements that would help FDA identify and monitor significant issues with IVDs offered as LDTs.

Enforcement of the MDR requirements under 21 U.S.C. 360i(a) through (c) and part 803 (21 CFR part 803), in particular, will enable FDA to systematically monitor significant adverse events to identify problematic IVDs offered as LDTs, such as those with poor performance or other safety issues. FDA has made a determination that gathering this information early in the phaseout period is important for IVDs that do not have the safeguards associated with compliance with other FDA requirements, such as manufacturing under QS requirements or confirmation of appropriate safety and effectiveness through premarket review.

For similar reasons, FDA is prioritizing the collection of information about when a manufacturer has initiated a correction or removal of its IVD to reduce a risk to health or to remedy a violation of the FD&C Act that may present a risk to health. Under 21 U.S.C. 360i(g) and part 806 (21 CFR part 806), manufacturers are required to report

such corrections or removals to FDA, and FDA intends to phase out the general enforcement discretion approach for these requirements at the same time it does so for MDR requirements.

In addition, FDA has determined that it should include compliance with one additional regulatory provision at stage 1 of the phaseout policy. In particular, while FDA generally expects compliance with most QS requirements beginning in stage 3 of the phaseout policy (as described below), FDA intends to phase out the general enforcement discretion approach with respect to the QS requirements under § 820.198 (complaint files)[42] in stage 1 of the phaseout policy, given the connection between the complaint investigation and complaint file requirements under § 820.198 and the MDR reporting regulations. Under § 820.198, manufacturers are required to document complaints, investigate them, and determine if they require reporting under MDR requirements. Absent compliance with these requirements under § 820.198, manufacturers would not be able to comply with applicable MDR requirements (see § 803.18(e)), and FDA believes that developing procedures for compliance with § 820.198 can be accomplished on the same timeline as compliance with MDR requirements.

2. Stage 2: Beginning 2 Years After the Publication Date of This Final Rule, FDA Will Expect Compliance With Requirements Not Covered During Other Stages of the Phaseout Policy, Including Registration and Listing Requirements, Labeling Requirements, and Investigational Use Requirements

After considering the comments, FDA has determined to phase out the general enforcement discretion approach for requirements not covered during other stages of the phaseout policy (*i.e.,* requirements other than MDR, correction and removal reporting, QS, and premarket review requirements) 2 years after publication of this final rule. These other requirements include registration and listing requirements under 21 U.S.C. 360 and parts 607 and 807 (excluding subpart E); labeling requirements under 21 U.S.C. 352 and parts 801 and 809, subpart B (21 CFR parts 801 and 809, subpart B); and investigational use requirements under 21 U.S.C. 360j(g) and part 812 (21 CFR part 812).[43] We have included compliance with investigational use requirements at this stage, in recognition that there has been some confusion about our enforcement approach in this area. Our understanding is that laboratories often are not complying with investigational use requirements currently, even though FDA has generally expected compliance with these requirements.[44] We are therefore including these requirements in the phaseout policy.

As described in the NPRM (88 FR 68006 at 68025), FDA anticipates that it will best serve the public health to phase out the general enforcement discretion approach for these requirements at the 2-year mark, and FDA did not receive information changing its view with respect to that timeline. Under this timeline, FDA will obtain registration and listing information before the enforcement discretion phaseout for premarket review requirements, which may give the Agency a better understanding of the universe of IVDs offered as LDTs to facilitate premarket review of those IVDs. Relatively few commenters raised concerns about this timeline, and FDA's estimates of the resources required for compliance with the requirements covered by stage 2 suggest 2 years is adequate time (see FRIA section II.F.2). Furthermore, the new enforcement discretion policies set forth in section V.B may free up time and resources for laboratories to focus on compliance with requirements at stage 2. FDA has determined that this timeline appropriately balances the importance of compliance with registration and listing, labeling, and investigational use requirements, among others, relatively quickly—in order to address IVDs offered as LDTs that are problematic, among other things—with the recognition that laboratories generally have not complied with FDA requirements and may need time to order their affairs and build out FDA-compliant systems.

FDA notes that the labeling requirements under part 801 include unique device identification (UDI) requirements, as applicable (see part 801, subpart B).

3. Stage 3: Beginning 3 Years After the Publication Date of This Final Rule, FDA Will Expect Compliance With QS Requirements

At the 3-year mark, FDA generally will expect compliance with the CGMP requirements of the QS requirements under 21 U.S.C. 360j(f) and part 820. (FDA notes that we expect compliance with requirements under § 820.198 (complaint files) during stage 1 of the phaseout policy.) We recognize that the costs of compliance with QS requirements are comparatively high among the range of costs quantified in the FRIA (and as suggested in certain comments), but FDA continues to believe that the 3-year timeline is appropriate given, in particular, the new enforcement discretion policies in section V.B.3, which we anticipate will significantly reduce laboratories' work at this stage (see section II.F.3 of the FRIA). FDA has determined that this timeline is consistent with our goal of improving the quality of IVDs manufactured by laboratories as soon as feasible while also taking into account the resources and time required to set up quality systems.

FDA also notes that we expect laboratories to retain manufacturing records they may already have or may create for certain IVDs prior to stage 3 of the phaseout policy. In particular, for any IVDs for which FDA generally intends to exercise enforcement discretion for all QS requirements other

[42] 21 CFR 820.198 generally requires that a manufacturer maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints, including requiring that certain complaints which are required to be reported to FDA under part 803 be promptly reviewed, evaluated, and investigated. When the final rule to amend part 820 takes effect in February 2026, the comparable requirements can be found in International Organization for Standardization (ISO) 13485 subclause 8.2.2 as modified by part 820. Under these provisions, manufacturers will generally be required to document procedures for timely complaint handling, including minimum requirements and responsibilities for receiving and recording information, evaluating whether the information constitutes a complaint, investigating complaints, determining the need to report information to appropriate regulatory authorities, handling of complaint-related product, and determining the need to initiate corrective action. Additionally, new § 820.35 will require, among other things, that manufacturers maintain records of such review and report to FDA complaints that are required under part 803.

[43] An IVD that is also a biological product and subject to licensure under section 351 of the PHS Act may be studied under an IND and subject to the investigational use requirements in section 351(a)(3) of the PHS Act and 21 CFR part 312, instead of the IDE requirements in part 812 (see, *e.g.,* 21 CFR 312.2(a) and Ref. 65). IVDs studied under an IND are generally those intended for use as blood donor screening or HCT/P donor screening tests to which FDA's general enforcement discretion approach for LDTs has not applied (see section V.A.2). Therefore, we anticipate that there would be a limited number of IVDs offered as LDTs, if any, subject to investigational use requirements under 21 CFR part 312 for which the phase out of enforcement discretion would be relevant. However, to the extent such IVDs offered as LDTs exist, we intend to phase out enforcement discretion with respect to those investigational use requirements at stage 2, consistent with our policy regarding other investigational use requirements.

[44] For example, FDA stated in the ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' draft guidance that ''FDA intends to *continue to enforce* investigational device requirements under 21 CFR part 812 for all clinical investigations of LDTs that are conducted under clinical protocols that require institutional review board approval'' (Ref. 38).

than requirements under part 820, subpart M (Records), FDA expects laboratories to retain existing records and records created prior to the start of stage 3 that are relevant to validation and the other topics covered under part 820, subpart M (Records)). This documentation will help FDA understand the manufacturing for IVDs offered as LDTs that are marketed prior to stage 3, including helping FDA identify IVDs that are potentially problematic.

FDA issued its final rule amending the QSR on February 2, 2024, which will take effect on February 2, 2026, meaning that the amended QS requirements will be in effect before the beginning of stage 3. When a laboratory undertakes to comply with QS requirements, FDA will expect compliance with the QS requirements that are in effect at that time whether that be at the start of stage 3 or earlier (if the laboratory complies with QS requirements prior to the start of stage 3).[45] For further information on the QS requirements established pursuant to the amendments to the QSR, please refer to 89 FR 7496.

In addition, specifically for LDTs,[46] FDA is adopting the enforcement discretion policy proposed in the NPRM under which FDA generally will expect compliance at the 3-year mark with some, but not all, of the QS requirements (88 FR 68006 at 68025). FDA continues to believe this policy is helpful and appropriate. Although FDA and CMS regulation are different and complementary, compliance with CLIA requirements provides some quality assurances that may be relevant to laboratories' manufacturing practices. In particular, laboratories may in practice be able to apply concepts set forth under CLIA requirements for laboratory operations to certain manufacturing activities regulated by FDA. For FDA to effectively take into account the CLIA requirements, this policy will apply only for LDTs (*i.e.,* when all manufacturing activities occur within a single laboratory and the IVD is not transferred outside that laboratory). However, this policy is limited in scope because CLIA regulations do not provide relevant assurances for certain QS requirements. These requirements include design controls under § 820.30; purchasing controls (including supplier controls) under § 820.50; acceptance activities (receiving, in-process, and finished device acceptance) under §§ 820.80 and 820.86; CAPA under § 820.100; and records requirements under part 820, subpart M.[47] [48] Because CLIA does not provide assurances relevant to these requirements, FDA has determined to phase out the general enforcement discretion approach for these specific requirements 3 years after publication of this final rule (except for requirements under § 820.198 (complaint files), for which FDA intends to phase out the general enforcement discretion approach during stage 1 of the phaseout policy).

Finally, FDA notes that under section 515(d)(2) of the FD&C Act, the Agency may not approve a PMA if the applicant fails to demonstrate conformity with the QS requirements. Therefore, compliance with the QS requirements is needed to support approval of a PMA. As provided in section 520(f)(2) of the FD&C Act, any person subject to the QS requirements may petition for an exemption or variance from any QS requirement (see also § 820.1).

4. Stage 4: Beginning 3½ Years After the Publication Date of This Final Rule, FDA Will Expect Compliance With Premarket Review Requirements for High-Risk IVDs Offered as LDTs, Unless a Premarket Submission Has Been Received by the Beginning of This Stage in Which Case FDA Intends To Continue To Exercise Enforcement Discretion for the Pendency of Its Review

FDA has determined that the phaseout for the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs offered as LDTs should occur 3½ years from publication of this final rule, consistent with the timeline proposed in the NPRM (88 FR 68006 at 68026). The premarket review requirements for PMAs are set forth in 21 U.S.C. 360e and part 814 (21 CFR part 814). The information in the record has not changed our view that 3½ years will provide sufficient notice and opportunity for laboratories manufacturing IVDs to plan for and prepare PMAs.[49] Although we received comments indicating that it would be difficult for laboratories to comply within this 3.5-year timeline, the new enforcement discretion policies included in this final phaseout policy should help address those concerns. For example, the policy for currently marketed IVDs offered as LDTs and the policy for certain unmet needs LDTs mean FDA generally does not expect compliance with premarket review requirements for a substantial subset of IVDs. Overall, in light of these policies, FDA has determined that a 3.5-year period is a reasonable amount of time to expect laboratories to come up to speed on PMA requirements, gather the information required for PMAs, and complete their PMA submissions (see section II.F.4 of the FRIA).

This timeline is also intended to align the phaseout for the general enforcement discretion approach for premarket review requirements for high-risk IVDs offered as LDTs with the start of fiscal year 2028, which coincides with the beginning of a new user fee cycle. This alignment will provide an opportunity for industry participation in

[45] As noted elsewhere in this phaseout policy, FDA intends to phase out the general enforcement discretion approach with respect to requirements under § 820.198 (complaint files) during stage 1 of the phaseout policy. However, upon the start of stage 1, and prior to the effective date of the amended QSR, FDA intends to exercise enforcement discretion and generally not enforce requirements under § 820.198 for laboratories that are in compliance with Subclause 8.2.2 of ISO 13485. Following the effective date of the amended QSR (February 2, 2026), laboratories must comply with the QS requirements that are in effect at that time.

[46] As explained elsewhere in this preamble, FDA has generally considered the term ''laboratory developed test (LDT)'' to mean an IVD that is intended for clinical use and that is designed, manufactured, and used within a single CLIA-certified laboratory that meets the regulatory requirements under CLIA to perform high complexity testing.

[47] For LDTs, FDA generally expects compliance with requirements under part 820, subpart M (Records) but not §§ 820.20, 820.22, and 820.40 (which are cross-referenced in subpart M), or comparable provisions of ISO 13485 in accordance with the amendments to part 820 once that rule takes effect in February 2026.

[48] Upon the effective date of the amendments to the QSR, the requirements relating to design controls, purchasing controls, acceptance activities, CAPA, and records requirements will be set forth in the following ISO 13485 clauses as modified by the codified for part 820: Clause 4. Quality Management System, Subclause 4.2.5; Clause 6. Resource Management; Clause 7. Product Realization, Subclause 7.1, Subclause 7.3, Subclause 7.4, and Subclause 7.4.3; and Clause 8. Measurement, Analysis, & Improvement, Subclause 8.2.2., Subclause 8.2.5, Subclause 8.2.6, and Subclause 8.3.

[49] Under the phaseout policy, laboratories that intend to submit an HDE application or a BLA should do so within the same 3½-year timeframe for submission of PMAs. As in the case of PMAs, under the phaseout policy, FDA generally does not intend to enforce against IVDs after a complete HDE application or BLA has been submitted (within the 3½-year timeframe) until FDA completes its review of the application. Premarket review requirements specific to HDE applications are set forth in 21 U.S.C. 360j(m) and part 814, subpart H. Licensure requirements are set forth in 42 U.S.C. 262 and 21 CFR part 601.

negotiations regarding the next user fee cycle with the knowledge that laboratory manufacturers will be expected to comply with premarket review requirements. (Although a trade association representing laboratories previously has participated in Medical Device User Fee Amendments (MDUFA) negotiations, the prior negotiations have not incorporated similar expectations regarding laboratory compliance with premarket requirements.) Thus, we have determined that this amount of time is appropriate to foster stability and consistency in the marketplace for the current MDUFA cycle, and FDA will take into account the need for adequate FDA resources to implement the phaseout policy in a manner that does not compromise the capacity to achieve MDUFA V performance expectations. FDA anticipates that during this 3½-year period, laboratories will work with FDA to determine whether PMAs should be submitted for their IVDs.

Under this phaseout policy, FDA generally does not intend to enforce against IVDs offered as LDTs for lacking premarket approval after a complete PMA has been submitted until FDA completes its review of the application, provided that the PMA has been submitted within the 3½-year timeframe. Given that such IVDs may already be on the market and available to patients, FDA generally does not intend to interrupt access at the point when a submission is made. IVDs for which a PMA is submitted after the 3½-year timeframe would not fall within this enforcement discretion policy; FDA approval is expected prior to such IVDs being offered.

Based on a review of the comments, FDA is also adopting a policy under which it generally does not intend to enforce premarket review requirements for certain laboratory changes to another manufacturer's lawfully marketed test. In particular, this policy applies when a laboratory certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, following design controls and other quality system requirements for which FDA expects compliance as described in section V.C.3, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification. FDA is adopting this policy to promote more efficient and effective use of Agency resources and because it understands laboratories may make such changes to, for example, integrate a test into its operations, accommodate local conditions (*e.g.,* storage conditions), or address supply shortages. Under the policy, FDA would expect premarket submissions from laboratories modifying a third party's 510(k) cleared or De Novo authorized test for the same types of changes for which FDA would expect a premarket submission from the *original* manufacturer making changes to its own IVD. Taking into account the risks associated with relatively minor changes to 510(k) cleared or De Novo authorized tests when they occur in a single laboratory (*i.e.,* without broad distribution), at this time, we believe the resources needed to review these types of changes generally can be better spent on other Agency priorities and activities. For a description of changes that could significantly affect the safety or effectiveness of the test or constitute a major change or modification in intended use under this policy, see FDA's regulations at § 807.81(a)(3) and further discussion in the final guidance ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (Ref. 61). If the modification (individually or in the aggregate) could significantly affect the safety or effectiveness of the test or does constitute a major change or modification in intended use and the modified test does not fall within an enforcement discretion policy discussed in section V.B above, FDA expects laboratories to submit the applicable premarket submission. If the laboratory modification is so significant that the IVD is no longer substantially equivalent to the original IVD and requires a PMA, FDA expects the PMA to be submitted either by stage 4 or before the modified test is marketed, whichever comes later.

We are not applying this enforcement discretion policy to modifications to another manufacturer's PMA-approved or BLA-licensed test because such tests are high-risk, and changes to such tests pose corresponding increased risks. We note that relatively few IVDs are considered high risk today, and, further, FDA has announced its intent to initiate the reclassification process for most IVDs that are currently class III into class II (Ref. 66). FDA aims to complete this reclassification process before stage 4 of the phaseout policy. We therefore anticipate that there will be even fewer class III (high-risk) IVDs going forward. As such, these tests present resource considerations that are different from those discussed above.

5. Stage 5: Beginning 4 Years After the Publication Date of This Final Rule, FDA Will Expect Compliance With Premarket Review Requirements for Moderate-Risk and Low-Risk IVDs Offered as LDTs (That Require Premarket Submissions), Unless a Premarket Submission Has Been Received by the Beginning of This Stage in Which Case FDA Intends To Continue To Exercise Enforcement Discretion for the Pendency of Its Review

FDA has determined to phase out the general enforcement discretion approach with respect to premarket review requirements for moderate-risk IVDs offered as LDTs (IVDs that may be eligible for classification into class II) and low-risk IVDs offered as LDTs (IVDs that may be eligible for classification into class I) that require a premarket submission 4 years from publication of this final rule. These premarket submissions include 510(k) submissions, the requirements for which are set forth at 21 U.S.C. 360(k), 360c(i), and part 807, subpart E. These submissions also include De Novo requests, which laboratories may submit for IVDs offered as LDTs for which there is no legally marketed device upon which to base a determination of substantial equivalence, and for which the laboratory seeks classification into class I or class II. These requirements are set forth at 21 U.S.C. 360c(f)(2) and 21 CFR part 860, subpart D.

FDA is retaining the same 4-year timeline that was proposed in the NPRM for stage 5 for reasons similar to those for stage 4 (see 88 FR 68006 at 68027). Specifically, when taking into account the enforcement discretion policies in section V.B, we believe the original timeline for compliance with 510(k) and De Novo requirements is feasible, particularly given that these submissions are generally less resource-intensive than PMAs (for additional information see section II.F.4 of the FRIA (Ref. 10)). As noted in the NPRM, the 6-month interval between stages 4 and 5 will enable FDA to prioritize the review of applications for high-risk IVDs offered as LDTs (subject to premarket approval requirements), so that we can focus first on IVDs for which the consequences of a false result are generally most significant (88 FR 68006 at 68027). In addition, this timeline aligns with the user fee cycle, as previously discussed.

FDA generally does not intend to enforce against IVDs offered as LDTs for lacking premarket authorization after a complete 510(k) or De Novo request has been submitted until FDA completes its

review of the submission, provided that the 510(k) or De Novo request has been submitted within the 4-year timeframe. Given that such IVDs may already be on the market and available to patients, FDA generally does not intend to interrupt access at the point when a submission is made. IVDs for which a 510(k) or De Novo request is submitted after the 4-year timeframe would not fall within this enforcement discretion policy; FDA clearance or authorization is expected prior to such IVDs being offered.

FDA is also adopting the policy regarding laboratory modifications to another manufacturer's lawfully marketed test that is discussed under stage 4. As explained in that discussion, under this policy, FDA generally does not intend to enforce premarket review requirements when a laboratory certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, following design controls and other quality system requirements for which FDA expects compliance as described in section V.C.3, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification. If the modification (individually or in the aggregate) could significantly affect the safety or effectiveness of the test or does constitute a major change or modification in intended use and the modified test does not fall within an enforcement discretion policy discussed in section V.B above, FDA expects laboratories to submit the applicable premarket submission. If the applicable premarket submission is a 510(k) or De Novo request, FDA expects the 510(k) or De Novo request to be submitted either by stage 5 or before the modified test is marketed, whichever comes later.

FDA also anticipates that laboratories may seek to utilize FDA's Third Party review program. FDA currently operates a Third Party review program for medical devices, and multiple organizations are accredited to conduct reviews of 510(k) submissions for certain IVDs (see Ref. 67). We anticipate interest in the Third Party review program among IVD manufacturers, as well as potential new 3P510k Review Organizations. In particular, FDA is aware of certain CLIA accreditation organizations that have expressed interest in potentially becoming Third Party reviewers under FDA's program, and to the extent laboratories are already familiar with these organizations, laboratories may be more inclined to use the Third Party review program. In addition, under the MDUFA V agreement, FDA is currently working to enhance the Third Party review program, which may make it more attractive to manufacturers including laboratories.

VI. Comments on the Notice of Proposed Rulemaking and FDA Responses

We received more than 6,500 comment letters on the NPRM by the close of the comment period, each containing one or more comments on one or more issues. We received comments from medical device associations, members of the medical device and pharmaceutical industries, medical and healthcare professional associations, hospitals and AMCs, accreditation organizations, other advocacy organizations, government agencies, and individuals. We describe and respond to the comments in this section of the document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number so that FDA's responses can be addressed by topic, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received or considered.

A. General Comments on the Notice of Proposed Rulemaking

(Comment 1) FDA received comments in support of and in opposition to the NPRM. Comments supporting the proposal generally discussed the importance of FDA oversight of IVDs offered as LDTs to protect the public health and ensure that patients and healthcare providers are able to trust and rely on test results which impact important healthcare decisions. Some comments expressed concern regarding the use of IVDs offered as LDTs that are not clinically validated, and regarding scientifically dubious claims made about such IVDs, especially in areas like cancer prognosis and genetic screening. Several comments noted that without independent oversight the work to ensure LDT effectiveness and consistency is left to those with a financial interest in the continued use of those LDTs. Comments expressing general opposition cited various reasons for their opposition, including that the proposal is too broad in scope, is too difficult for laboratories to follow, would require laboratories to ''follow processes that are unfit for the purpose of assessing the quality of laboratory tests,'' is not necessary, and reflects regulatory overreach.

(Response 1) FDA agrees that phasing out the general enforcement discretion approach for LDTs is important to protect the public health, as discussed further in section III.B. Current evidence points to problems associated with IVDs offered as LDTs such that there is a fundamental uncertainty about whether IVDs offered as LDTs provide accurate and reliable results. These issues highlight the need for increased oversight to help ensure the safety and effectiveness of IVDs offered as LDTs.

FDA disagrees with the comments stating that FDA's proposal is overly broad. As described throughout this preamble and in the NPRM, the evidence supports increased oversight of IVDs offered as LDTs. The final phaseout policy fulfills the goal of greater oversight of such IVDs while also accounting for other key public health interests. For example, upon further consideration, including of the comments received regarding particular aspects of the phaseout policy, FDA is adopting several new targeted enforcement discretion policies, as detailed in section V.B.

FDA also disagrees with comments stating that FDA's proposal is difficult to follow. We believe the scope and five stages of the proposed and final phaseout policy, discussed further in section V, are clear and, as noted throughout this preamble, we intend to issue additional guidance as appropriate and offer other resources to the public, which will assist stakeholders during implementation of the phaseout.

In addition, we disagree with the statement that the proposal would require laboratories to follow processes that are ''unfit for the purpose of assessing the quality'' of IVDs offered as LDTs. As further discussed in sections VI.C.2 and VI.C.3 of this preamble, FDA has the experience and the scientific and regulatory expertise to oversee IVDs, including LDTs. Moreover, the requirements and processes for devices in the FD&C Act and FDA regulations apply to all IVDs, including LDTs, and the requirements/processes set forth in part 809 are specifically tailored to IVDs, including LDTs. We also disagree that the proposal (or final rule) reflects ''regulatory overreach'' for the reasons discussed in section VI.D.

B. Definitions

(Comment 2) Several comments stated that the rule should explicitly define in § 809.3 terms such as ''LDTs,'' ''IVDs,'' and ''enforcement discretion'' for clarity. Other comments suggested that FDA identify the differences between IVDs and LDTs, with one comment suggesting that FDA refer to LDTs as CLIA–LDTs because laboratories must be CLIA-certified. Another comment requested that FDA define the terms ''diagnostic'' and ''impact clinical outcomes'' as used in the proposed rule. One comment requested clarity on whether digital scanning of pathology slides is within the scope of the LDT definition included in the NPRM.

(Response 2) The term ''in vitro diagnostic products'' (IVDs) is defined in § 809.3(a). Through this rulemaking, FDA is amending the definition of ''in vitro diagnostic products'' in its regulations to state that IVDs are devices under the FD&C Act ''including when the manufacturer of these products is a laboratory.'' Therefore, as amended by this rule, IVDs are defined in § 809.3(a) as those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the FD&C Act, and may also be biological products subject to section 351 of the PHS Act, including when the manufacturer of these products is a laboratory.

FDA disagrees that the terms ''LDTs'' and ''enforcement discretion'' should be defined in § 809.3. Neither term is used in part 809, so adding definitions to part 809 would have no effect, and would likely be confusing. To the extent the commenter believed the use of those terms in the NPRM was not sufficiently clear, FDA also disagrees, as it has clearly explained those terms in both the proposed and final rules (see, *e.g.,* 88 FR 68006 at 68008 (stating that ''FDA has generally exercised enforcement discretion such that it generally has not enforced applicable requirements with respect to most LDTs''); 88 FR 68006 at 68009 (stating that ''FDA has generally considered an LDT to be an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under [CLIA] and meets the regulatory requirements under CLIA to perform high complexity testing'')).

With regards to the definition of ''diagnostic,'' FDA interprets this comment as a request to further define the term in the definition of an IVD. We see no reason, and the comment does not include any rationale, why this term should be defined. Moreover, we note that the term applies across many devices and so defining it in part 809, which is limited in scope to IVDs, would likely cause confusion. With regard to the comment requesting clarification of the phrase ''impact clinical outcomes,'' FDA did not use the phrase ''impact clinical outcomes'' in the NPRM and, as a result, does not understand this request.

Finally, regarding the comment requesting clarity on whether digital scanning of pathology slides is within the scope of the LDT definition, FDA would need to know more about the product to assess whether it falls within what FDA has generally considered to be an LDT—*i.e.,* an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing. FDA notes that whole slide imaging systems are class II devices with special controls and are subject to 510(k) notification requirements (21 CFR 864.3700). For additional information about specific classifications for devices, we recommend consulting 21 CFR parts 862 through 892.

(Comment 3) A comment requested FDA clarify how it regulates common laboratory equipment (such as general-purpose computer monitors or printers, microscopes, centrifuges, and incubators), and expressed concern that increased FDA oversight of LDTs would impact FDA's regulation of such equipment.

(Response 3) FDA regulates common laboratory equipment that meets the FD&C Act's definition of a device. Section 201(h)(1) of the FD&C Act defines a device, in relevant part, as ''An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: . . . . (B) intended for use [50] in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, ... The term 'device' does not include software functions excluded pursuant to section 520(o) [of the FD&C Act].'' Whether a product falls within the device definition involves a fact-specific inquiry, including an inquiry into the product's intended use. In general, general-purpose computer monitors or printers that are not intended for a medical use would not fall within the device definition, whereas general purpose laboratory equipment labeled or promoted for specific medical uses intended to prepare or examine specimens from the human body would fall within the device definition.

FDA has classified such general purpose laboratory equipment into class I and has exempted these devices from premarket notification under section 510(k) of the FD&C Act (21 CFR 862.2050). FDA has also classified certain microscopes and accessories and microbiological incubators into class I and has exempted them from premarket notification under section 510(k) of the FD&C Act (21 CFR 864.3600 and 866.2540). For additional information about specific classifications for devices, we recommend consulting 21 CFR parts 862 through 892. This rule does not change FDA's authority to regulate such equipment and FDA does not anticipate a significant impact from the phaseout policy on such equipment, which is generally not designed, manufactured, and used within a single CLIA-certified laboratory.

C. Need for the Rule

1. FDA's Description of the Current State of the LDT Market

(Comment 4) FDA received several comments on the current state of the LDT market. Some asserted that the potential risk to patients of false results from LDTs remains unchanged from 1976.

(Response 4) FDA disagrees with comments which claim that the risk to patients is unchanged from 1976. As discussed in the NPRM and this preamble, today LDTs are commonly used to diagnose infectious diseases, screen for various diseases and conditions, and identify the best treatment for patients with cancer, among other uses. The consequences of false results in these contexts can include spread of disease, missed diagnoses, misdiagnoses, use of ineffective treatments with toxic side effects, and lack of use of life-saving treatments. LDTs are relied upon for high stakes medical decisions. Further, genetic sequencing technology has advanced such that a person's

[50] ''Intended use'' as used in this provision is determined by the objective intent of the persons legally responsible for the labeling of an article (or their representatives) (see § 801.4). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article (*Id.*).

deoxyribonucleic acid (DNA) can be quickly sequenced and different variations identified in a single analysis; the clinical significance of many of these variations is unknown. FDA is aware of IVDs offered as LDTs, particularly genetic IVDs offered as LDTs, that are offered for uses that lack sufficient scientific support. The availability of new technologies and increasing reliance on them for clinical decision-making has increased the risk of IVDs offered as LDTs.

(Comment 5) Some comments claimed FDA overestimated the number of IVDs offered as LDTs on the market while others claimed FDA underestimated the number of IVDs offered as LDTs on the market. Some comments said the breadth of reach of LDTs is small whereas another comment pointed out that LDTs are used for routine clinical tests in addition to ''advanced diagnostics.'' One comment claimed that FDA's estimate of the number of IVDs offered as LDTs was more than ''10 times what researchers found in a peer-reviewed study published in the American Journal of Clinical Pathology of actual clinical test orders at University of Utah Health: 3.9%'' (see Ref. 68).

(Response 5) FDA acknowledges that it does not know exactly how many IVDs are currently offered as LDTs, precisely what those IVDs are used for, or the exact breadth of the reach of those IVDs. FDA will receive information regarding IVDs offered as LDTs and their intended uses through registration and listing in stage 2 of the phaseout policy. FDA disagrees with the assertion that the cited publication suggests that FDA's estimates may be 10 times higher than what has been reported in scientific literature. According to the publication cited in the comment, the percentage of test orders fulfilled with IVDs offered as LDTs at a single health system was 3.9 percent (which seems to have been the basis of the commenter's ''10 times higher'' claim) but the percentage of distinct tests that were IVDs offered as LDTs within this health system was 45 percent (880/1,954). While it is helpful to understand that 3.9 percent of test orders were fulfilled with IVDs offered as LDTs, this does not support the assertion that FDA's estimate of the percentage of *distinct* IVDs offered as LDTs is ''10 times higher'' than that reported by the publication. In section II.D of the PRIA, FDA estimated that LDTs account for about 50 percent of total IVDs that are used in some laboratories (see Ref. 60), which is very similar to the 45 percent reported in the publication. Additional information regarding these estimates is provided in response to comment 3 in the FRIA (see Ref. 10).

(Comment 6) One comment questioned FDA's statement that test results are often used by treating clinicians to inform their professional judgments and that the incidence of false positive and false negative test results inherent in any form of testing can present treatment challenges. This comment asserted that treating clinicians are well aware of the inherent limitations of testing, regardless of whether the test is an LDT or not, and that such clinicians base their treatment on holistic considerations of treatment factors. Thus, an erroneous test result from an LDT does not necessarily mean an erroneous treatment decision. A similar comment from a physician stated that FDA oversight will not increase the safety of LDTs and any risks associated with inaccurate test results are better left to physicians to assess.

(Response 6) FDA disagrees with these comments. Despite the suggestion to the contrary, not all clinicians are ''well aware'' of limitations of tests, including tests that are not FDA-authorized. Rather, FDA routinely consults with experts and has encountered many who do not understand the limitations of tests and do not consider that a test result provided by a test may be incorrect. For example, a cardiologist at an FDA public workshop on troponin testing stated, ''[d]octors trust numbers and if they are wrong we don't care we trust them anyway'' (Ref. 69). Similarly, an article authored by a physician and published in the Washington Post explained that his ''research has found that many physicians misunderstand test results'' and noted that ''your doctor may have a blind spot, an unconscious tendency to have too much trust in a test'' (Ref. 70). While we agree that erroneous test results do not *always* lead to direct harm/erroneous treatment decisions, they often do, and FDA is addressing these risks in the phaseout policy.

2. CLIA Oversight

(Comment 7) FDA received comments stating that CLIA and CLIA regulations do not provide sufficient regulation of manufacturer laboratories and their tests. One comment noted that this is because laboratories are not equipped with appropriate ''QMS systems,'' development teams, manufacturing, and production processes. Some comments stated that CLIA lacks requirements related to design controls and other important QS requirements. Comments also asserted that CMS does not review a laboratory's methodology for assessing analytical validity, does not assess clinical validity, and inspects only every 2 years under CLIA. A comment stated that CLIA and the related laboratory accreditation by CMS do not necessarily preclude additional oversight by FDA, especially for direct-to-consumer and ''commercialized'' products.

(Response 7) FDA agrees that CLIA and CLIA regulations are not a substitute for FDA's oversight of IVDs offered as LDTs under the FD&C Act. As discussed in the NPRM, laboratories that offer IVDs as LDTs are subject to both the FD&C Act and CLIA (88 FR 68006 at 68013–14). CMS determines whether a laboratory meets CLIA requirements, which is a specific role distinct from FDA's statutory responsibilities. FDA's device authorities under the FD&C Act are intended to help ensure that devices, including IVDs offered as LDTs, have appropriate assurance of safety and effectiveness.

FDA acknowledges that CLIA establishes requirements for laboratory operations and personnel and the issuance of clinical laboratory certifications. However, those requirements do not provide sufficient assurance of safety and effectiveness for the tests themselves. For example, in administering CLIA, CMS does not regulate critical aspects of laboratory test development; does not evaluate the performance of a test before it is offered to patients and healthcare providers; does not assess clinical validity (*i.e.,* the accuracy with which a test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient); does not regulate certain manufacturing activities, such as design controls and acceptance activities; does not provide human subject protections for individuals who participate in clinical trials; and does not require adverse event reporting. FDA also agrees that inspections under CLIA do not provide sufficient assurances of safety and effectiveness for IVDs offered as LDTs, as discussed further in response to comment 8.

CMS has consistently agreed that its role in administering the CLIA Program, which regulates the operations of clinical laboratories performing testing, is distinct from FDA's role in enforcing the FD&C Act to ensure that tests have appropriate assurance of safety and effectiveness. In order to ensure the accuracy and reliability of patient test results, the CLIA regulations provide oversight covering the operation and administration of the laboratory, to

include the appropriate qualification of its personnel. For example, the CLIA regulations include requirements pertaining to proficiency testing, laboratory personnel qualifications, test ordering and reporting, quality control, and the development and use of laboratory processes and procedures. FDA and CMS have long stood together in mutual support of FDA oversight of the analytical and clinical validity of LDTs, and CMS agrees with FDA that the CLIA program is separate in scope and purpose from FDA oversight (Ref. 71). Each regulatory scheme serves a different function, and as CMS notes, ''CMS and FDA's regulatory schemes are different in focus, scope, and purpose, but they are intended to be complementary'' (Ref. 26). In 2015, Dr. Patrick Conway, then the Deputy Administrator for Innovation and Quality & Chief Medical Officer of CMS, stated that ''CMS does not have scientific staff capable of reviewing complex medical and scientific literature in determining clinical validity. This expertise resides within the FDA, which assess the clinical validity in the context of premarket reviews and other activities aligned with their regulatory efforts under the Food, Drug and Cosmetic Act.'' Statement of Dr. Patrick Conway, Deputy Administrator for Innovation and Quality & Chief Medical Officer, CMS, Committee Hearing (October 29, 2015), at 25. This was not a new position for CMS; nearly 30 years earlier, the then-Administrator of the Health Care Financing Administration (HCFA, CMS's predecessor agency) stated that FDA, under the FD&C Act, had a role to play in the regulation of laboratory testing: ''On the quality issue, first, the Health Care Financing Administration has oversight authority and will use that to do a better job under our new regulations. The role of the Centers for Disease Control is to provide expert advice to us on how we regulate laboratories. The role of the FDA is in oversight of the devices and other technical aspects of lab testing.'' Statement of Dr. William L. Roper, Administrator, HCFA, Committee Hearing on H.R. 4325 (July 6, 1988), at 77.

(Comment 8) FDA received several comments stating that CLIA provides sufficient regulation of IVDs offered as LDTs. Some comments stated that regulation under CLIA is sufficient because obtaining a CLIA certificate requires a laboratory to demonstrate that the personnel in the laboratory have the training, experience, and level of proficiency required to perform the types of tests offered by the laboratory. Other comments stated that regulation under CLIA is sufficient because CLIA-certified laboratories are subject to inspections to confirm that the testing complies with CLIA regulations, including ensuring that there is adequate validation of the tests, supervision by the laboratory director, and quality procedures. Many comments contended that laboratories certified by CLIA follow a robust and rigorous set of requirements regarding validation, verification, and monitoring of IVDs offered as LDTs. In particular, some comments asserted that CLIA provides a regulatory mechanism designed to ensure accurate test results. Other comments stated that FDA has not demonstrated that FDA's premarket review process is more effective than CLIA in ensuring the accuracy of tests.

(Response 8) FDA acknowledges that CLIA and CLIA regulations establish requirements for laboratory operations and laboratory personnel, and specific requirements that must be met to obtain a clinical laboratory certification (see, *e.g.,* 42 CFR part 493 subparts C, K, and M). CLIA-certified laboratories also are subject to inspection under 42 CFR part 493 subpart Q to verify that laboratories are conducting testing in compliance with the CLIA regulation. Inspections do not, however, verify that the tests themselves comply with the requirements of the FD&C Act that are designed to ensure that tests have appropriate assurance of safety and effectiveness for their intended purpose. Likewise, while FDA agrees that CLIA-certified laboratories are required to meet certain verification, validation, and monitoring requirements, FDA disagrees that those requirements provide sufficient assurance of safety and effectiveness for the tests themselves. As more fully set forth in response to comment 7, CMS does not regulate critical aspects of laboratory test development; does not evaluate the performance of a test before it is offered to patients and healthcare providers; does not assess clinical validity; does not regulate certain manufacturing activities; does not provide human subject protections for individuals who participate in test clinical trials; and does not require adverse event reporting.

FDA disagrees with comments indicating that FDA's premarket review process ''is not more effective'' than CLIA regulation. FDA's premarket review process serves a role that CLIA regulation does not. During review of a marketing submission for an IVD, FDA reviewers closely examine data relevant to safety and effectiveness and draw on their expertise and experience to understand both the product and the science supporting the product. FDA reviewers evaluate whether a test accurately and reliably detects or quantifies its intended target and whether results from the test accurately and reliably identify, measure, or predict the presence or absence of the intended clinical condition or predisposition. For example, for a test that is intended to detect genetic variants to predict the risk of a person developing a particular disease, FDA reviewers would evaluate whether the test can accurately and reliably detect the intended genetic variants in the intended use specimen type (*e.g.,* blood, saliva), and they would also evaluate evidence demonstrating whether the genetic variant is associated with the risk of developing that particular disease. As another example, for a test intended to quantify the levels of a protein to aid in the diagnosis of a particular disease, FDA would evaluate whether the device can accurately and reliably quantify the levels of the protein in the intended specimen type and also whether the levels of protein quantified by the test can be used to diagnose the disease. FDA also reviews IVD labeling to ensure there are adequate instructions for use, which includes directions for performing the test and interpreting the results, warnings, limitations, a summary of test performance (for example, accuracy), and how the results are reported. See our response to comment 10 for additional discussion of FDA's expertise.

(Comment 9) FDA received comments stating that regulation under CLIA is sufficient because CLIA-certified laboratories perform proficiency testing to ensure that assays are performing properly. One comment suggested that FDA authorization is a one-time event with no ongoing monitoring of product performance, whereas proficiency testing is an ongoing requirement through which laboratories periodically confirm their capabilities to perform tests. In contrast, FDA received a comment which suggested that proficiency testing is not sufficient, as a laboratory may fail proficiency testing several times before receiving a notice to cease testing.

(Response 9) FDA disagrees that proficiency testing provides sufficient regulation of IVDs offered as LDTs. Under CLIA, enrollment in a Department of Health & Human Services (HHS)-approved proficiency testing program is a requirement for only a portion of tests that a laboratory offers, and proficiency testing programs do not

address all IVDs offered as LDTs (see 87 FR 41194). Under the CLIA regulations, proficiency testing is required for only the limited number of analytes found in 42 CFR part 493 subpart I (Proficiency Testing Programs for Nonwaived Testing), which are referred to as ''regulated'' analytes by CMS. From the list of LDTs approved by NYS CLEP, FDA has seen that many IVDs offered as LDTs are tests for analytes other than the regulated analytes listed in 42 CFR part 493 subpart I. Additionally, the list of regulated analytes does not include any genetic markers, and FDA is aware from the NYS CLEP approval database as well as discussions with stakeholder that many IVDs offered as LDTs are genetic tests. There are also many other analytes for which there are no programs that offer proficiency testing. When a laboratory performs tests, including IVDs offered as LDTs, for analytes that are not regulated under CLIA or where there is no proficiency testing program available, the laboratory is required only to verify the accuracy of the test at least twice annually, which may be done by splitting a patient sample with a laboratory that offers the same test and comparing results. The number of samples tested and the acceptability of the results is determined by the laboratory director. Comparing results from a small number of samples, possibly even a single sample, without prospective metrics for success is not equivalent to a prospective determination of safety and effectiveness prior to initiating testing on patient samples. FDA also appreciates the concern raised in the comment which stated that laboratories may potentially continue testing after failing proficiency testing. For these reasons, proficiency testing alone does not provide sufficient assurance of safety and effectiveness for an IVD offered as an LDT for its intended use.

FDA also disagrees with the suggestion that FDA regulation involves no ongoing monitoring of product performance. Under FDA regulations, test manufacturers are generally subject to a variety of ongoing requirements, including labeling requirements, registration and listing, quality system requirements, adverse event reporting, and periodic inspections that confirm compliance with design controls and other QS requirements.

(Comment 10) A number of comments suggested that FDA is not the appropriate entity to oversee LDTs, and that any changes to the manner in which tests are regulated should be implemented through amendments to CLIA, or through modifications to the CLIA regulation, which many comments described as ''modernizing'' that regulation. Comments asserted that FDA does not have the required expertise, and one comment stated that CMS/CLIA and certain CLIA accreditation organizations are best able to verify the accuracy of laboratory testing. This comment stated that requiring all ''laboratory testing'' to be certified under CLIA would be better than enforcing laboratory compliance with medical device regulations. Other comments stated that complaints about test quality should be evaluated by CMS rather than FDA, to avoid creating what the comments described as duplicative regulation. Some comments noted that laboratories are unfamiliar with the premarket requirements and other requirements of the FD&C Act. Some comments argued that FDA is slow to clear or approve tests, and asserted that for that reason, FDA should not oversee IVDs offered as LDTs. On the other hand, some comments asserted that FDA has a role to play in assuring that tests produce reliable results for patients and providers, and some comments pointed to FDA's demonstrated expertise in review of analytical and clinical validity of IVDs.

(Response 10) FDA does not agree that concerns regarding the safety and effectiveness of LDTs should be addressed by amending CLIA or modifying the CLIA regulation. CMS determines whether a laboratory and its personnel meet CLIA requirements, whereas FDA, among other things, reviews and evaluates the tests themselves, including IVDs offered as LDTs, to ensure that they have appropriate assurance of safety and effectiveness under the FD&C Act. CMS and FDA agree: CMS does not have the resources and expertise to assure that tests work for their intended clinical purpose; FDA does (Ref. 71). Congress specifically charged FDA with such oversight, as discussed further in response to comments in section VI.D.2. In particular, FDA has the scientific and regulatory expertise to review data and information on individual IVDs offered as LDTs and determine their safety and effectiveness. FDA employs hundreds of scientists with expertise in review of safety and effectiveness, including those who have worked in clinical laboratories and developed LDTs. FDA is comprised of physicians, statisticians, engineers, biologists, chemists, geneticists, and others, who evaluate the science behind medical products before they are marketed and utilized. Understanding the complex technical information in applications, such as clinical trial data, bench testing results, and product design characteristics—and putting that information in context to assess whether a product has appropriate assurance of safety and effectiveness for its intended use—is within FDA's unique expertise. This type of expertise is no less important for IVDs offered as LDTs, the safety and effectiveness of which may significantly impact not only individual health but also the public health, as described elsewhere in this preamble.

Moreover, establishing a duplicative system for the oversight of IVDs would create bureaucracy and inconsistencies (Ref. 71). As described in the NPRM, such an approach would cause a problematic split in oversight, with the same types of IVDs being reviewed by different Agencies depending on where the IVD was made (88 FR 68006 at 68014). For example, a cancer diagnostic test developed by a conventional manufacturer would be reviewed by FDA while a similar cancer diagnostic test (using the same sample type and testing for the same analytes) developed by a laboratory would be reviewed by another Agency. Further, with that divided oversight, an IVD developed by a conventional manufacturer could even be reviewed and cleared by FDA and subsequently reviewed by another Agency if a laboratory made certain modifications to it. However, if those same modifications were made by the original manufacturer, they would be reviewed by FDA. This could lead to confusion and inconsistency.

In response to the comment that stated that CLIA should require certification of all ''laboratory testing,'' FDA acknowledges that CLIA establishes requirements for laboratory operations and their personnel and issues clinical laboratory certifications. However, FDA disagrees that those requirements provide sufficient assurance of safety and effectiveness for the tests themselves. CLIA does not assess clinical validity or certain manufacturing activities.

We further note that to the extent laboratories may be unfamiliar with the premarket requirements of the FD&C Act, current familiarity with applicable requirements is not determinative of the need for such requirements to be enforced. FDA has made several resources available to stakeholders to increase familiarity with applicable requirements, including final guidance documents and information on FDA's website (see, *e.g.,* Ref. 72), and will provide additional materials and outreach to laboratories during the phaseout period. In addition, with respect to the speed of FDA's premarket

review, FDA notes that its premarket review timelines are negotiated with industry in connection with MDUFA reauthorization. For information regarding FDA's recent performance with respect to MDUFA decision goals, see Ref. 73. FDA generally meets the timeframes for MDUFA decisions negotiated with industry, including for IVD submissions. However, FDA's response to the unprecedented COVID–19 public health emergency significantly impacted the Agency's ability to meet its MDUFA IV performance goals, resulting in some missed decision goals.

(Comment 11) Comments stated that CLIA has its own mechanism for making improvements to its regulations, through the Clinical Laboratory Improvement Advisory Committee (CLIAC), which includes members from the Centers for Disease Control and Prevention (CDC) and FDA. Comments noted that CLIAC has provided advice and guidance to HHS on revisions and improvements to the CLIA standards. Comments suggested that modernizing CLIA is a pathway which is supported by a significant number of ''major organizations.'' A comment stated that effectuating changes through CLIA would be a streamlined and cost-effective approach, for both the government and laboratories, and the least disruptive and burdensome approach to addressing clinical and analytical validity, transparency, and other concerns.

(Response 11) FDA disagrees with these comments. CLIAC's advice is one of many sources available to the Secretary of HHS (Secretary) and is only a recommendation (Ref. 74). As set forth in response to comments 7 and 10, neither CMS nor FDA consider changing CLIA or the CLIA regulations to be appropriate to address the issues discussed in this preamble; to the contrary, it would lead to costly and inefficient bifurcation of the regulation of IVDs offered as LDTs. FDA appreciates that stakeholders seek a streamlined, cost-effective approach that is the least disruptive to their laboratories. FDA shares those goals, which are addressed throughout this preamble, and particularly in the phaseout policy described in section V.

(Comment 12) FDA has received comments stating that FDA oversight of IVDs offered as LDTs would be duplicative of, or conflict with, CLIA. In particular, comments stated that QS requirements and validation requirements would be duplicative or conflict. A comment stated that FDA oversight of LDTs is not in line with Executive Order (E.O.) 13563, which asks executive branch agencies to harmonize regulatory requirements. In addition, some comments stated that increased oversight would be cumbersome, and therefore would not follow FDA's least burdensome principles.

(Response 12) FDA disagrees with these comments. As set forth elsewhere in this preamble, CMS and FDA enforce two different regulatory schemes, separate in scope and purpose from each other. CMS agrees the two are complementary, not duplicative, as discussed in response to comment 7. The portion of CLIA that addresses quality systems relates to laboratory operations, laboratory personnel, and requirements for laboratory procedures relevant to testing. FDA's QS requirements are focused on design control and validation and other requirements intended to ensure that the IVD has appropriate assurance of safety and effectiveness for its intended use. FDA also notes that this rule comports with E.O. 13563 because this rule promotes coordination and harmonization by taking into account the assurances that CLIA provides (see section V.C).

As described in section V.C regarding FDA's intention to phase out the general enforcement discretion approach with respect to QS requirements during stage 3 of the phaseout policy (other than requirements under § 820.198 (complaint files), which are addressed in stage 1), FDA intends to take into account CLIA requirements as appropriate. As to validation, CLIA regulations do not address clinical validation of tests, and analytical validation under CLIA is different from that under the FD&C Act. FDA's review of analytical validity (*i.e.,* the ability of the test to accurately and reliably measure or detect the analyte(s) it is intended to measure or detect) is done prior to marketing, and FDA assesses the analytical validity of the IVD offered as an LDT in greater depth and scope. FDA also assesses clinical validity, which is the accuracy and reliability with which the test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient, in reviewing the safety and effectiveness of the test. As noted, unlike the FDA regulatory scheme, CMS' CLIA program does not address the clinical validity of any test.

We also note that FDA collaborates closely with CMS. The two Agencies have entered into a memorandum of understanding that facilitates information sharing, and FDA, CMS, and CDC participate in monthly ''Tri-Agency'' meetings to discuss topics related to CLIA oversight. Tri-Agency meetings often include sharing of non-CLIA information that is pertinent to the CLIA program, such as issues related to specific tests, safety communications, recalls, or warning letters. FDA and CMS also share information between meetings as needed, particularly when there are signals that may warrant investigation by either Agency.

FDA also disagrees that increased FDA oversight of IVDs offered as LDTs would not follow FDA's least burdensome principles. As explained in a final guidance document issued by FDA on February 5, 2019, entitled ''The Least Burdensome Provisions: Concept and Principles,'' FDA ''defines least burdensome to be the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time (*e.g.,* need to know versus nice to know). Our least burdensome definition and principles do not change the applicable statutory and regulatory standards, such as the device authorization standards, nor the applicable requirements, including premarket submission content requirements and the requirement for valid scientific evidence'' (Ref. 75). In developing the phaseout policy, FDA has considered least burdensome principles consistent with this definition. As described extensively in the NPRM and this preamble, oversight of LDTs is necessary to adequately address safety and effectiveness concerns regarding LDTs. The phaseout policy is designed to achieve this objective in the most efficient manner and at the right time, by phasing out the general enforcement discretion approach with respect to applicable statutory and regulatory requirements in a gradual manner and including various targeted enforcement discretion policies, as further described in section V. With respect to the comment that invoked E.O. 13563, we note that section 7(d) of the E.O. states that it ''is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity. . . .''

(Comment 13) FDA received comments which stated that FDA oversight is not necessary, as CLIA has its own enforcement mechanism. Some comments stated that CMS can, and has, used its enforcement capability from CLIA to sanction both laboratories and individual laboratory directors. Some comments stated that FDA oversight is unnecessary, because laboratory medical directors have medical, legal, and ethical responsibility for their laboratories, which includes personally

approving all new technical procedures and approving all test validations. One comment stated, however, that when an LDT does not meet specifications or ''quality standards,'' a laboratory director can continue to release results after making ''a deviation/exception report.''

(Response 13) FDA agrees that CLIA has certain enforcement capabilities, and that CMS has exercised those enforcement tools to take certain actions against laboratories that do not comply with CLIA regulations. FDA also agrees that medical and laboratory directors have responsibilities for their laboratories, and that some of those responsibilities include approving certain procedures and activities. However, FDA disagrees that relying on CMS enforcement tools, personal responsibilities, or the activities of the laboratory director alone are sufficient to protect the public health if a test does not have appropriate assurance of safety and effectiveness. As one comment noted, under CLIA, laboratory directors may continue to release test results that do not meet their own specifications. The CLIA regulations focus on laboratory operations whereas the FD&C Act focuses on the design and manufacturing of the test. While this rule does not change the responsibilities of a laboratory director, FDA oversight ensures compliance with quality requirements set forth in the FD&C Act.

In contrast to CMS, FDA generally is authorized to review the safety and effectiveness of individual IVDs, including an IVD offered as an LDT, prior to marketing, to impose special controls or post-approval conditions for certain tests as risk mitigations, to receive reports of device malfunctions and adverse events, and to require reports of corrections and removals of a device, as well as to take specific steps when a device presents a risk to the public health such as advisory, administrative, or enforcement actions, including issuance of warning letters, injunction, seizure, mandatory recall, and assessment of civil monetary penalties.

(Comment 14) A comment suggested that instead of implementing FDA's proposal, FDA should work with CMS to establish a national registry of LDTs to register all existing and new LDTs. The comment suggested that FDA include in that registry test type classification, clinical utility claims, and validated performance with confidence intervals or other relevant statistics. The comment further suggested that FDA coordinate with CMS, CAP, clinical laboratory professional organizations, AMCs, and ''commercial'' laboratories to establish a system for LDT review and regulation.

(Response 14) FDA enforcement of existing registration and listing requirements is appropriate for IVDs offered as LDTs. FDA already has a process and database for establishment registration and device listing, and there is no need to establish a new ''registry'' for LDTs. FDA also has labeling requirements for IVDs in part 809 that include, among other things, required information on performance characteristics. Given the existing statutory and regulatory framework, there is no need to establish a new system for LDT review and regulation as suggested by the comment. As set forth in section V.C, FDA is phasing out the general enforcement discretion approach with respect to registration and listing requirements (21 U.S.C. 360, part 607 (for IVDs subject to licensure), and part 807 (excluding subpart E)) 2 years after the phaseout policy is published. Under this timeline, FDA will be able to utilize registration and listing information to obtain an initial understanding of the universe of IVDs offered as LDTs to facilitate premarket review of those IVDs. As set forth in section V.C, FDA also is phasing out the general enforcement discretion approach with respect to labeling requirements 2 years after the phaseout policy is published.

(Comment 15) Some comments claimed that the fact that FDA has identified some problematic tests demonstrates that CLIA is providing sufficient oversight. Comments requested that FDA explain why CLIA regulation is insufficient for the majority of laboratories that follow CLIA guidelines. See also comment 16.

(Response 15) FDA agrees that CLIA serves an important role: CMS regulates laboratories that perform testing on individuals in the United States by regulating laboratory testing and personnel under CLIA. As discussed elsewhere in this preamble, CLIA is separate in scope and purpose from the FD&C Act and FDA regulations. CLIA regulations help to determine whether laboratories are conducting testing in a manner consistent with CLIA, but CLIA does not ensure that the test itself has appropriate assurance of safety and effectiveness for its intended use.

As more fully set forth in section III.B and in response to comments in section VI.C.4, FDA is aware of numerous examples of potentially inaccurate, unsafe, ineffective, or poor quality IVDs offered as LDTs that caused or may have caused patient harm. FDA would not expect the types of problems observed among these IVDs offered as LDTs to be identified under CLIA, and as described elsewhere in this preamble, the evidence of these problems cuts across test types and laboratories and is from a variety of sources, including published studies in the scientific literature, allegations of problematic tests reported to FDA, FDA's own experience in reviewing IVDs offered as LDTs, news articles, and class-action lawsuits.

(Comment 16) Several comments asserted that FDA's experience with Theranos is evidence that FDA oversight will not address problematic tests, particularly those that are fraudulent. They pointed out that FDA cleared a 510(k) from Theranos and that the company's fraudulent behaviors were addressed by CMS through the CLIA program.

(Response 16) This comment does not reflect a complete accounting of events. First, FDA cleared one test from Theranos early in our experience with the company. Per standard practice, FDA reviewed the data provided and based our decision on it. We subsequently identified significant device performance concerns based on the data submitted in submissions for other tests of Theranos, including questions about inaccurate results that may put patients at risk. We did not clear those devices. Less than 2 months after the clearance of the one test, we sent investigators to all Theranos sites, where we identified concerns with IVDs offered as LDTs and an unapproved collection device (Ref. 76). Recognizing the immediate risk to patients, we took a strategic compliance approach. Specifically, FDA took quick action that directly led to the firm ceasing distribution of its unapproved collection device. We also alerted CMS to potential CLIA concerns, and CMS promptly confirmed CLIA violations in a follow-up inspection. Thus, FDA was integral to the government's handling of Theranos, and FDA disagrees with the comment's assertions that FDA did not address problematic IVDs offered as LDTs by Theranos.

(Comment 17) Some comments suggested that CLIA could be ''modernized'' to incorporate oversight of clinical validity and address concerns raised by FDA.

(Response 17) These comments are outside the scope of this rulemaking. This rulemaking is focused on FDA's oversight of devices under the current statutory authorities set forth in the FD&C Act, and in consideration of CMS's current authorities under CLIA.

In any event, FDA disagrees that concerns with IVDs offered as LDTs should be addressed through expansion

of CLIA. First, the authority and expertise to oversee the safety and effectiveness of tests already lies with FDA, and not with CMS; expanding CMS oversight would require legislation and would establish a duplicative regulatory program. Second, neither FDA nor CMS supports such an approach. It would establish a dual system for the oversight of tests and create more government bureaucracy, duplication of effort, and potential inconsistencies. For example, a test made by a non-laboratory manufacturer (and any modifications to that test made by the laboratory manufacturer) would be regulated by FDA, but if the test is modified by a laboratory, CMS would regulate it. The same/similar tests made by a laboratory and non-laboratory manufacturer would be reviewed by two different agencies under different frameworks. This approach does not make sense.

3. Other Controls

(Comment 18) FDA received comments claiming that FDA should not enforce the requirements of the FD&C Act for IVDs offered as LDTs, as it is more appropriate for accrediting entities, including the Commission on Office Laboratory Accreditation (COLA), CAP, the Accreditation Commission for Health Care (ACHC), the Association for the Advancement of Blood and Biotherapies (AABB), the Joint Commission, and ASHI to oversee IVDs offered as LDTs. Some comments suggested that FDA should exercise enforcement discretion with respect to IVDs offered as LDTs at certain facilities with relevant accreditations, such as accreditation by ASHI or the Foundation for the Accreditation of Cellular Therapy (FACT), because such accreditations provide the necessary assurances relevant to the type and volume of work performed by these accredited facilities.

(Response 18) FDA disagrees that CLIA accreditation organizations such as COLA, CAP, or ACHC provide sufficient oversight of IVDs offered as LDTs. As discussed in response to comment 7, CLIA accreditation entities, including COLA, CAP, and ACHC, determine whether a laboratory meets CLIA requirements. Moreover, various accreditation entities, including AABB, the Joint Commission, ASHI, and FACT, may also determine whether a laboratory meets these organizations' voluntary accreditation standards. Unlike these organizations, which assess laboratories/laboratory operations under CLIA and their own accreditation standards, FDA (and FDA's device authorities under the FD&C Act) focus on whether devices, including IVDs offered as LDTs, have appropriate assurances of safety and effectiveness.

In particular, COLA evaluates and, if appropriate, certifies that certain laboratories that conduct tests in certain specialties (chemistry, hematology, microbiology, immunology, and immunohematology/transfusion services) meet CLIA requirements and any applicable COLA accreditation standards (Ref. 77). CAP conducts inspections to determine compliance with CLIA and applicable CAP accreditation standards (Ref. 78). Although CAP and COLA have their own accreditation standards, these additional standards address the manner in which the laboratory performs tests, and do not assess the clinical validity of the test itself. COLA and CAP do not perform premarket review of individual IVDs offered as LDTs for overall safety and effectiveness for the devices' intended uses. More generally, third-party accreditation entities have their own standards for accreditation of facilities that may not assess the clinical validity of the tests that the facility performs. Thus, an accreditation of a facility by one of these third parties does not, on its own, provide sufficient assurance of safety and effectiveness for the IVDs offered as LDTs by the accredited facility for their intended uses.

We note that pursuing CAP, COLA, ACHC, AABB, Joint Commission, ASHI, or FACT (or other) accreditation is a voluntary process. CAP, COLA, and other accreditation organizations' standards are not regulatory or statutory requirements.

Finally, we note that for reasons more fully set forth in response to comment 7, FDA is the appropriate entity to provide the necessary oversight of IVDs offered as LDTs to better assure their safety and effectiveness.

(Comment 19) FDA received comments stating that many laboratories follow guidelines provided by the Association for Molecular Pathology (AMP), the International Clinical Cytometry Society (ICCS), and the Clinical and Laboratory Standards Institute (CLSI), and voluntary standards issued by ISO. Some comments suggested that laboratories that follow such standards are already highly regulated. Other comments stated that following such guidelines and/or standards provides a level of assurance that the laboratories' assays are ''safe and reliable.'' Comments recommended that FDA permit AMP, ICCS, CLSI, and other entities to continue to offer such guidelines. Another comment stated that the ''solution for . . . incompetent tests should be . . . standardization and not regulation.''

(Response 19) FDA acknowledges that many entities, including the entities that the comments listed, offer guidelines, standards, and other resources to laboratories. However, the guidelines and standards that the comments describe are, in most instances, voluntary and non-binding.[51] FDA disagrees that a laboratory that chooses to follow such guidelines or standards is ''highly regulated'' as a result of these voluntary actions. FDA further disagrees that following such voluntary guidelines or standards provides assurances of safety or reliability (or effectiveness), as the guidelines and standards do not address IVD safety and effectiveness (see, *e.g.,* Refs. 79 to 81). Notably, nothing in this rule will prevent AMP, ICCS, CLSI, or other entities from continuing to provide voluntary guidelines or standards to laboratories.

(Comment 20) Comments asserted that the Federal program entitled Molecular Diagnostic Services (MolDx) already provides significant regulatory oversight and overlaps with FDA's proposal. Comments also stated that MolDx addresses technical requirements for assays by assessing a test's analytical and clinical validity, and for this reason, the comments suggested that increased FDA oversight is not needed.

(Response 20) FDA regulation and the MolDx program differ in several key respects. MolDx is a limited program, which evaluates whether tests are reasonable and necessary with a focus on the Medicare population (Ref. 82). In contrast, FDA's authority extends to IVDs for all people and includes various compliance and enforcement authorities (that MolDx lacks), which enable FDA to take action when an IVD presents a risk to health (*e.g.,* through recalls). The MolDx program does not mitigate the need for increased FDA oversight of IVDs offered as LDTs.

(Comment 21) FDA received a comment stating that CDC's Newborn Screening Laboratory Quality Assurance Program (NSQAP) administers proficiency testing and validates new screening tests, ensuring the accuracy of results generated by laboratories. The comment suggested that because of this program, increased FDA oversight is not needed.

(Response 21) FDA disagrees that NSQAP is a substitute for FDA oversight

[51] FDA may incorporate a voluntary consensus standard by reference. *See* 5 U.S.C. 552(a) and 1 CFR part 51. Where FDA has incorporated a voluntary consensus standard by reference, that standard is treated as if it were published in the **Federal Register** and CFR, and this material has the full force and effect of law.

of IVDs offered as LDTs. The NSQAP program provides quality assurance services to newborn screening laboratories by providing reference materials, providing proficiency testing regarding laboratory operations, providing quality control reports, and offering training and consults (Ref. 83). NSQAP evaluates the proficiency of laboratory personnel and procedures, not the safety and effectiveness of IVDs offered as LDTs. See our response to comment 9 for additional discussion regarding proficiency testing.

(Comment 22) Comments stated that New Jersey and Washington certification programs ensure that laboratories conduct LDT validations and proficiencies at high quality standards. The comments stated that laboratories that adhere to New Jersey's certification requirements and other certification programs provide patients with a high level of care. The comments suggested that such certification programs obviate the need for increased FDA oversight.

(Response 22) FDA acknowledges that several States have certification programs. New Jersey and Washington State certification programs certify laboratories within those states if they meet the State certification requirements. FDA disagrees, however, that compliance with these State certification requirements provides sufficient risk mitigations for IVDs offered as LDTs. For example, there is no indication that these State programs evaluate both the analytical and clinical validity of LDTs (see Refs. 84 and 85). According to the website of the cited program in Washington State, the program covers licensure, biennial surveys, and proficiency testing (Ref. 84). In the comment submitted to the docket regarding New Jersey's program, no specific information or citation was provided regarding the program. Nor did FDA receive a comment to the docket from the New Jersey program. Based on information available to FDA regarding New Jersey's program, we believe this program is focused on laboratory operations, and not the evaluation of the IVDs themselves (see Ref. 85).

(Comment 23) Some comments stated that when electronic medical records (EMRs), inter-specialty cooperation, and educational and safety-reporting systems are integrated within a healthcare system, the risk to patients from IVDs manufactured by the laboratory within that system is minimized and there is no need for additional FDA oversight.

(Response 23) FDA disagrees that these elements alone are a substitute for FDA oversight of IVDs offered as LDTs. FDA acknowledges that these elements may play a role in patient care, but FDA oversight of IVDs offered as LDTs serves a vital role in assuring the appropriate safety and effectiveness of the IVDs. Critical aspects of FDA's oversight, including premarket review, QS, registration and listing, centralized adverse event reporting, labeling, and other requirements, are not addressed by the elements described in these comments.

We note that FDA does believe that integration of a laboratory within a healthcare system provides some risk mitigations, as discussed further in section V.B.3. FDA has taken those risk mitigations into consideration in adopting an enforcement discretion policy for premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

(Comment 24) One comment stated that concerns about manufacturing controls and other device-specific concerns regarding IVDs offered as LDTs are managed by ''lot-to-lot'' validation and a laboratory's quality control.

(Response 24) FDA disagrees with this comment. While premarket and post-market validation activities are an essential element of quality management, there are other critical aspects of a quality management system, and a laboratory's quality control does not address other critical aspects of FDA oversight.

(Comment 25) FDA received comments which noted that laboratories consult with clinicians, diagnosticians, tumor boards, and case conferences, and which suggested that this consultation provides clinical validation and ensures that tests are interpreted appropriately.

(Response 25) FDA disagrees that consultation provides clinical validation, or that consultation alone is a substitute for FDA oversight of IVDs offered as LDTs. Although FDA agrees that consultation between laboratories and clinicians, diagnosticians, and others as described in this comment may help to mitigate risks from IVDs offered as LDTs in certain circumstances and particularly in the context of LDTs for unmet needs (see further discussion in section V.B.3), such consultation does not obviate the need for FDA oversight such as would justify continuing the general enforcement discretion approach for all FDA requirements for all LDTs, as suggested by the comments.

(Comment 26) FDA received a comment stating that ''financial restrictions to laboratory testing'' represent another layer of oversight beyond CMS and FDA regulation, and serve to maintain the quality of laboratory testing. The comment did not define ''financial restrictions,'' but referenced payment codes and payor coverage decisions. The comment suggested that because of this additional layer of oversight, increased FDA oversight is not needed.

(Response 26) FDA disagrees that ''financial restrictions'' related to coverage and reimbursement considerations provide sufficient assurances of safety and effectiveness for IVDs offered as LDTs. In the analysis that CMS conducts to determine Medicare coverage, it may consider various factors, including coverage indications, coverage limitations, and the clinical circumstances that demonstrate medical necessity, but those factors are not equivalent to, or a substitute for, the assurances of safety and effectiveness provided by FDA oversight. In general, CMS considers claims after marketing evaluations regarding whether expenses incurred are reasonable and necessary for the diagnosis and treatment of illness or injury or improve the functioning of a malformed body member, and whether the claim for payment contains the necessary information for CMS to process the claim (see section 1862(a)(1)(A) and section 1833(e) of Title XVIII of the Social Security Act).

(Comment 27) One comment indicated that ''review by peer organizations'' would be superior to FDA review due to subspecialty expertise and cost ''to the taxpayer.''

(Response 27) FDA disagrees that review by peer organizations would be superior to FDA review of IVDs offered as LDTs due to subspecialty expertise. First, FDA has the appropriate expertise to review the safety and effectiveness of IVDs, as discussed in response to comments 7 and 10. Where additional expertise may be beneficial, FDA can seek input from advisory committees in accordance with the Federal Advisory Committee Act. Second, peer review may introduce bias and variability of oversight, particularly if unblinded. For example, where two peers review each others' work, they may potentially be inclined to overlook issues and expect the same in return.

Use of peer reviewers is also not necessary to address costs to taxpayers or FDA. FDA receives funding from Congressional non-user fee appropriations (''budget authority'') and user fees to support operation of the

medical device program, including premarket review. FDA also intends to enhance the Third Party review program, which will reduce costs to the Agency while providing for assistance with 510(k) reviews by entities that are independent of the manufacturer.

4. Evidence of the Need for Greater FDA Oversight

(Comment 28) FDA received comments stating that there is no problem with LDTs. One comment from a laboratory director voiced confidence in LDT results and stated that any areas for improvement seldom have to do with ''faulty results or improper care related to testing.'' Other comments stated that the errors in laboratory testing often stem from operational issues and human error rather than the design or nature of LDTs, and opined that FDA oversight would not address these issues. Several asserted that laboratories are diligent in their validation of LDTs, that there is no evidence of problems with LDTs, and that LDTs are as safe as FDA-authorized tests. One comment cited a 2014 publication concluding that the quality of clinical DNA testing for rare diseases in the United States was excellent (Ref. 86). Another comment pointed to a 2022 opinion article in the Wall Street Journal claiming ''a review of all reported cases in state and federal courts reveals no reported suits filed against a laboratory for an LDT result'' (Ref. 87).

FDA also received comments indicating problems with LDTs. One comment described the commenter's experience witnessing ''unsafe practices similar to those described in FDA's proposed rule'' while working in a profitable laboratory. This commenter left that laboratory to work at ''labs that care for the health of individuals.'' Another comment described the commenter's experience with marketing of RUO products for clinical diagnostic testing. One company reported that laboratories offer inferior LDTs that compete with the company's FDA-approved test, and that proficiency testing programs allow inferior tests to pass. In these cases, patients receiving an inferior test may not get the most up to date treatment they should have. An AMC laboratory director indicated the laboratory often sees inconsistent results for the same patient tested in the AMC laboratory and at reference laboratories. Several other comments, including comments submitted by healthcare providers, laboratorians, patients, and public interest organizations, provided specific examples of problematic IVDs offered as LDTs, including IVDs offered as LDTs that, according to the comments, lacked clinical validity, provided false results, provided inconsistent results, or were promoted with false or misleading claims. A comment submitted by NYS CLEP described several examples of LDTs that NYS CLEP did not approve based on the original application due to issues such as design flaws and inadequate validation data, including an LDT with an ''error [that] would have endangered patient safety.'' Another comment submitted in support of FDA's proposal stated that ''[t]he current state of laboratory developed testing in the US is quite honestly, astonishingly bad. . . . as a CAP inspector, I have seen firsthand the absolutely shoddy laboratory developed tests in place at many laboratories.''

(Response 28) The information discussed in the NPRM, and additional information provided in various comments submitted to the Agency, demonstrates that performance problems exist with certain IVDs offered as LDTs (see 88 FR 68006 at 68010–12). FDA disagrees with comments claiming that there is no problem with LDTs or that deficiencies in laboratory testing are mostly caused by operational or human error. As described in the NPRM (88 FR 68006 at 68010–12), in memoranda included in the docket for this rulemaking (Refs. 16 and 18), and in other comments submitted to the docket such as those described above, we are aware of problems with IVDs offered as LDTs, many of which stem from issues with the IVD itself, such as design issues. We have become aware of these problems even though the general enforcement discretion approach has applied to requirements for postmarket reporting, such as MDR requirements.

We acknowledge that the 2014 publication cited in the comment refers to a ''high level of confidence that most U.S. laboratories offering rare disease testing are providing consistent and reliable clinical interpretations''; however, this is based on a survey conducted from 2010 through 2012 for a proficiency testing program to assess the performance of laboratories running Sanger sequencing IVDs for rare and ultra-rare disorders. Laboratory proficiency testing results for Sanger sequencing IVDs for rare and ultra-rare diseases from over a decade ago do not support the assertion that the quality of clinical DNA testing in the United States is excellent today, let alone that there are no concerns with IVDs offered as LDTs generally. First, proficiency testing data are not appropriate as standalone or comparative results to support test validation and performance. Please see our response to comment 34 for a more detailed assessment of the limitations of proficiency testing data. Second, laboratory performance for Sanger sequencing IVDs for rare and ultra-rare disorders, which are a limited subset of genetic IVDs, do not represent the landscape of clinical genetic tests used today where most tests use next generation sequencing (NGS) and other technologies. As noted in the NPRM, FDA's concerns with IVDs offered as LDTs have grown in recent years (88 FR 68006 at 68010). Moreover, we disagree with the statement that no suits have been filed against a laboratory for a false result associated with an IVD offered as an LDT; the NPRM cited evidence to the contrary (see 88 FR 68006 at 68012 (stating that ''consumers, shareholders, and investors are filing lawsuits against laboratory manufacturers for false and misleading statements about test efficacy,'' and citing to Complaint, *Davis* v. *Natera, Inc.,* No. 3:22–cv–00985 (N.D. Cal. 2022); *Biesterfeld* v. *Ariosa Diagnostics, Inc.,* No. 1:21–CV–03085, 2022 WL 972281 (N.D. Ill. 2022); and other lawsuits)). FDA shares the concern of comments that described problems observed with IVDs offered as LDTs.

(Comment 29) FDA received comments stating that the proposed rule is not necessary for FDA ''to take action against bad actors'' or ''ill-intended individuals and laboratories'' that abuse the system, because FDA could choose to enforce in ''egregious cases of patient harm or attempts to exploit regulatory loopholes.''

(Response 29) FDA agrees that the Agency may choose to enforce against violations of the FD&C Act or PHS Act at any time, including (but not limited to) in response to egregious cases of patient harm, attempts to exploit loopholes, or other conduct involving ''bad actors'' or ''ill-intended individuals and laboratories.'' The general enforcement discretion approach does not bind the Agency or prevent FDA from taking enforcement action. However, as described in section III.B of this preamble, FDA is choosing to adjust its approach to enforcement discretion moving forward to address the fundamental uncertainty about whether IVDs offered as LDTs provide accurate and reliable results. The phaseout policy clarifies FDA's expectations regarding laboratories' compliance with applicable requirements and will bring more stability to the overall testing market. By phasing out the general enforcement discretion approach for LDTs, FDA may gain a more comprehensive understanding of the universe of IVDs

offered as LDTs (through enforcement of registration and listing requirements), monitor safety signals and more readily identify problematic IVDs (through enforcement of MDR requirements and corrections and removals reporting requirements), better assure that patients and providers have access to the information they need and that IVDs are not promoted with false or misleading claims (through enforcement of labeling requirements), and better assure analytical validity, clinical validity, and safety (through enforcement of QS, premarket review, and other applicable requirements). Ultimately, as noted elsewhere in this preamble, by applying the same general oversight approach to both laboratory and non-laboratory manufacturers of IVDs, FDA may better assure the safety and effectiveness of IVDs offered as LDTs, incentivize innovation by nonlaboratory manufacturers, and help ensure that innovation from laboratory manufacturers yields IVDs for which there is a reasonable assurance of safety and effectiveness (Refs. 15, 22, 88 to 90).

(Comment 30) FDA received comments suggesting certain steps FDA should take prior to phasing out the overall general enforcement discretion approach. Different comments provided different suggestions, but several suggested that FDA first gather more information about IVDs offered as LDTs through, for example, a survey, use of CMS's ''data from every licensed laboratory on the test type and annual volume,'' use of data available from CAP, or a U.S. GAO study. One comment suggested FDA enforce registration and listing and adverse event reporting requirements in order to gather information prior to determining whether to phase out the general enforcement discretion approach for premarket review requirements. Another comment stated that FDA needed to develop a better understanding of how ''in-office'' tests in particular are operationalized in clinical practice and undertake a more ''inclusive and deliberative process'' that accounts for ''diverse stakeholders,'' but did not specify how.

(Response 30) FDA acknowledges that we do not know exactly how many laboratories manufacture IVDs offered as LDTs nor precisely how many such IVDs they make. Based on direct interactions with CMS and CAP, FDA understands that neither organization collects this information for all IVDs offered as LDTs. However, FDA's FRIA provides estimates of how many laboratories currently offer IVDs as LDTs and how many IVDs offered as LDTs are on the market (Ref. 10). The basis for these estimates is described in section II.D.1 and appendix A of the FRIA. FDA does not agree that it should wait until it has more precise information about how many laboratories offer IVDs as LDTs and how may IVDs offered as LDTs are on the market before finalizing this rule, because more precise numbers would not affect the fundamental public health concerns that have motivated this rulemaking. FDA also notes that the longer it waits, the higher the numbers will become and the greater the risk posed to patients. Nor does FDA believe it should gather more information about potential problems with IVDs offered as LDTs prior to phasing out the overall general enforcement discretion approach; as discussed further in response to comments 32 and 160, while FDA is uncertain of the impact to the existing market, FDA already possesses enough information to conclude that there is no longer a sound basis to generally treat LDTs differently from other IVDs, and that the general enforcement discretion approach for LDTs does not best serve the public health.

With respect to the suggestion that FDA initially focus solely on registration and listing and adverse event reporting requirements, please see the response to comment 160 in section VI.F.6 of this preamble.

With respect to the comment about a more inclusive and deliberative process, FDA notes that, through this rulemaking, it has solicited and received many comments from diverse stakeholders that provided information on how in-office and other tests are operationalized in clinical practice, and we have carefully considered those comments. Furthermore, FDA has engaged with the public on this topic on multiple occasions over the last 30 years, including through draft guidances and public meetings. This rulemaking reflects FDA's best judgment based on a significant amount of input over many years, and we intend to continue to engage with the public on this topic. See our response to comment 296 for additional discussion regarding stakeholder engagement.

We also note that FDA does not control the U.S. GAO, and cannot compel a U.S. GAO study.

(Comment 31) Comments called on CMS, the National Institutes of Health (NIH), and HHS to review FDA's proposal.

(Response 31) Per standard practice, all relevant components of HHS, including CMS, NIH, and HHS leadership, reviewed and cleared FDA's proposed rule and this final rule.

(Comment 32) FDA received comments calling on FDA to produce more evidence of a problem. Some noted that FDA's existing evidence is largely anecdotal and called for ''evidence of multiple, conclusive, high-quality studies that show . . . that errors in laboratory testing are a pervasive and particularly dangerous problem.'' Other comments asked FDA to provide evidence of a problem with LDTs in specific areas, such as clinical toxicology. Some stated that the examples provided are not reflective of the landscape of LDTs, particularly at AMCs.

(Response 32) FDA does not agree with these comments. FDA has considered a wide range of evidence, including evidence described in the NPRM (88 FR 68006 at 68010–12) and information submitted in comments, and has determined that this evidence is adequate to conclude that there is a concerning level of variability in the performance of IVDs offered as LDTs.

As discussed in the NPRM, information about IVDs offered as LDTs in the scientific literature, as well as news articles and anecdotal reports submitted to the Agency, among other sources, has exposed evidence of problems associated with some of these tests (88 FR 68006 at 68010–12; Refs. 20 and 91 to 97). Regarding the scientific literature, the NPRM described multiple publications that document high variability in performance among IVDs offered as LDTs, including the potential for inaccurate or incomplete results (see comment responses 38, 39, and 41 for additional information) (88 FR 68006 at 68010–12). In addition, in support of this rulemaking, FDA prepared and submitted a memorandum to the docket regarding ''Examples of In Vitro Diagnostic Products (IVDs) Offered as Laboratory Developed Tests (LDTs) that Raise Public Health Concerns,'' which contained additional details from non-public sources (and some public MDRs) regarding examples of IVDs offered as LDTs with reported or known issues that were referenced in the NPRM (Ref. 16). FDA also submitted a second memorandum to the docket entitled ''Summary of 2020 Assessment of the First 125 EUA Requests from Laboratories for Molecular Diagnostic Tests for SARS–CoV–2'' (Ref. 18). Comments submitted to the docket provided additional evidence that further exposed problems associated with IVDs offered as LDTs (see discussion in response to comment 28). FDA also notes that the evidence of problematic IVDs offered as LDTs has

been growing, a trend that increases FDA's concerns.[52]

To the extent that comments raised questions about the quality of the evidence cited in the NPRM, FDA has addressed those questions in our responses to other comments in this section, including comments 36, 37, 38, and 43.

FDA does not take the position that all IVDs offered as LDTs are problematic, but the collective evidence, including anecdotal evidence, regarding certain IVDs offered as LDTs is of significant concern, especially given there is no consistent reporting of adverse events. Because this evidence covers a wide variety of tests across a range of laboratories, including AMCs, FDA considers it fairly representative of the landscape of IVDs offered as LDTs, contrary to one comment's claim. FDA also disagrees that it must have evidence specific to every type of test, such as clinical toxicology tests, in order to justify this rulemaking, and we disagree that ''multiple, conclusive, high-quality studies'' are needed here. *See FCC [Federal Communications Commission]* v. *Prometheus Radio Project,* ____ U.S. ____, 141 S. Ct. 1150, 1160, 209 L.Ed.2d 287 (2021) (''[T]he [Administrative Procedure Act (APA)] imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies.''). Instead, FDA has ''made a reasonable predictive judgment based on the evidence it ha[s].'' Id. Specifically, based on careful consideration of the information in the record, FDA has determined that the final phaseout policy appropriately balances the relevant considerations and will advance public health.

(Comment 33) FDA received comments regarding the risks and benefits of FDA's proposal, with some comments indicating that FDA has not adequately considered the benefits of IVDs offered LDTs. One comment stated that the data provided by FDA ''appears to overstate the risks associated with LDTs, while understating the benefits.''

(Response 33) FDA disagrees that the data provided in the NPRM overstates the risks associated with IVDs offered as LDTs. FDA has considered evidence from a variety of sources that, taken together, demonstrates fundamental uncertainty about whether such IVDs provide accurate and reliable results. FDA acknowledges the benefits that IVDs offered as LDTs offer when those IVDs do provide accurate and reliable results, and has taken these and other public health considerations into account in developing the phaseout policy. The fact that accurate and reliable IVDs offered as LDTs have benefits does not mean that the current status quo—in which problematic IVDs offered as LDTs are marketed with limited FDA oversight—should continue indefinitely.

(Comment 34) FDA received comments indicating FDA failed to include all available data relevant to the need for rulemaking. For example, one comment stated FDA is ''ignoring broad evidence of the high quality of genetic LDTs.'' Comments asserted that there was omission of multiple publications claiming comparable or better performance of IVDs offered as LDTs compared to ''FDA IVDs.'' Comments pointed to the following publications:

- Benayed, R., Offin, M., Mullaney, K., Sukhadia, P., et al. (2019). ''High Yield of RNA [Ribonucleic acid] Sequencing for Targetable Kinase Fusions in Lung Adenocarcinomas with no Mitogenic Driver Alteration Detected by DNA Sequencing and Low Tumor Mutation Burden.'' *Clinical Cancer Research,* 25(15), 4712–4722. (Ref. 98).
- Keegan, A., Bridge, J.A., Lindeman, N.I., Long, T.A., et al. (2020). ''Proficiency Testing of Standardized Samples Shows High Interlaboratory Agreement for Clinical Next-Generation Sequencing-Based Hematologic Malignancy Assays with Survey Material-Specific Differences in Variant Frequencies.'' *Archives of Pathology & Laboratory Medicine,* 144(8), 959–966. (Ref. 99).
- Kim, A.S., Bartley, A.N., Bridge, J.A., Kamel-Reid, S., et al. (2018). ''Comparison of Laboratory-Developed Tests and FDA-Approved Assays for BRAF, EGFR, and KRAS Testing.'' *JAMA Oncology,* 4(6), 838–841. (Ref. 100).
- Merker, J.D., Devereaux, K., Iafrate, A.J., Kamel-Reid, S., et al. (2019). ''Proficiency Testing of Standardized Samples Shows Very High Interlaboratory Agreement for Clinical Next-Generation Sequencing-Based Oncology Assays.'' *Archives of Pathology & Laboratory Medicine,* 143(4), 463–471. (Ref. 101).
- Moncur, J.T., Bartley, A.N., Bridge, J.A., Kamel-Reid, S., et al. (2019). ''Performance Comparison of Different Analytic Methods in Proficiency Testing for Mutations in the BRAF, EGFR, and KRAS Genes: A Study of the College of American Pathologists Molecular Oncology Committee.'' Archives of Pathology & Laboratory Medicine, 143(10), 1203–1211. (Ref. 102).
- Zehir, A., Nardi, V., Konnick, E.Q., Lockwood, C.M., et al. ''SPOT/Dx Pilot Reanalysis and College of American Pathologists Proficiency Testing for KRAS and NRAS Demonstrate Excellent Laboratory Performance.'' *Archives of Pathology & Laboratory Medicine.* (Ref. 103).
- Zhang, B.M., Keegan, A., Li, P., Lindeman, N.I., et al. (2021). ''An Overview of Characteristics of Clinical Next-Generation Sequencing-Based Testing for Hematologic Malignancies.'' *Archives of Pathology & Laboratory Medicine,* 145(9), 1110–1116. (Ref. 104).

One comment further asserted that ''publications have demonstrated major deficiencies in FDA-approved tests that would result in patient mismanagement had LDTs not been available to address those deficiencies,'' citing to the above-listed publication from Benayed et al. There were two other publications referenced by a comment that were mis-cited or not identifiable from the information provided.

(Response 34) FDA does not agree that the publications cited by these comments vitiate the need for greater oversight of IVDs offered as LDTs. FDA does not take the position that all IVDs offered as LDTs are problematic. Instead, as described in section V.B.3, FDA believes that beneficial IVDs offered as LDTs are likely on the market. But the fact that some IVDs offered as LDTs that are on the market may be beneficial does not mean that the current status quo—in which problematic IVDs offered as LDTs are marketed with limited FDA oversight—should continue indefinitely. Thus, even if the seven articles cited above showed that certain IVDs offered as LDTs have performance comparable to or better than that of certain FDA-authorized tests—which FDA does not believe to be the case, as discussed below—that would only support the accuracy and reliability of the cited tests. It would not negate evidence of problematic IVDs offered as LDTs or uncertainty as to whether IVDs offered as LDTs provide accurate and reliable results, as discussed in the NPRM and elsewhere in this preamble.

Moreover, we disagree that the referenced publications demonstrate comparable or better performance of IVDs offered as LDTs compared to FDA-authorized IVDs, for the reasons described below.

a. Six of the 7 publications report results from proficiency testing, which are not appropriate as standalone or comparative results to support test validation and performance. Performing well during proficiency testing does not mean that a test is analytically and clinically valid. Kim et al., Moncur et al., Keegan et al., Merker et al., and Zehir et al. (Refs. 99 to 103) use data from the CAP proficiency testing programs for NGS, which are only a subset of IVDs overall, to contend that IVDs offered as LDTs are accurate and have comparable performance to FDA-

[52] For example, consider the years in which concerns with the IVDs offered as LDTs that raise public health concerns described in FDA's memorandum in the docket (Ref. 16) were first identified. Four concerns were identified between 2008 and 2011, 10 concerns between 2012 and 2015, 15 concerns between 2016 and 2019, and 23 concerns between 2020 and 2023.

authorized tests. However, proficiency testing data, as standalone or comparative results, do not support test validation and performance expectations. Proficiency testing programs evaluate the performance of laboratories running tests that should have already been validated. Proficiency testing is performed to ensure that certain characteristics, *e.g.,* detection of a specific analyte, can be achieved at a similar level in relation to results obtained by a group of referee laboratories or ''peers.'' Proficiency testing samples ensure results are detected within an acceptable range within a pre-determined limit, independent of an individual test's performance specifications. Proficiency testing program data is an aggregate assessment of laboratory performance rather than an evaluation of results on a test-by-test basis, the latter of which is more aligned with the clinical reality that patient care is generally determined by a single test performed in a single laboratory. One cannot assess the performance of an individual test from aggregate data across multiple tests. Looking at data in aggregate can mask poor performance of an individual test. Proficiency testing programs are not adequately representative of the routine conditions of clinical use, do not consider a test's intended use, and do not represent the challenges encountered in routine testing. For example, proficiency testing does not cover the entire test procedure. Specimens in proficiency testing are generally highly contrived and do not closely mimic patient specimens. Proficiency testing is generally insufficiently challenging (*e.g.,* less complex variant types and variant allele fractions for genetic tests). Although laboratories are expected to adhere to their typical testing protocols, proficiency testing exercises are highly controlled and come with specific instructions, so laboratories are aware that they are participating in a proficiency testing exercise, which may influence how the test is performed and results obtained. Proficiency testing does not ensure that a test has been analytically and clinically validated based on its intended use.

b. Even if the results of proficiency testing were appropriate to evaluate the performance of IVDs offered as LDTs compared to FDA-authorized tests, these studies only evaluated NGS-based IVDs, which are only a subset of IVDs. In addition, 2 publications purported to compare the performance of IVDs offered as LDTs to FDA-authorized tests but because of flawed methodology did not do so; 1 publication reported results that suggest performance issues with IVDs offered as LDTs; and 1 publication did not evaluate the performance of IVDs offered as LDTs compared to FDA-authorized tests. Two publications (Kim et al. and Moncur et al.) (Refs. 100 and 102) purporting to compare IVDs offered as LDTs with FDA-authorized tests were actually mainly comparing IVDs offered as LDTs with other IVDs offered as LDTs and not comparing IVDs offered as LDTs with FDA-authorized tests. These publications provided limited information about the relative performance of FDA-authorized tests and IVDs offered as LDTs because the majority of tests referred to as ''FDA-approved companion diagnostics'' had been modified in ways outside of their FDA authorizations, rendering them IVDs offered as LDTs. In addition, the authors considered any test from a manufacturer with any FDA-approved companion diagnostic (CDx) to be ''FDA-approved,'' even though some of these tests may not in fact have been FDA-authorized.

Zehir et al. (Ref. 103) used CAP proficiency testing methods and data to reanalyze a comparison of the performance of an FDA-approved CDx with IVDs offered as LDTs intended for the same use using the same set of samples that was reported in another publication (Pfeifer et al) (Ref. 20). Despite the authors' claims that the study demonstrated excellent laboratory performance, individual laboratories had a significant number of errors. Only eight laboratories correctly reported all variants in Zehir et al.'s reanalysis, and four laboratories had greater than five errors. The laboratory performing the FDA-approved CDx correctly reported all variants in both dry and wet samples. Therefore, while FDA does not consider it appropriate to use proficiency testing data to demonstrate or compare test performance (as earlier explained), this study does not in any way undermine FDA's position regarding the need for increased oversight. Please see our response to comment 38 for a more detailed assessment of this study.

Zhang et al. provided an overview of certain NGS-based test characteristics for hematologic malignancies with no discussion of test validation or performance and, therefore, does not conclude or even assert equivalence between IVDs offered as LDTs and FDA-authorized IVDs (Ref. 104). This may be an erroneous citation given the lack of relevant content to support the comment's assertion.

c. Of the 7 publications cited above, only one (Benayed et al.) did not report on proficiency testing results. This publication did not demonstrate comparable or better performance of IVDs offered as LDTs compared to FDA-authorized tests, nor did it identify ''major deficiencies'' in FDA-authorized tests as the comments assert. FDA disagrees that the publication from Benayed et al. supports the assertion that ''publications have demonstrated major deficiencies in FDA-approved tests that would result in patient mismanagement had LDTs not been available to address those deficiencies.'' (Ref. 98). After careful review, FDA has determined that the study did not identify a ''major deficiency'' with an FDA-approved test and does not demonstrate that the unauthorized IVD offered as an LDT in question was necessary in order to avoid patient mismanagement. Moreover, even if the study had demonstrated that the unauthorized IVD offered as an LDT was necessary to avoid patient mismanagement in certain instances, that fact would not mean that FDA oversight is unnecessary for IVDs offered as LDTs in general.

The Benayed study evaluated the use of the FDA-authorized MSK–IMPACT DNA sequencing test and use of the unauthorized MSK–FUSION RNA sequencing IVD offered as an LDT in patients with lung cancer. The MSK–FUSION was designed to detect fusions and rearrangements (complex variants) while the MSK–IMPACT is authorized for detection of single nucleotide variants, insertions and deletions (indels), MET exon 14 skipping, and microsatellite instability but not complex variants. The authors concluded that the IVD offered as an LDT identified complex variants that were not detected by the FDA-authorized test (and which the FDA-authorized test was not intended to detect). However, a test's inability to identify variants that it is not intended to detect is not inherently a ''major deficiency'' for that test. We note that FDA oversight of IVD labeling helps ensure that the instructions for use are clear, including clearly describing the intended use, which for genetic tests includes describing the variants detected by the test.

The authors of the Benayed study reported that 10 patients received targeted therapy based on identification of complex variants by the MSK–FUSION test and claimed that 80 percent of those patients had clinical benefit. FDA disagrees with the authors' conclusions that 80 percent of patients experienced clinical benefit. First, the authors considered the denominator to include only those patients who went

on to receive targeted therapy (n=10) rather than all patients identified by the MSK–FUSION test as having complex variants (n=33). Second, the authors considered clinical benefit to include stable disease, which FDA does not consider to be an appropriate endpoint for therapeutic efficacy when treating cancer. Adjusting for these considerations, only 6 percent of patients identified by the MSK–FUSION test as having complex variants (2 out of 33) experienced clinical benefit, and both of these patients could have been identified for therapy with FDA-authorized tests. Only 2 of the 10 patients who received therapy based on the MSK–FUSION test would not have otherwise been identified, and neither of those patients necessarily benefited from the therapy. Following treatment, one had progression of disease and the other had stable disease (*i.e.,* disease with no substantial change). Thus, it cannot be concluded that patients would have been mismanaged had the IVD offered as an LDT not been available.

(Comment 35) FDA received a comment that increased FDA oversight will not result in quantitative agreement between assays, and that any implication that it will result in such agreement ''is not supported by an empirical evaluation of approved, marketed tests.''

(Response 35) FDA has not implied that increased FDA oversight would ensure quantitative agreement for all tests. FDA's discussion regarding variability between tests in the NPRM referred primarily to variability in tests' clinical interpretation (*e.g.,* positive or negative for the clinical condition being diagnosed by the test) based on differing results (88 FR 68006 at 68011). For example, when two different tests are both intended to determine whether a patient with cancer is eligible for a specific treatment and one result is ''negative'' while the other is ''positive,'' there is variability between those tests that represents a clinically significant problem.

For tests that provide a numerical value, there is reasonable quantitative agreement for FDA-authorized tests that are standardized (for example tests that are traceable to a reference material) or harmonized. However, not all tests are standardized or harmonized, nor do all tests provide a numerical result (for example, qualitative genetic tests).

(Comment 36) FDA received comments regarding FDA's use of a New York Times article on non-invasive prenatal screening (NIPS) as evidence of a problem (Ref. 96). Specifically, comments stated that the article conflated screening with diagnostic testing. They asserted that the article mischaracterized false positive results as test failures and that the ''problem'' with this category of tests is with ''the lack of understanding of its purpose and limitations by the providers and patients who were interviewed by the reporters.''

(Response 36) FDA agrees that NIPS tests, which may tell people the risk of their fetus having certain genetic abnormalities, are different from diagnostic tests used to more definitively confirm or rule out a suspected genetic abnormality. FDA agrees with comments that NIPS tests should not be used to confirm or rule out a suspected abnormality. After publication of the New York Times article, FDA issued a safety communication to explain the limitations of NIPS tests and provide information to educate both patients and healthcare providers to help reduce the inappropriate use of NIPS tests (Ref. 97). Increased oversight of NIPS tests, including an expectation of compliance with labeling requirements, can help ensure such tests are appropriately labeled with transparent information regarding performance, clear instructions, and appropriate limitations.

(Comment 37) FDA received several comments regarding experience with IVDs offered as LDTs during the COVID–19 pandemic. Some suggested that FDA's policies slowed availability of tests early in the pandemic and slowed down development of over-the-counter (OTC) home tests. Some pointed to long review times for EUA requests as indicative that FDA does not have the bandwidth to handle review of IVDs offered as LDTs. Others suggested that it is unfair to point to problems with COVID–19 laboratory-made tests as evidence of a broader problem with IVDs offered as LDTs given that COVID–19 laboratory-made tests were developed under unusual circumstances, including ''overnight demands to dramatically expand testing capacity, continuous reagent shortages, [and] global supply chain disruptions.'' Another comment, from an AMC, reported on the AMC's own experience and that of colleagues at other AMCs, stating that ''in no case that I know of was anyone submitting data that was remotely representative of what we would generally consider sufficient for an assay.'' The comment explained that their strategy involved submitting ''minimal verification data so that we could get feedback on the initial submission . . . about how to proceed.''

(Response 37) As an initial matter, we disagree that FDA's policies unnecessarily slowed availability of COVID–19 laboratory-based or home tests that had appropriate assurances of safety and effectiveness. As discussed in section V.A.2, FDA has not applied the general enforcement discretion approach to LDTs used for declared emergencies because of the significant risk posed by the disease (as signified by the unusual step of issuing a declaration under section 564 of the FD&C Act) and because false results can have serious implications for disease progression and public health decision-making, as well as for the individual patient's care. For these reasons, FDA generally expected EUA authorization for COVID–19 LDTs.

Notably, FDA took steps to expedite submission and review of EUA requests for COVID–19 IVDs to help ensure that patients and providers had access to authorized IVDs. FDA made a template available in January of 2020 to help manufacturers prepare and submit EUA requests for COVID–19 IVDs, and engaged with 100 manufacturers by the end of February 2020 to discuss EUA requests and the EUA process. Early in the pandemic, FDA authorized IVDs, including several IVDs offered as LDTs, within a day of receiving complete datasets. Moreover, FDA issued enforcement discretion policies to help address access concerns as appropriate. FDA acknowledges that review times grew as a backlog of EUA requests grew, but we note that many test manufacturers offered their tests as described in these enforcement discretion policies while FDA review of their EUA requests was pending.

FDA also acknowledges that the entire healthcare community, including test manufacturers, operated under unusual circumstances that do not reflect the environment in which tests are typically developed. However, while the pandemic was an unusual circumstance, our conversations with laboratory manufacturers during that time revealed that many were unfamiliar with what constitutes appropriate analytical and clinical validation for an IVD generally. FDA's validation expectations for tests seeking EUAs were also lower than expectations for traditional marketing authorization, and many allegedly ''complete'' validation packages in EUA requests submitted to FDA were still insufficient. FDA appreciates that many laboratories were new to interactions with FDA and not familiar with FDA's expectations for validation, but we note that many of these laboratories were nonetheless offering their unvalidated IVDs as LDTs for COVID–19, and in

many cases for other diseases or conditions, to the public.

Moreover, the issues identified with COVID–19 IVDs offered as LDTs were similar to those that FDA has identified with IVDs manufactured by non-laboratory manufacturers. FDA's identification of these issues for IVDs offered as LDTs, by laboratories certified under CLIA, highlights the importance of FDA phasing out the general enforcement discretion approach for LDTs. Once the phaseout described in this preamble is complete, laboratory manufacturers will gain experience with FDA's general expectations for validation, providing greater assurances of safety and effectiveness for tests and making the country better prepared for future outbreaks. Further, FDA intends to publish guidance on validation of tests used after a determination and declaration under section 564 of the FD&C Act.

Finally, FDA disagrees that EUA review times for COVID–19 IVDs indicate that FDA does not have the capacity to handle review of IVDs offered as LDTs, as explained in response to comment 275.

(Comment 38) Several comments suggested that a study cited by FDA as evidence of variable performance among IVDs offered as LDTs was flawed (Pfeifer et al. (Ref. 20)). One comment suggested that FDA incorrectly described the findings of the study. Comments also referenced a recent publication that purported to be a reanalysis of the same data but was by different authors (Zehir et al. (Ref. 104)). Comments claimed that the reanalysis showed ''excellent'' LDT performance and that the original analysis was biased. Others questioned the use of the FDA-approved comparator in the original study. One comment suggested that FDA failed to disclose the reanalysis publication.

(Response 38) As an initial matter, FDA disagrees that the Zehir et al. study has any bearing on FDA's reliance on the Pfeifer et al. publication to support the need for this rulemaking. CAP proficiency testing programs' performance data are not appropriate comparative results to those reported in Pfeifer et al. due to various limitations with proficiency testing programs, including that the programs are not sufficiently challenging and adequately representative of the routine conditions of clinical test use. For example, proficiency testing does not cover the entire test procedure, proficiency testing specimens that are highly contrived do not closely mimic patient specimens, proficiency testing samples include less challenging variant types and variant allele fractions, and laboratories are aware of participation in highly controlled proficiency testing exercises, which may influence how the test is performed and results obtained. Furthermore, aggregate data reported by Zehir et al. (Ref. 103) and referenced by the comments may mask individual poor performing laboratories. Please see our response to comment 34 for additional details regarding FDA's concerns with the use of proficiency testing data to evaluate the performance of IVDs. The SPOT/Dx pilot study reported in Pfeifer et al. was intended to evaluate laboratories individually, using samples that mimic as closely as possible patient samples, and compares the accuracy of LDTs with an FDA-approved CDx in a specific clinical scenario, to model an actual patient encounter (Ref. 20). Thus, it is one of the only truly reliable head-to-head comparisons between IVDs offered as LDTs and a parallel FDA-authorized IVD.

We also disagree with the assertion that SPOT/Dx was confounded by comparing the performance of IVDs offered as LDTs with that of the FDA-approved CDx because the CDx was performed as intended, and the SPOT/Dx pilot was intended to assess the performance of IVDs offered as LDTs in detecting the same variants as the FDA-approved CDx. In both the SPOT/Dx pilot study and the Zehir et al. reanalysis, testing using the CDx led to accurate reporting of all variants for both wet and dry samples while testing involving IVDs offered as LDTs did not accurately report all variants. SPOT/Dx demonstrated that using the same set of samples, intended to mimic formalin-fixed paraffin embedded samples, certain IVDs offered as LDTs would not identify the same patient population as the approved CDx. FDA notes that the SPOT/Dx working group that developed the pilot comprised many stakeholders, including NGS laboratories, professional oncology organizations, payors, regulatory agencies, patient advocacy groups, and others. CAP specifically coordinated the Scientific and Technical Working Group and provided professional, logistical, and operational expertise in support of the pilot.

FDA disagrees with the comments' assertion that FDA incorrectly described the findings of the SPOT/Dx pilot study (Ref. 20). The description of this study in the NPRM stated that ''the same samples were sent to 19 laboratories for testing using their own manufactured test, and only 7 of those laboratories correctly reported all results. For almost half of the tests studied, analytical accuracy was significantly lower than that of the parallel test approved by FDA'' (88 FR 68006 at 68011). This aligns with the findings reported by the study authors that, of the 19 laboratories that analyzed both the wet and dry samples, ''7 (37 percent) of 19 laboratories correctly reported all variants, 3 (16 percent) of 19 had fewer than five errors, and 9 (47 percent) of 19 had five or more errors.'' The authors also reported that the Praxis Extended Ras Panel correctly reported all variants for both wet and dry samples. As discussed in the NPRM (88 FR 68006 at 68010 and 68011), this study documents high variability in performance among IVDs offered as LDTs, which is reflected in the study authors' key point that ''the accuracy of detection of genetic variants differed among the laboratory-developed tests (LDTs) performed by different laboratories,'' as well as the authors' conclusion that ''variable accuracy in detection of genetic variants among some LDTs may identify different patient populations for targeted therapy'' (Ref. 20).

FDA disagrees that the findings from the referenced reanalysis (Ref. 103) show ''excellent'' LDT performance. Despite Zehir et al.'s claims that the reanalysis demonstrated excellent laboratory performance, individual laboratories still had a significant number of errors, with only eight laboratories correctly reporting all variants in the reanalysis (compared to seven in SPOT/Dx) and four laboratories still had greater than five errors.

Finally, FDA did not fail to disclose the published reanalysis, as it was not published prior to the posting of FDA's NPRM for public inspection by the Office of the Federal Register on September 29, 2023. It has since been published and, in addition to the discussion in our comment responses, is included as a reference to the rule.

(Comment 39) One comment claimed that the Friends of Cancer Research Tumor Mutational Burden (TMB) study cited by FDA as evidence of variability among laboratories' tests actually showed similar variability as that seen in two FDA-approved tests.

(Response 39) FDA acknowledges there can be variability among FDA-approved tests and that the referenced TMB study included two FDA-authorized tests, one tumor mutation profiling test that includes detection of TMB, and one CDx test for detection of TMB for identifying patients for treatment with pembrolizumab. FDA further acknowledges that the results from the laboratories performing those tests were included among the authors' conclusions regarding variability across tests. The authors of the study did not

conduct an analysis to compare variability of IVDs offered as LDTs to those that are FDA-authorized nor comment on differences in variability between the two. While FDA accurately described the results of this study as finding ''substantial variability among tumor mutational burden (TMB) tests manufactured by laboratories and used to identify patients with cancer most likely to benefit from immunotherapy'' in the NPRM (88 FR 68006 at 68011), FDA does not mean for this to imply that the results of this study indicate greater variability in the studied IVDs offered as LDTs compared to the studied FDA-authorized tests. As such, FDA is clarifying here that the study does not support the proposition that TMB tests manufactured by laboratories have worse performance than FDA authorized TMB tests. However, other evidence in the NPRM supports this proposition as applied to tests more generally (see Refs. 20, 91 to 96, 105 to 110).

(Comment 40) One comment claimed that the publication on epidermal growth factor receptor (EGFR) testing for non-small cell lung cancer that was referenced in the PRIA is biased in multiple ways: the authors had a vested interest in the outcome, the work was funded by a company with a vested interest in the outcome, the IVD offered as an LDT was in Europe and therefore not required to comply with CLIA, and the trial did not assess the same material extracted from residual tissue specimens with the laboratory-made and FDA-approved test.

(Response 40) FDA acknowledges that, as is clear from the study publication, the work reported in this publication: (1) was authored and funded by a company who may be a competitor with the relevant laboratory manufacturers and (2) utilized IVDs offered as LDTs in Europe, which may not be representative of IVDs offered as LDTs in the United States. This study was not included in the NPRM but was included in the PRIA. FDA no longer cites this publication in the FRIA.

(Comment 41) One comment addressed FDA's citation of Manrai et al., 2016 (Ref. 95), arguing that this publication did not show that IVDs offered as LDTs exacerbate health disparities. The comment claimed that FDA did not properly describe the findings of the publication, stating that ''the message of the paper was the lack of testing in both control and diseased populations for underrepresented minorities is what led to poorer outcomes.'' The comment also asserted that an FDA-approved assay would have similar limitations to those described for IVDs offered as LDTs.

(Response 41) FDA cited this publication for the proposition that IVDs offered as LDTs *may* exacerbate health disparities. FDA did not contend that the publication showed that IVDs offered as LDTs do in fact exacerbate health disparities. FDA also separately cited this publication because it describes problems with IVDs offered as LDTs, regardless of any impact on health disparities (see 88 FR 68006 at 68011 (stating that the publication ''reported false positive results from genetic IVDs offered as LDTs for hypertrophic cardiomyopathy in multiple patients of African American descent.'')).

FDA believes it is appropriate to cite this publication to support that IVDs offered as LDTs may exacerbate health disparities for the following reasons. First, the study identified multiple persons of African or unspecified ancestry who had received false positive test results from IVDs offered as LDTs related to the historical dearth of data that include persons of diverse racial and ethnic backgrounds, which prevented accurate variant interpretation at the time of results reporting; higher rates of these types of false results in underrepresented populations may exacerbate health disparities. Second, the paper reports on disparities that may result from errors unrelated to access to care, particularly genetic variant misclassification (a type of inaccurate test result). The authors specifically state that their findings ''show how health disparities may arise from genomic misdiagnosis'' (*i.e.,* a type of inaccurate result) and describe the negative consequences of the ''provision of false genetic information'' not just to a patient but to their relatives as well. The authors also report that their ''findings suggest that false positive reports are an important and perhaps underappreciated component'' of certain tested persons. Despite the comment's assertion that the message of this paper was that the lack of testing in underrepresented minorities is what led to poorer health outcomes, that message was not explicitly stated in the publication. Rather, the authors call for diverse genomic data in their conclusion: ''the misclassification of benign variants as pathogenic that we found in our study shows the need for sequencing the genomes of diverse populations, both in asymptomatic controls and the tested patient population.''

FDA acknowledges that lack of data on the genomes of diverse populations makes demonstrating accurate genetic variant classification in diverse populations challenging. While FDA-authorized tests may face challenges due to the paucity of data from genetically diverse populations, FDA-authorized tests generally have greater transparency regarding the population(s) in which they were validated, information pertaining to device safety and effectiveness for specific demographic characteristics if performance differs within the target population, and population-specific limitations, if applicable. In addition, during FDA premarket review, FDA may ask that sponsors provide data for different intended use populations as well as diversity action plans to improve the generation of evidence regarding device performance in diverse populations. As such, in general, there is greater confidence in the accuracy and reliability of FDA authorized genetic tests, and FDA oversight of IVDs offered as LDTs may help to advance health equity, as discussed in the NPRM and in our responses to comments in section VI.K of this preamble.

(Comment 42) FDA received a comment from a sponsor that submitted a 510(k) for an IVD offered as an LDT that was discussed in FDA's memorandum to file regarding ''Examples of In Vitro Diagnostic Products (IVDs) Offered as Laboratory Developed Tests (LDTs) that Raise Public Health Concerns,'' which was included in the docket for this rulemaking (Ref. 16). The comment expressed concerns regarding the inclusion of this particular submission in the memorandum, contending that FDA's review of the submission was inappropriate and that the validation data submitted for this IVD offered as an LDT was sufficient. In particular, the comment stated that ''leading journals'' had published studies demonstrating the utility of the sponsor's techniques; that the sponsor withdrew its submission because FDA refused to use a certain ''fit-for-purpose'' assessment of the data; that the sponsor had demonstrated the detection limits and precision of the IVD; that quality controls embedded in the IVD provided for the identification of any interfering substances; that FDA inappropriately focused on certain details while dismissing other important information; that the review process was overly time-consuming and expensive; and that the IVD has become standard of care.

(Response 42) FDA disagrees with this comment. In relevant part, the memorandum to file stated that ''[i]n 2021, FDA received a 510(k) submission from [redacted] for their [redacted] test for monitoring changes in burden of

disease in pediatric and adult patients with [acute myeloid leukemia (AML)] during and after treatment. The submission did not contain adequate analytical and clinical validation studies to show the test worked as intended. For example, the sponsor did not provide any data from interference, detection limit, and reagent stability studies; did not submit data from precision studies to demonstrate the test is reliable in intended use specimens; only used one specimen to evaluate sample stability rather than the recommendation of at least ten; and included samples in the clinical study that were not the sample type intended for use with the test. The sponsor withdrew the submission after FDA raised concerns with the inadequate validation data. Without sufficient information to demonstrate adequate validation, a test's performance is unknown, which may put patients at risk of harm due to inaccurate results. In general, inaccurate results from tests to monitor disease burden during and after treatment for AML could lead to suboptimal clinical management of patients with AML. The risk of false negative results (*i.e.,* a patient assumed to have a more favorable prognosis based on the false negative result) could potentially result in a reduction in the level of care such as less medication use, subsequent confirmatory testing, and other possible treatment decisions. False positive results (*i.e.,* a patient who is disease free presumed to have a hematologic malignancy based on the positive test result) could result in additional unnecessary testing'' (Ref. 16).

With respect to the comment's statement that ''leading journals'' published studies demonstrating the utility of the sponsor's techniques, FDA notes that during review of the 510(k) submission, the sponsor referenced three publications that it claimed supported the clinical validation of the IVD. The first publication described a feasibility study and was not a validation study. The second publication described a clinical validation study that used a different version of the device than the subject device under review (*i.e.,* the device evaluated had a different operating principle than the device under review). The sponsor did not provide information adequate to support leveraging clinical performance data from a version of the device that differed in significant ways from the subject device. In addition, there was a difference in the limit of quantitation (LoQ) reported in the publication and the LoQ estimated by precision and linearity data submitted by the sponsor, which raised significant uncertainty in the clinical validation data. The third publication was a clinical study that utilized the device to aid in the diagnosis of a different disease and was thus for a different intended use. Therefore, the data could not be leveraged to support the device's safety and effectiveness for the AML claim being sought.

FDA also disagrees with the comment's statement that FDA refused to use a ''fit-for-purpose'' assessment of the data. FDA's review was risk-based and intended to be consistent with least burdensome principles. The expectations for safety and effectiveness for this test were based on the intended use of the device and in the context of special controls required for devices of this type, thereby ensuring the device performance was validated in a fashion encompassed by the fit-for-purpose concept. Throughout the review, FDA considered and proposed multiple alternatives as least-burdensome approaches.

The comment further contended that the sponsor had demonstrated the detection limit of the assay and had submitted precision studies to demonstrate test reliability. However, during FDA's review of the submission, the Agency did not agree that the detection limit of the assay could be demonstrated solely in the manner suggested by the sponsor as the output assessed by the sponsor in the studies conducted was different from the output of the device. In addition, although the sponsor had submitted multiple precision studies, the sponsor failed to provide information on how the studies were conducted and how the data were analyzed (*e.g.,* study protocols), such that FDA could not determine whether the reported precision would be adequate to support a determination that the test was as safe and effective as the predicate device. In addition, when the sponsor provided a reanalysis of the precision data, there were unexplained deviations in results calculations, raising concerns with the reliability of the data submitted.

With respect to the comment's assertion that quality controls embedded in the IVD provided for the identification of any interfering substances, the sponsor made this assertion during FDA's review of the submission as well, in an effort to justify why studies to assess the impact of potentially interfering substances on test performance were inapplicable. However, the sponsor did not provide critical explanatory information or documentation, or any validation data to demonstrate the capability of the laboratory's continuous process controls to identify failures in instrument, reagent, or specimen integrity. FDA also disagrees that the Agency focused too heavily on certain aspects of the submission, such as cell counting, and dismissed the importance of other aspects, such as fluorescence intensity. FDA discussed fluorescence intensity with the sponsor on several occasions. The comment's assertion that FDA never asked about the results from three clinical trials is likewise not accurate; during review of the submission, FDA made multiple requests to the sponsor for additional information on the studies submitted, and identified various concerns with the studies. Ultimately, throughout the review, FDA considered the available data and least burdensome approaches for providing the data necessary to demonstrate that the device was as safe and effective as the predicate device, considering the intended use and special controls for this device type, but the sponsor's assertions did not obviate the need for adequate clinical validation. During the review process, the sponsor acknowledged its ability to perform validation studies requested by FDA, but stated that it declined to do so.

The comment also suggested that FDA's review took too long and was too expensive, stating that the review process took 9 years and cost more than $1,000,000. FDA acknowledges that the Agency worked with the sponsor over 9 years, but notes that much of this interaction was in the context of 6 voluntary Pre-Submissions submitted by the sponsor, beginning approximately 9 years before the 510(k) was submitted.

With respect to the comment's statement that the subject assay has become the standard of care, FDA was not able to determine whether in fact this test is now used as part of the standard of care. Regardless, a test being used as part of the standard of care is not sufficient to provide appropriate assurances regarding safety and effectiveness. Use in clinical practice does not necessarily establish that a device is appropriately safe and effective.

(Comment 43) One comment stated that FDA's memorandum regarding examples of IVDs offered as LDTs that raise public health concerns did not provide enough details to determine whether the stated problems were related to assay design or procedural issues, and noted that procedural issues are under the regulatory authority of CLIA. The comment also asserted that FDA's statement in the memorandum

that FDA did not confirm the veracity of the reports suggests that FDA did not deem the public health risks severe enough to warrant investigation by the Agency at the time of submission.

(Response 43) FDA disagrees that the Agency did not deem the public health risks severe enough to warrant investigation by the Agency. The referenced statement regarding the Agency not confirming the veracity of information was specific to complaints, MDRs, and allegations, where FDA relies on information submitted by the entity filing the report. As described in that memorandum, any follow up by the Agency on the complaints, MDRs, and allegations is not included in the memorandum. As a general matter, FDA does not comment on such investigations.

FDA acknowledges that the details included in the memorandum regarding the MDRs and allegations cited therein do not indicate whether the problems were related to assay design or other aspects not covered by CLIA, due to the nature of MDRs where the information available to the Agency is the information submitted in the report and does not typically include detailed information on test design or validation of the test. The memorandum describes what was reported in the MDR or allegation. However, all of the examples from submissions FDA reviewed had issues related to analytical validation that would negatively impact the test's intended clinical use, or inadequate clinical validation that CLIA does not address. For these examples, FDA had sufficient data and information that pointed to issues CLIA would not address. Furthermore, FDA was able to confirm that the laboratories that developed 22 of the 26 IVDs offered as LDTs reviewed in these submissions were CLIA-certified laboratories. For the others that FDA was not able to confirm, those laboratories should have been CLIA certified since they were performing the tests on samples from United States subjects. Taken together, FDA identification of these issues demonstrates potential problems with the tests despite CLIA regulation.

D. FDA Authority To Regulate LDTs

1. General Comments Regarding FDA's Authority

(Comment 44) Various comments stated that FDA has statutory authority over LDTs. Other comments asserted (without specific analysis) that FDA lacks authority to finalize the proposed rule.

(Response 44) For the reasons set forth in the NPRM and this preamble, FDA agrees with the commenters who stated that FDA has this authority. FDA has long stated that LDTs, like other IVDs, are ''devices'' subject to applicable requirements in the FD&C Act (see 62 FR 62243 at 62249 (November 21, 1997), 65 FR 18230 at 18231 (April 7, 2000), Ref. 27, Ref. 32–33, Ref. 35, Ref. 39, Ref. 57, Ref. 97, Ref. 111–121). FDA responds to more specific jurisdictional arguments in the paragraphs that follow.

(Comment 45) Some comments suggested that FDA's failure to publicly announce its authority over LDTs closer to enactment of the FD&C Act or MDA raises questions about whether the Agency has authority over LDTs. Several comments noted that FDA did not communicate its authority over LDTs until 1992, 16 years after enactment of the MDA. Two comments suggested that FDA's position that it gained authority over IVDs, including LDTs, ''when key legislation was passed'' but exercised enforcement discretion constitutes ''revisionist history'' or an ''ex post facto'' narrative.

(Response 45) FDA disagrees with these comments. First, the Agency's jurisdiction depends on the scope of authority granted to it under the statute, and that jurisdiction existed (as explained in the NPRM and elsewhere in this preamble) regardless of when FDA publicly discussed it. *See Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731, 1737 (2020) (''extratextual considerations'' do not trump ''the express terms of a statute'').

Second, the comments appear to take the position that FDA may not assert its statutory authority unless it issued a public statement announcing that authority within some timeframe after which Congress granted it. FDA is aware of no such obligation. On the contrary, the U.S. Supreme Court has held that agencies are not required to prospectively announce their interpretations to the public before applying that interpretation in an individual case. *SEC* v. *Chenery Corp.,* 332 U.S. 194 (1947). Moreover, because FDA generally did not enforce device requirements with respect to LDTs when the MDA was passed (as a matter of practice and based on relevant public-health considerations), it would not necessarily have made sense for FDA to expend resources to issue a public statement about its authority. FDA did not put itself to that task until public-health considerations justified it in 1992. (Ref. 111). Thus, as these comments appear to concede, FDA squarely announced its understanding that LDTs are devices over 30 years ago, nearly double the 16-year period cited in these comments.

Third, to the extent that comments are suggesting that laboratories would not have understood their potential status as manufacturers around the time the MDA was passed, FDA disagrees. FDA signaled this interpretation in various contemporaneous materials. In 1973, before enactment of the MDA, FDA issued a final rule announcing regulatory requirements for IVD products, including systems, which contained no carveout or exception for laboratories (38 FR 7096, March 15, 1973). Following the MDA, FDA amended the rule to clarify that IVDs are devices, consistent with Congress's intent. 45 FR 7474, 7484 (February 1, 1980) (revising the definition to state that IVD products are ''devices'' rather than ''drugs or devices'' under the FD&C Act). Again, FDA did not create any carveout or exception for LDTs. These facts put laboratories on notice that FDA interpreted the device requirements to apply to test systems regardless of who manufactured them. In addition, 3 years earlier, in 1977, FDA issued regulations regarding device registration and listing and exempted only those clinical laboratories ''whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device'' (see § 807.65(i) (21 CFR 807.65(i)); 42 FR 42520 at 42528, August 23, 1977)). This exemption conveyed that: (1) FDA considered clinical laboratories to manufacture devices (otherwise this exemption would not have been necessary) and (2) some laboratories are not exempt from registration and listing (*i.e.,* those who fall outside the ''use of a previously manufactured device'' limitation). In addition, in the context of a different exemption, the preamble to that rule emphasized that ''exemption from registration does not relieve such persons from their obligation to comply with other provisions of the act or regulations'' (42 FR 42520 at 42521). Thus, laboratories were on notice that FDA considered them device manufacturers subject to applicable provisions of the FD&C Act and regulations.

(Comment 46) Several comments suggested that FDA's enforcement discretion approach for LDTs raises questions about FDA's authority in this area. One comment stated that the commenter ''believes that any authority to regulate LDTs has been waived through the agency's actions since 1988 if they even existed when the Medical Device Amendments passed in 1976.'' Another comment noted, in arguing that

FDA lacks authority, that the Agency has a ''history of inconsistent positions on LDTs'' and ''has never exercised [its] claimed authority in a comprehensive manner in the 85 years it had authority over devices.'' Other comments stated that FDA's ''position on [its] authority has vacillated in significant ways, even recently.''

(Response 46) FDA disagrees that its enforcement discretion approach suggests that FDA lacks or ''waived'' authority over LDTs. As an initial matter, FDA is not aware of any legal support for the proposition that an agency can waive statutory authority granted to it by Congress through the exercise of enforcement discretion. Indeed, the Supreme Court has expressly distinguished an agency's exercise of enforcement discretion—what FDA has done in the case of LDTs—from the refusal to initiate enforcement proceedings based on the agency's conclusion ''that it lacks jurisdiction''—a conclusion FDA has never reached in this context. *Heckler* v. *Chaney,* 470 U.S. 821, 833 n.4 (1985).

In addition, although FDA recognizes that it has initiated a number of efforts to address LDTs, as explained in section III.D.2 of the NPRM, these policy efforts do not cast doubt on FDA's authority or its understanding of its authority (88 FR 68006 at 68016). On the contrary, FDA's initiation of different policy approaches over the course of many years confirms that it uniformly believed it had authority and certain discretion with respect to LDTs. Furthermore, as explained in response to comment 45, FDA interpreted laboratories to be manufacturers, and IVD products, including systems, to be devices, even before the initiation of these policy efforts. And since 1992, FDA has consistently and publicly announced that IVDs manufactured by laboratories are devices under the FD&C Act (see section III.D.1 of the NPRM, ''FDA's Longstanding Recognition That IVDs Manufactured by Laboratories Are Devices,'' 88 FR 68006 at 68015–16). Thus, contrary to commenters' suggestion, FDA has not had ''inconsistent positions'' but rather has consistently maintained a single position: it has authority over LDTs.

(Comment 47) One comment argued that ''it has long been the mainstream view of legal experts that the FDA lacks authority to regulate LDTs in the absence of legislation to grant them such authority,'' referencing a white paper coauthored by Paul Clement and Laurence Tribe as well as a June 2020 memorandum by the then-General Counsel of HHS. Another comment also quoted the HHS then-General Counsel's June 2020 memorandum for the proposition that ''the Agency's jurisdiction to regulate these devices is not uniform and not as plenary as it is for a traditional device.''

(Response 47) FDA disagrees with the assertion that legal experts generally think FDA lacks authority over LDTs. In FDA's experience, many legal scholars who have occasion to discuss LDTs describe them as tests treated differently as a matter of Agency discretion, rather than because FDA lacks authority.[53] Although the first comment relies on a document authored by Paul Clement and Lawrence Tribe as support for the proposition regarding the ''mainstream view of legal experts,'' these authors did not write that document in their capacity as independent legal experts, but as counsel to the American Clinical Laboratory Association (ACLA). Therefore, that document reflects the view of one interested party. To the extent that particular commenters incorporated arguments from that document, we address the substance of those arguments in our responses to the specific comments in question. In any event, FDA's analysis is based upon the substantive merits of the issues, not upon surveying how many ''legal experts'' have advocated for or against a given view.

In addition, the June 2020 memorandum identified in the comments did not (contrary to one comment's suggestion) take the position that FDA lacks authority to regulate LDTs in the absence of legislation. Instead, the memorandum indicated that FDA has discretion to treat LDTs as devices but that there is legal risk in taking that position absent notice-and-comment rulemaking (for further detail on the June 2020 memorandum's position, see, for example, Ref. 125 at 2, n. 5). As noted by the second comment, the memorandum did suggest that FDA's authority over LDTs was constrained by certain statutory limitations; the memorandum focused in particular on the following statutory language: ''introduction or delivery for introduction into interstate commerce,'' ''commercial distribution,'' ''held for sale,'' and ''person.'' HHS no longer agrees with that memorandum, which has since been superseded, for the reasons set forth in sections VI.D.3, VI.D.4, and VI.E (comment response 105) of this preamble. More generally, we note that even if FDA's authorities were limited in the ways proposed in the June 2020 memorandum, that would not implicate the question of whether LDTs are devices and thus FDA's authority to regulate LDTs under other relevant provisions of the statute and regulations. Not all provisions apply equally to all regulated products. For example, some statutory provisions apply depending on the specific activities of a manufacturer (see response to comment 54). Similarly, some statutory provisions impose requirements with respect to a device on certain actors but not others—for example, some provisions apply only to manufacturers and importers but not to distributors (*e.g.,* 21 U.S.C. 360i(a)(1)) and others apply to all three (*e.g.,* 21 U.S.C. 360h(a))—but the device is nonetheless within FDA's jurisdiction. FDA has jurisdiction to regulate devices including LDTs, even if some subset of substantive statutory provisions do not apply to LDTs.

(Comment 48) One comment stated that ''[f]alse advertising by some rogue companies overstating the benefits of their tests is the purview of the [Federal Trade Commission (FTC)], not the FDA.''

(Response 48) Although the comment appears to argue that IVDs manufactured by laboratories are not devices (and instead fall solely within an FTC-regulated category), laboratory-made IVDs are devices, as explained elsewhere in this preamble and the NPRM. Because these IVDs are devices, advertising for them does not fall within the sole purview of the FTC. Such IVDs are subject, for example, to the provisions in the FD&C Act that deem a device misbranded if its labeling (or advertising, in the case of a restricted device) is ''false or misleading in any particular.'' 21 U.S.C. 352(a)(1) and (q). FDA recognizes that the FTC also has authority regarding the advertising of devices. *E.g.,* 15 U.S.C. 52(a)(1) (prohibiting the dissemination of ''any false advertisement . . . for the purpose of inducing, or which is likely to induce, directly or indirectly, . . . the purchase . . . of . . . devices''). Because the two Agencies share authority, they have long worked together to effectively coordinate and use their authorities in complementary ways, particularly mindful of each Agency's substantive expertise, such as FDA's scientific expertise. Thus, the FTC is not the sole regulator of device advertisements.

(Comment 49) Two comments drew an analogy between the preparation of a laboratory test and the preparation of a restaurant meal. One comment stated that while FDA regulates the ingredients of a restaurant meal, such as pasta, it does not regulate the preparation of a restaurant meal, and the same should be true for laboratory tests. Another comment stated that restaurant recipes

[53] *See, e.g.,* Refs. 122–124.

are like laboratory testing procedures and should be regulated in the same manner.

(Response 49) Food and devices present different public health considerations and are subject to different requirements under the FD&C Act, including differing premarket review requirements, so FDA oversight of restaurants should not be understood to determine FDA's authority over, or approach to, laboratory tests. Furthermore, these comments appear to take as their premise that restaurants are exempt from the FD&C Act, but that is not the case. FDA has jurisdiction over ''food,'' a term defined broadly at 21 U.S.C. 321(f), and restaurants are subject, for example, to the prohibition on doing an act with respect to a food if such act is done while the food is held for sale after shipment in interstate commerce and results in it being adulterated or misbranded (21 U.S.C. 331(k)).

(Comment 50) One comment argued that if the Supreme Court overturns or narrows the *Chevron* doctrine through its decision in *Loper Bright Enterprises* v. *Raimondo,* that would ''further undermine FDA's authority to regulate LDTs and further place in question the validity of a final LDT rule.''

(Response 50) Because the FD&C Act confers clear authority on FDA to regulate IVD products, without any exception for products made by laboratories, the *Chevron* doctrine is not necessary to resolve any question of FDA's authority over LDTs. FDA's reasoning for this position, taking into account the traditional tools of statutory construction, is set forth in the following responses to comments 51–54.

2. Application of the Device Definition to LDTs

A number of comments argued that LDTs are not devices within the meaning of 21 U.S.C. 321(h)(1) because they are intangible services rather than tangible or material objects. Comments raised arguments related to the plain language, canons of construction, legislative history, and other provisions of the FD&C Act to support this position.

(Comment 51) Several comments took the position that because the device definition does not contain the terms ''in vitro diagnostic product'' (as defined in § 809.3), ''system,'' ''assay,'' ''test,'' or ''laboratory developed test,'' it does not encompass these articles. Some stated that these terms are broader than the terms that do appear in the definition, including ''in vitro reagent,'' ''instrument,'' and ''similar or related article,'' and concluded that they therefore fall outside the definition. One comment stated that because Congress presumably was aware that diagnostic tests are ''key elements of medical diagnoses'' when it enacted the MDA, if Congress had intended to cover such tests, it would have done so expressly. Several comments stated that Congress's decision not to include the term ''system'' in the device definition in 1976, following issuance of the IVD regulations in 1973, undermines the Agency's reliance on that concept. One commenter also noted that the concept of an LDT was not discussed in congressional hearings prior to the passage of the MDA, suggesting that Congress did not intend for LDTs to be included.

(Response 51) FDA disagrees with the position that the device definition does not include IVD systems because it does not contain the terms ''system,'' ''assay,'' ''test,'' or ''laboratory developed test.'' As explained in the NPRM, IVD systems fell within the device definition (which included the terms ''apparatus'' and ''contrivance'') even before passage of the MDA (88 FR 68006 at 68017). In FDA's 1973 rulemaking, which occurred 3 years before the MDA's enactment, the Agency publicly announced its view that IVD systems fell within the device and drug definitions and thus within its authority. If Congress had disagreed with FDA's interpretation, it had the opportunity to clarify that in the MDA, but it did not do so. Instead, it retained the same terms from the device definition in the 1938 Act, without any exemption for ''systems,'' ''assays,'' ''tests,'' or ''laboratory developed tests.'' This sequence of events indicates that despite numerous opportunities to do so, over decades' worth of subsequent legislation concerning devices, Congress did not disagree with FDA's interpretation that IVD systems fall within its authority.

In fact, Congress clarified in the MDA that IVD systems are devices and not drugs. To do so, it added the terms ''in vitro reagent'' and ''other similar or related articles'' to the device definition. *See* S. Rep. No. 93–670 at 16 (January 29, 1974) (explaining, with respect to nearly identical language, that ''[t]he Committee recognizes that there is confusion at the present time about whether certain articles are to be treated as devices or drugs under the Food, Drug and Cosmetic Act. Therefore, the Committee reported bill has carefully defined 'device' so as to specifically include implants, in vitro diagnostic products, and other similar or related articles.''). The purpose of adding the term ''in vitro reagent'' was not to narrow FDA's authority over IVD products (again, Congress had much clearer ways to accomplish that); instead, the goal was to clarify that all in vitro diagnostic products were devices rather than drugs. Id. (explaining that the term ''device'' includes ''in vitro diagnostic *products*'') (emphasis added). Other evidence in the legislative history confirms that Congress intended for FDA to regulate IVD systems as devices, as explained in response to comment 53. More recently, in the Protecting Access to Medicare Act of 2014 (PAMA) (passed in 2014), Congress enacted provisions that support an interpretation that LDTs are subject to FDA regulation. 42 U.S.C. 1395m–1(d)(5) & (d)(5)(B).

FDA also disagrees with the comment that suggested that Congress would have discussed LDTs in congressional hearings if it had intended for LDTs to be included in the definition. The topics covered in congressional hearings do not trump the plain text of the device definition, which encompasses LDTs. *See Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731 at 1754 (''Judges are not free to overlook plain statutory commands on the strength of nothing more than suppositions about intentions or guesswork about expectations.''). Also, it would not be reasonable to expect that Congress would have discussed every conceivable device during congressional hearings.

(Comment 52) Many comments stated that tests made by laboratories, or some subset of such tests termed ''LDTs,'' are not devices under the FD&C Act because the device definition is limited by its plain language to physical objects or material things, and tests made by laboratories are intangible methods, services, procedures, or processes. One comment stated that a device within the definition has ''mass and volume'' and ''can be touched and held.'' Another comment relied on a canon of construction that words grouped together in a list should be given related meaning, and stated that because, according to the comment, the terms ''instrument,'' ''implement,'' ''machine,'' ''implant,'' and ''in vitro reagent'' refer to tangible objects, the terms ''apparatus'' and ''contrivance'' should also be understood to be tangible objects. The same comment noted that an ''article'' is defined as a ''particular material thing'' in the Oxford English Dictionary (OED). Several comments stated that courts have construed the term ''article'' to mean a material thing.

(Response 52) The FD&C Act defines a device, in relevant part, as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro

reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.'' 21 U.S.C. 321(h)(1)). FDA does not agree that this definition is limited by its plain language to physical objects or material things, but even if it were, a test system is a physical object and a material thing.

As an initial matter, FDA does not read the definition of device to encompass only physical objects. The definition includes terms such as ''contrivance,'' whose plain meaning goes beyond objects that can be ''touched and held.'' Contrivance, Merriam-Webster.com (last accessed January 5, 2024) (defining ''contrivance'' as ''a thing contrived'' and ''an artificial arrangement or development,'' among other things). (Ref. 126). (*See also* Ref. 127 (defining ''contrivance'' as ''an arrangement or thing in which the foregoing action or faculty is embodied; something contrived for, or employed in contriving to effect a purpose.'') Although commenters advocate for a narrow interpretation of the device definition, the Supreme Court has specifically considered and rejected a narrow reading of the FD&C Act, instead embracing broad constructions of the FD&C Act based on the Court's understanding of its text, congressional intent, and remedial purpose. *See United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (''Congress fully intended that the [FD&C] Act's coverage be as broad as its literal language indicates.'').[54] Software is an example of an article that cannot be ''touched and held'' but falls within the device definition. FDA has long interpreted software to be a device, see, *e.g.,* 52 FR 36104, September 25, 1987, and Congress reinforced that interpretation in the 21st Century Cures Act (Cures Act) (Pub. L. 114–255). The Cures Act, enacted in 2016, amended the FD&C Act to exclude certain software functions from the statutory ''device'' definition unless certain criteria are met. *See* 21 U.S.C. 360j(o). Congress would have had no need to make this amendment to the FD&C Act if the device definition did not already cover software, which is a thing that cannot be ''touched and held.'' This underscores that a plain reading of the device definition may include things that cannot be ''touched and held.''

Regardless, a test system manufactured by a laboratory is a physical product and a material thing. As explained in the NPRM, a test system is a set of components—such as reagents, instruments, and other articles—that function together to produce a test result (88 FR 68006 at 68017). No comment disputed that these individual components are physical or tangible, and there is no reason to think that uniting those physical objects in a system takes away from their physical or material nature. The instrument clause of the device definition clearly encompasses collections of this sort because it includes the term ''apparatus,'' which Merriam-Webster defines as ''a set of materials or equipment designed for a particular use'' (Ref. 128. See also Ref. 129–130). The fact that there is human involvement to fulfill the intended use of the system does not exclude it from the definition of a device. Such involvement is neither unique to LDTs nor unusual for devices more generally, as the examples offered in comment response 66 illustrate.

In short, the statute makes clear that test systems, including those manufactured by laboratories, are devices. To argue otherwise not only would be inconsistent with the FD&C Act's plain text, but also would be at odds with the way FDA has understood and regulated IVDs (and other devices) for at least half a century. *See* 38 FR 7096 at 7098, see 62 FR 62243 at 62249 (November 21, 1997), 65 FR 18230 at 18231 (April 7, 2000), Ref. 27, Ref. 32–33, Ref. 35, Ref. 39, Ref. 57, Ref. 97, Refs. 111 to 121. Indeed, under the commenters' construction of the FD&C Act, FDA would not be able to regulate any test systems at all, such as a COVID–19 test for at-home use: the Agency could oversee the safety and effectiveness of the individual test components in the context of their individual intended uses, but it could not evaluate the safety and efficacy of the COVID–19 test system as a whole, including the accuracy and reliability of the test results yielded when those individual components are used together. Such a construction defies the basic theory and premise of FDA's existing IVD program, which is to ensure that tests work. Nothing in the text or history of the FD&C Act justifies the commenters' proposed interpretation of the definition. On the contrary, the device definition specifically includes ''any component, part, or accessory,'' showing that the mere fact that an article, such as a COVID–19 test system, has individual components does not defeat the possibility that the article is a ''device.'' The legislative history also supports that Congress intended for FDA to regulate such systems, as discussed in response to comment 53. And Congress, which has been aware of FDA's interpretation for over 50 years (see 38 FR 7096), has never expressed disagreement with it. *See, e.g., United States* v. *Tuente Livestock,* 888 F. Supp. 1416, 1423 (S.D. Ohio 1995) (upholding FDA interpretation of statutory term ''food'' based, among other things, on the fact that ''Congress has been aware of the FDA's understanding and practice concerning live animals for almost twenty-five years, yet has in no way acted to limit the agency's jurisdiction'').

Furthermore, at least two Federal statutes contemplate that tests manufactured by laboratories can be subject to FDA regulation. First, CLIA refers to ''laboratory examinations and procedures'' that have been ''approved by the Food and Drug Administration for home use'' as among the types of tests a laboratory with a CLIA certificate of waiver can perform. 42 U.S.C. 263a(d)(3). Second, in PAMA, Congress expressly recognized that ''a clinical diagnostic laboratory test . . . offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner),'' a description that may include an LDT, can be ''cleared or approved by the Food and Drug Administration.'' 42 U.S.C. 1395m–1(d)(5) and (d)(5)(B). These provisions refute the comments' suggestion that tests developed by laboratories never fall within the definition of a device.

Various comments focused specifically on the term ''article'' in the device definition, citing narrow descriptions of the term ''article'' in a dictionary or in case law to support a narrow understanding of the term ''device.'' For example, one comment indicated that the term ''article'' is limited to a ''particular material thing'' based on a definition in the OED,

[54] *See also United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943) (''The purposes of [the FD&C Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.''); *United States* v. *25 Cases,* 942 F.2d 1179, 1182 (7th Cir. 1991) (quoting 79 Cong. Rec. at 4841 (1935)) (''the language [of the bill] is broad enough to cover any device of which the Food and Drug Bureau . . . . . chooses to take jurisdiction''); *United States* v. *Diapulse Corp. of America,* 457 F.2d 25, 27–28 (2d Cir. 1972) (''[t]he reach of the Act is broad''); *Clinical Reference Lab.* v. *Sullivan,* 791 F. Supp. 1499, 1508–09 (D. Kan. 1992), *rev'd in part on other grounds sub nom U.S.* v. *Undetermined No. of Unlabeled Cases,* 21 F.3d 1026 (10th Cir. 1994) (''congressional reports . . . . . indicate approval of the Supreme Court's method in *Bacto-Unidisk* of broadly defining terms within the [FD&C Act]'').

arguing that the definition of ''device'' cannot include intangible objects. FDA disagrees that this OED definition narrows the meaning of ''article'' in the FD&C Act's device definition. As an initial matter, other dictionary definitions of the term ''article'' are not so limited. See, *e.g.,* Merriam-Webster.com (Merriam Webster Collegiate Dictionary), article (''a member of a class of things'') (Ref. 131). More important, the text of the FD&C Act indicates that ''article'' is not so limited. As explained above, Congress has made clear that as used in the device definition, the term article includes software, an intangible thing. It has also made clear that the device definition encompasses clinical diagnostic laboratory tests, as just discussed.

With respect to comments' citations to cases interpreting the term ''article,'' FDA notes that none of these cases interpret language in the FD&C Act. Because these cases involve different legal schemes, contexts, and history, they are of limited relevance. Regardless, FDA has reviewed the cases and has concluded that they do not counsel in favor of a different understanding of the device definition as applied to LDTs.

Comments cited three cases: *ClearCorrect Operating, LLC* v. *ITC,* 810 F.3d 1283 (Fed. Cir. 2015), petition for rehearing en banc denied, 819 F.3d 1334 (Fed. Cir. 2016); *Wilton Meadows Ltd. P'ship* v. *Coratolo,* 14 A.3d 982 (Conn. 2011); and *Fortin* v. *Marshall,* 608 F.2d 525 (1st Cir. 1979). In *ClearCorrect,* the Federal Circuit determined that the term ''articles'' in the Tariff Act does not include digital data, relying on certain dictionary definitions contemporaneous with passage of the 1922 Tariff Act, among other things. This case is particularly inapposite because, as discussed previously, the FD&C Act specifically lists (to name one example) a ''contrivance,'' as within the device definition (unlike the Tariff Act, which does not further define the term ''articles''), and Congress has endorsed the view that the device definition in the FD&C Act (both as drafted in 1976 and currently) includes software functions. Regardless, an IVD system falls within the *ClearCorrect* court's understanding of an article because it is comprised of material things, as discussed earlier in this comment response. In *Fortin* and *Wilton Meadows,* courts interpreted the term ''article'' to exclude services (air transportation services in the former case and nursing home services in the latter). However, FDA's position is not that laboratory services are articles but that in vitro diagnostic products used in laboratories (such as test systems) are articles. Courts have agreed that medical services and articles used in medical services are distinguishable for purposes of FDA regulation. *See, e.g., United States* v. *Regenerative Sciences,* 741 F.3d 1314, 1319 (D.C. Cir. 2014). And the *Wilton Meadows* court itself acknowledged this distinction, 14 A.3d at 987 (holding that the term ''article'' does not include nursing home services but ''could reasonably be construed to include food, medicine or many other items that are associated with nursing home care,'' although upon review of relevant ''extratextual sources,'' it did not).

(Comment 53) Several comments asserted that the legislative history of the MDA bolsters the interpretation that the definition of ''device'' under 21 U.S.C. 321(h)(1) means physical objects. For example, these comments pointed to use of the terms ''products,'' ''machines'' and ''articles'' in congressional reports to argue that Congress only intended for physical objects to be devices.

(Response 53) At the outset, FDA notes that even if it were true that the legislative history suggested a narrow understanding of the device definition, that history would not trump the definition's plain text, which encompasses LDTs, as explained in comment response 52. *See Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731 at 1737 (''When the express terms of a statute give us one answer and extratextual considerations suggest another, it's no contest. Only the written word is the law.''). Moreover, FDA does not agree that the legislative history suggests a narrow understanding of the device definition. Comments point to passing references to terms such as ''products,'' ''machines'' and ''articles'' in the legislative history, but these terms, such as the term ''article,'' do not necessarily refer solely to tangible objects, as discussed in the previous comment response. Likewise, ''product'' commonly refers to things that are either tangible or intangible, insurance and software being examples of the latter. Regarding software, the FD&C Act uses the term ''product'' to specifically refer to ''software'' in section 520(o)(2). This is consistent with dictionary definitions of ''product.'' *See, e.g.,* Merriam-Webster.com (Merriam Webster Collegiate Dictionary), product (''(1): something produced'' ''(2): something (such as a service) that is marketed or sold as a commodity'') (Ref. 132). The legislative history's passing references to ''machines'' also could not have been intended to limit the scope of the device definition to tangible objects. The instrument clause of that definition, section 201(h)(1) of the FD&C Act, is not limited to machines. Rather, it refers to ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory.'' In accordance with this definition, FDA regulates as devices a wide variety of products—such as surgical instruments, surgical masks, and blood collection containers—that are not ''machines.'' In addition, the legislative history does not indicate that Congress intended for these references to limit the scope of FDA's authority; in fact, the legislative history also includes terms that cut in the opposite direction, such as a reference to a ''diagnostic service,'' as discussed later in this comment response.

Regardless, as explained in response to comment 52, LDTs are physical objects. Generally, they are systems consisting of a combination of physical objects. FDA has not identified evidence in the legislative history to suggest that when IVD components are combined as intended, the resulting in vitro diagnostic product falls outside FDA's jurisdiction; rather, the legislative history states the opposite. For example, a House report issued months before enactment of the MDA noted a district court's skepticism of FDA authority over a ''pregnancy detection kit'' and then emphasized the need for ''more comprehensive authority,'' suggesting that the Committee agreed that this type of kit (or combination of components) should fall within FDA's authority. H.R. Rep. 94–853 at 9 (February 29, 1976). A Senate report signaled Congress's intent that FDA regulate a test system (described as a ''diagnostic service'' in the report) under which an ''operator'' used various physical components—a ''Blood Specimen Carrier,'' a ''wand,'' ''metal plates,'' and a machine known as the ''Radioscope''—to determine the ''identity, kind, location, and significance of any disease present.'' S. Rep. 94–33 at 4–5 (March 11, 1975). The Committee described the system in detail, including how the individual components were used, and explained that practitioners ''received, for a fee, a diagnosis blank filled in with the diseases which the patient was supposed to have.'' Id. It noted with concern that the ''service was incapable of distinguishing the blood of animals or birds from that of man, or that of the living from the dead.'' Id. at 5. The Committee's emphasis on faulty results makes clear that it was focused on the harms from the test system, not from

any one individual component. (Although one commenter argued that the relevant ''device'' in this passage of the Senate Report was the Radioscope, that interpretation fails to account for the Committee's overall focus on the results, which were attributable to the combination of components.) The discussions in these reports reflect the degree of focus on IVDs at the time and show that, contrary to some commenters' suggestions, the MDA was enacted precisely with test systems in mind. The Committees' support for FDA authority over IVD systems is particularly notable given that FDA had, by regulation, announced that a ''system'' was a type of IVD only a few years before passage of the MDA. *See* 38 FR 7096. If Congress has disagreed with FDA's position, it presumably would have said so.

In sum, FDA does not agree that the legislative history casts doubt on its authority over LDTs; instead, it supports it. *See Clinical Reference Lab.* v. *Sullivan,* 791 F. Supp. 1499, 1508–09 (D. Kan. 1992) (''congressional reports [associated with the MDA] . . . indicate approval of the Supreme Court's method in Bacto-Unidisk of broadly defining terms within the [FD&C Act]'').

(Comment 54) Some comments stated that various provisions of the FD&C Act do not apply in the context of LDTs, which they contended supports their interpretation that LDTs do not fall within the device definition. These comments cited: (1) provisions referencing interstate commerce or movement in interstate commerce, commercial distribution, and ''held for sale,'' (2) requirements to repair, replace, or refund the purchase price of a device under 21 U.S.C. 360h(b); (3) provisions related to packaging; (4) packing, storage, and installation requirements at 21 U.S.C. 351(h), 360b, and 360j(f)(1); (5) import and export provisions at 21 U.S.C. 381; and (6) labeling requirements, such as those at 21 U.S.C. 352(a), (f). These comments concluded that FDA authority over LDTs is incompatible with the statute as a whole. Several comments also suggested that FDA regulations undermine the Agency's position, including the reference to ''in-process devices, finished devices and returned devices'' at § 820.3(r) and the UDI requirements at part 801.

(Response 54) As an initial matter, FDA disagrees with the premise of these comments that if some particular provisions in the FD&C Act do not apply to a system which meets the statutory definition of ''device,'' that means FDA lacks authority over that system. That premise is incompatible with the FD&C Act itself, which contains detailed provisions laying out the scope of the Agency's authority, the Agency's obligations, private party obligations, and private party exemptions. Congress included, for example, express statutory exclusions from certain requirements for certain healthcare personnel (such as ''practitioners licensed by law to prescribe or administer drugs or devices and who manufacture . . . drugs or devices solely for use in the course of their professional practice'' under 21 U.S.C. 360(g)(2)). It would be incongruous to conclude that it also intended, without saying so, to exclude a whole type of healthcare product or institution (namely, a laboratory). Instead, courts ''assume that Congress meant what it said, and said what it meant.'' *See Aqualliance* v. *U.S. Bureau of Reclamation,* 856 F.3d 101, 105 (D.C. Cir. 2017). The comments' interpretive approach also is inconsistent with how the Supreme Court has counseled interpretation of the FD&C Act. *See United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (''[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.''). And it runs counter to Congress's understanding of the MDA as expressed in the legislative history. *See* H.R. Rep. 94–853 at 13 (''Because the Committee recognizes . . . that, in general, authority under the [FD&C Act] to regulate food, drugs, cosmetics, and devices is too often vague thus lending itself to interpretive regulation having the force of law, the Committee has attempted to design device authority such that the law and the intent of the Congress is clear.'').

Moreover, in the case of LDTs, the alleged ''inapplicability'' of many of the provisions identified by comments arises from a laboratory's own choice not to engage in certain activities that would be governed by such provisions, not from some fundamental incompatibility between the FD&C Act and LDTs. For example, even if a given laboratory chooses not to package or ship an IVD, that is not a reason to conclude that it, or the devices it makes, are excluded from the scope of the statute altogether. It simply means the laboratory is not engaged in conduct—such as packaging—that triggers a particular statutory requirement—such as the requirement that packaged devices bear certain information in their label under 21 U.S.C. 352(b).

Under commenters' logic, any manufacturer could narrow the scope of her or his operations, such that only some provisions of the FD&C Act applied, and then assert that none of its activities are ''what Congress had in mind when it drafted the statute'' (*i.e.,* that none of its activities are within FDA's jurisdiction). FDA disagrees with this logic. That would run counter to the statute's text and would cause negative public-health outcomes. If an entity is engaged in activities subject to the FD&C Act, even if those activities are limited in scope, the entity is subject to the FD&C Act—though obviously the nature of those activities will determine which provisions of the statute apply. A manufacturer's choice to engage in only a limited number of activities to which the FD&C Act is applicable should not mean that the FD&C Act does not apply at all.

FDA also has the following responses regarding specific provisions identified by commenters as inapplicable:

- For responses to comments regarding FD&C Act provisions that reference interstate commerce, commercial distribution, and ''held for sale,'' see sections VI.D.3 and VI.D.4 of this preamble.
- To the extent that commenters argued that the repair, replacement, and refund provisions in 21 U.S.C. 360h(b) do not apply to LDTs because they cannot be repaired, replaced, or refunded, FDA disagrees. A faulty IVD system could be repaired, for example, by repairing a faulty component, such as an instrument. The system could also be replaced with another IVD system, such as one from a conventional IVD manufacturer. Or the purchase price of the system could be refunded to the same extent and in the same manner as for most other devices that are used in medical practice.
- With respect to packaging, although it is true that laboratories making LDTs generally do not package those LDTs, the FD&C Act does not assume that regulated articles are packaged. On the contrary, the FD&C Act expressly contemplates that some drugs and devices will *not* be packaged, as it imposes certain label requirements only ''*[i]f* [the device is] in a package form.'' 21 U.S.C. 352(b)) (emphasis added).
- The provisions in 21 U.S.C. 351(h) and 360j(f)(1) do not contemplate that all devices will be packed, stored, and/or installed. Rather, these statutory provisions empower FDA to establish requirements governing these activities, to the extent they occur, and also require entities to comply with FDA requirements when applicable. *See* 21 U.S.C. 360j(f)(1) (authorizing the Secretary to ''prescribe regulations requiring that the methods used in, and the facilities and controls used for, the

manufacture, pre-production design validation . . ., packing, storage, and installation of a device conform to current good manufacturing practice''); 21 U.S.C. 351(h) (device adulterated if ''the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements''). It is not the case that all these activities must occur in order for an article to be a device. For example, a cotton swab or a tongue depressor intended for a use specified in the device definition is not ''installed'' but is indisputably a device. Neither the FD&C Act nor FDA regulations assume that all these activities will occur with respect to every device. *See, e.g.,* 21 U.S.C. 360e(c)(1)(C) (requiring premarket approval applications to contain ''a full description of the methods used in, and the facilities or controls used for, the manufacture, processing, and, *when relevant,* packing and installation of, such device'') (emphasis added); § 820.1(a)(1) (''If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.''). Therefore, FDA disagrees that the potential inapplicability of these statutory provisions to some laboratories signals a broader mismatch between the FD&C Act and LDTs. Finally, although a comment referenced 21 U.S.C. 360b in connection with packing, storage, and installation, that provision relates to new animal drugs and not to devices.

- Import and export are not necessary for an article to be a device. FDA regards arguments concerning the import and export provisions at 21 U.S.C. 381 to be similar to arguments about physical shipment of an article in interstate commerce. Please see section VI.D.3 of this preamble for a detailed response to those arguments.
- Labeling requirements, such as those at 21 U.S.C. 352(a) and (f), do apply to LDTs. Although laboratories generally choose not to package LDTs or place them in a container, LDTs are accompanied by ''written, printed, or graphic matter'' that falls within the definition of labeling at 21 U.S.C. 321(m). Therefore, the labeling requirements at 21 U.S.C. 352(a) and (f) apply to LDTs.
- The comments citing FDA regulations appear to argue that despite FDA's publicly stated view that LDTs are devices, certain regulations governing device packages or returned devices may not apply to LDTs, which calls into question FDA's view of its authority. FDA disagrees with that reasoning. FDA has stated its interpretation that LDTs are devices on many occasions in clear terms and that interpretation is not undermined if some regulations do not apply to LDTs. See 62 FR 62243 at 62249 (November 21, 1997), 65 FR 18230 at 18231 (April 7, 2000), Refs. 27, 32 and 33, 35, 39, 57, 97, 111 to 121). In any event, the regulations the comments point to are not necessarily inapplicable to LDTs. First, the terms ''in-process devices'' and ''finished devices'' in the definition of ''product'' at § 820.3(r) apply to LDTs. An LDT can be ''in-process,'' for example, when system components are in process, such as when a laboratory manufacturer is sourcing and qualifying critical reagents such as primers and probes or antibodies for their test system. In addition, FDA recognizes that the UDI requirements at part 801 generally apply to ''labels'' and ''device packages,'' and that laboratories generally do not package their IVDs, such as test systems. However, this is not necessarily the case for all laboratories' IVDs and does not mean that laboratories are incapable of compliance with UDI requirements. For the reasons previously stated, FDA does not agree that these UDI requirements have any broader meaning with respect to FDA's authority over LDTs.

3. Interstate Commerce and ''Held for Sale''

(Comment 55) Several comments asserted that FDA lacks authority to regulate LDTs under the FD&C Act because many of FDA's authorities to regulate devices, such as the premarket notification provision in section 510(k) of the FD&C Act (21 U.S.C. 360(k)), require introduction or delivery for introduction into interstate commerce and, according to the comments, LDTs do not meet this element. One comment argued that in addition to section 510(k), the FD&C Act's premarket approval and De Novo classification provisions are limited to devices that are or will be introduced or delivered for introduction into interstate commerce, citing sections 513(c)(2)(C)(ii), 513(f)(1), 515(b)(1), and 515(i)(1) of the FD&C Act.

(Response 55) We disagree that introduction or delivery for introduction into interstate commerce is required for FDA jurisdiction of devices, including LDTs, under the FD&C Act. The FD&C Act's definition of a ''device'' subject to FDA's jurisdiction does not include an interstate commerce element. Whether a particular provision of the FD&C Act requires a connection to interstate commerce goes to the reach of *that specific provision,* not of the device definition or of the Act as a whole. If an FD&C Act provision does not contain an interstate commerce element, ''interstate commerce'' imposes no limit on FDA's powers beyond the constitutional minimum.

Section 510(k) of the FD&C Act illustrates this point. That provision states that a person who is required to register and ''proposes to begin the introduction or delivery for introduction into interstate commerce'' of a device ''shall'' submit a premarket notification. The inclusion of an interstate commerce element in section 510(k) of the FD&C Act means that the requirements of *that section* do not apply where that element is not satisfied. It does not mean that FDA lacks jurisdiction to enforce *other* device provisions of the FD&C Act that do not include such an element.[55]

Contrary to the assertion in comments that ''many'' of the FD&C Act's device requirements require introduction or delivery for introduction into interstate commerce, relatively few of the device provisions in the FD&C Act and FDA regulations include a specific interstate commerce element, and most of the device-related prohibited acts do not. See, *e.g.,* 21 U.S.C. 331(e) (prohibiting the failure to establish or maintain any record, or make any report, required under the device adverse-event reporting requirements without reference to interstate commerce); 21 U.S.C. 331(p) (prohibiting the failure to register a device establishment without reference to interstate commerce); 21 U.S.C. 331(q)(1) (prohibiting the failure to comply with device investigational use requirements without reference to interstate commerce); 21 U.S.C. 331(f)(3) (prohibiting the doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or holding for sale or dispensing, of a counterfeit device without reference to interstate commerce). For further discussion, see the NPRM (88 FR 68006 at 68019–20). Additionally, the FD&C Act gives FDA authority to take action, without satisfying any particular interstate commerce element, when there is a violation of device requirements. For example, FDA has the

[55] Additionally, as discussed in the NPRM, section 510(k) of the FD&C Act does not *preclude* regulated entities from submitting premarket notifications even if the device is not introduced into interstate commerce (88 FR 68006 at 68020). Therefore, laboratories may utilize the less burdensome 510(k) process to market their LDT even assuming the device is not introduced or delivered for introduction into interstate commerce. Regardless, the inclusion of an interstate commerce element in section 510(k) in no way affects FDA's overall authority to regulate IVDs manufactured by laboratories.

authority to seize any ''adulterated or misbranded device'' without reference to an interstate commerce element (21 U.S.C. 334(a)(2)). Thus, FDA does not somehow lose jurisdiction if a particular device has not been introduced or delivered for introduction into interstate commerce.

Further, Congress clearly intended that FDA have jurisdiction over devices that violate the FD&C Act even if they are not introduced or delivered for introduction into interstate commerce. For example, as discussed in the NPRM, Congress intentionally revised the aforementioned seizure provision of the FD&C Act, section 304, to ensure that FDA could take action against devices without satisfying any particular interstate commerce element. For further discussion, see the NPRM (88 FR 68006 at 68020). Additionally, one of the key prohibited acts on which FDA relies, section 301(k) of the FD&C Act (21 U.S.C. 331(k)), contains an interstate commerce element, but it does not require a *complete* violative device to have itself been introduced or delivered for introduction into interstate commerce. That provision prohibits ''the doing of any . . . act with respect to, a . . . device . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.'' Courts have held that even if a product is wholly manufactured and sold intrastate, the interstate commerce element in this provision is satisfied if a component used in manufacturing the product has traveled in interstate commerce. (See, *e.g., United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314, 1320–21 (D.C. Cir. 2014) (upholding FDA enforcement action under section 301(k) of the FD&C Act because a drug component had traveled in interstate commerce); *Baker* v. *United States,* 932 F.2d 813, 814–15 (9th Cir. 1991); *United States* v. *Dianovin Pharm., Inc.,* 475 F.2d 100, 102–103 (1st Cir. 1973)). At least some components of test systems, such as reagents and instruments, are usually shipped in interstate commerce even if the system itself is designed, manufactured, and used within the laboratory. And section 709 of the FD&C Act (21 U.S.C. 379a) establishes a presumption that any required connection with interstate commerce exists for enforcement actions, meaning that the burden is on regulated parties to demonstrate, for example, that no component of a system traveled across State lines. (''In any action to enforce the requirements of this Act respecting a device . . . the connection with interstate commerce . . . shall be presumed to exist.''). Thus, under the FD&C Act, FDA has authority over devices even assuming they are not introduced or delivered in completed form for introduction into interstate commerce.

FDA also disagrees with the comment's apparent presumption that, if a device is not subject to 510(k) requirements (because that provision's interstate commerce element is not satisfied), then it must not be subject to any of the FD&C Act's other requirements for marketing a device. As explained in the rest of this response, the relevant statutory text contains no such limitation.

Section 513(f)(1) of the FD&C Act applies to devices intended for human use that were ''*not* introduced or delivered for introduction into interstate commerce for commercial distribution before [May 28, 1976].'' (emphasis added). Under sections 513(f)(1) and 515(a), such devices fall into class III by operation of law, and must have an approved PMA, unless either: (1) they are exempt as investigational devices under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)) or (2) they satisfy one of the criteria established in section 513(f)(1)(A)–(C) (21 U.S.C. 360c(f)(1)(A)–(C)).[56]

References in sections 513(c)(2)(C)(ii), 515(b)(1), and 515(i)(1) of the FD&C Act to devices that *were* ''introduced or delivered for introduction into interstate commerce for commercial distribution before [May 28, 1976]'' do not impose a general interstate commerce limitation on the FD&C Act's PMA requirements or the De Novo provisions. Rather, these sections use that language to identify the preamendments devices that are subject to specific processes under the FD&C Act.

The FD&C Act's De Novo and reclassification provisions (sections 513(f)(2) and (f)(3) of the FD&C Act, respectively) are also not limited to devices that are or will be introduced or delivered for introduction into interstate commerce. The De Novo provisions provide an alternative process for classifying new devices into class I or II where there is no legally marketed device upon which to base a substantial equivalence determination (section 513(f)(2) of the FD&C Act). Indeed, as mentioned above, De Novo is available as a non-PMA marketing pathway for certain devices that were ''*not* introduced or delivered for introduction into interstate commerce for commercial distribution before [May 28, 1976].'' (emphasis added). Manufacturers may also utilize the reclassification process in section 513(f)(3) of the FD&C Act, which likewise applies to devices ''*not* introduced or delivered for introduction into interstate commerce for commercial distribution before [May 28, 1976]'' (emphasis added) (see sections 513(f)(1) and (3)).

In sum, a device that is not subject to the premarket notification requirements under section 510(k) of the FD&C Act because it does not satisfy that provision's interstate commerce element is not thereby exempted from other requirements under the FD&C Act that do not include such an element.

(Comment 56) A comment asserted that FDA's interpretation of interstate commerce deviates from the plain language definition of the term and that FDA's concept of interstate commerce in section IV.B.3.a. of the NPRM (88 FR 68006 at 68019 and 68020) is so expansive as to negate the entirety of the meaning of the word interstate. Further, the comment asserted that if Congress did not intend to restrict FDA's authority to interstate commerce, it would not have used the term in legislation.

(Response 56) FDA did not provide a specific interpretation of the term ''interstate commerce'' in the NPRM but rather, we explained that interstate commerce is not a prerequisite to FDA device jurisdiction (beyond the constitutional minimum). To the extent the comment is asserting that interstate commerce is a prerequisite to FDA device jurisdiction, FDA disagrees. As explained in the NPRM and in response to comment 55, in the FD&C Act there are a limited number of provisions applicable to devices that include a specific interstate commerce element (88 FR 68006 at 68019–20). Where a provision applicable to devices includes an interstate commerce element, the particular interstate commerce element must be met in order for FDA to exercise authority under that provision. However, there are many provisions applicable to devices that do not include an interstate commerce element. Where a provision applicable to devices does not include an interstate commerce element, the provision applies without satisfying any particular interstate commerce element. ''[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'' *See,*

[56] Those criteria are substantial equivalence under section 513(i), reclassification under section 513(f)(3), and De Novo authorization under section 513(f)(2) of the FD&C Act.

e.g., Russello v. *United States,* 464 U.S. 16, 23 (1983) (quoting *United States* v. *Wong Kim Bo,* 472 F.2d 720, 722 (CA5 1972)). Additionally, as discussed in the NPRM and in response to comment 55, Congress intentionally revised section 304 of the FD&C Act (seizure provisions) to ensure that FDA could take action against devices without satisfying any particular interstate commerce element (88 FR 68006 at 68020; H.R. Rep. No. 94–853 (1976), at 15). Thus, the statutory text of the FD&C Act, caselaw construing that text (such as *United States* v. *Walsh,* 331 U.S. 432, 434–36 (1947), discussed in the NPRM (88 FR 68006 at 68020)), and the legislative history of the MDA clearly support that interstate commerce is not a prerequisite to FDA jurisdiction over devices under the FD&C Act (beyond the constitutional minimum).

(Comment 57) One comment asserted that the NPRM was dismissive of concerns that Congress, by granting FDA the statutory authorities relied on here, may have exceeded its authority under the Interstate Commerce Clause of the U.S. Constitution, adding that some current justices of the U.S. Supreme Court might not agree that Congress may constitutionally authorize FDA to regulate purely intrastate operations.

(Response 57) The legal position FDA described in the NPRM and reflected in the final rule is fully consistent with current Interstate Commerce Clause jurisprudence, including numerous cases decided over decades by the U.S. Supreme Court. *See, e.g., Gonzales* v. *Raich,* 545 U.S. 1, 17–18 (2005).

As an initial matter, many laboratories that at first glance might appear to be operating exclusively within a single state are in fact operating interstate. Their online advertising may attract patients, the human samples they test may have been collected, the components they purchase to assemble their LDTs may have been shipped, and the test reports they generate may go to ordering physicians, from out-of-state. So not all laboratory manufacturers have operations that are purely intrastate.

But, even if a laboratory's operations are purely intrastate, Congress can still regulate the laboratory's activities under the Interstate Commerce Clause. The Supreme Court's ''case law firmly establishes Congress' power to regulate purely local activities that are part of an economic 'class of activities' that have a substantial effect on interstate commerce.'' *Gonzales* v. *Raich,* 545 U.S. at 17. Congress ''may regulate these intrastate activities based on their aggregate effect on interstate commerce.'' *Taylor* v. *United States,* 579 U.S. 301, 303 (2016). When a laboratory offers a test for purchase and use by healthcare providers and patients for diagnosis or treatment, it is engaged in economic activity. And that economic activity, in the aggregate, has a substantial effect on interstate commerce. As explained in the FRIA, FDA's primary estimated market revenue for IVDs offered as LDTs for 2023 is, in 2022 dollars, approximately $20 billion. IVDs offered as LDTs divert patients and providers from using IVDs not offered as LDTs, whose market FDA estimates at 65 percent of all IVDs (Ref. 10). And the test results obtained from IVDs offered as LDTs will lead patients and providers to choose to undergo or forgo a variety of health treatment decisions, with clear effects in both directions on the markets for the relevant treatments.

(Comment 58) A comment argued that LDTs are not ''held for sale'' under section 301(k) of the FD&C Act because there is no transfer of title or possession of an LDT to the ordering physician, and that this view comports with case law, which extends FDA's jurisdiction to regulate drugs and devices after release by the original manufacturer, but only insofar as such regulated products are being delivered or transferred to another ultimate consumer. The comment also argued that *United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314 (D.C. Cir. 2014), is inapplicable to LDTs because that case involved a drug-cell mixture administered to a patient for treatment, and LDTs are not transferred to anyone but performed by the manufacturer. The comment further argued that ''held for sale'' does not include use of a device to facilitate the work of a healthcare professional where that device is not transferred to the patient, citing *Shahinian* v. *Kimberly-Clark Corp.,* No. 14–CV–8390, 2017 WL 11595343 (C.D. Cal. March 7, 2017). Additionally, the comment argued that in cases cited by FDA in its response to a citizen petition from ACLA and in a memorandum by the then-General Counsel to HHS, the regulated drug or device product was delivered or transferred from one party (typically a doctor) to an ultimate consumer (typically a patient), and that this does not occur with LDTs.

(Response 58) FDA disagrees with the comment. Section 301 of the FD&C Act identifies prohibited acts that are intended to provide protection against adulterated and misbranded devices all the way to the consumer or patient. For example, section 301(a) addresses acts early in the distribution chain, by prohibiting ''[t]he introduction or delivery for introduction into interstate commerce'' of an adulterated or misbranded device (21 U.S.C. 331(a)). Separately, section 301(k) of the FD&C Act addresses circumstances later in the distribution process, in which the defendant does an act that results in the adulteration or misbranding of a device that is held for sale. Specifically, this section prohibits ''the doing of any . . . act with respect to, a . . . device . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded'' (21 U.S.C. 331(k)). Courts have adopted a broad interpretation of the phrase ''held for sale'' in section 301(k) of the FD&C Act. This interpretation is based on the 1948 Supreme Court decision, *United States* v. *Sullivan,* 332 U.S. 689, in which the Court explained: sections 301(a)–(c) of the FD&C Act ''alone would not supply protection all the way to the consumer. The words of paragraph (k) 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.'' Id. at 696–97.

LDTs are ''held for sale'' under section 301(k) of the FD&C Act. Among other things, laboratories generally sell their LDTs. Similar to other prescription products, a physician orders a test (which may or may not be an LDT) and the patient (or another party such as the patient's insurer) pays for it. With LDTs, patients and their healthcare providers are the ultimate consumers. LDTs are used on patients, specifically their specimens (as is the nature of in vitro diagnostic products), and the LDT output—the test results—are provided to healthcare professionals and/or patients for use in diagnosing or treating patients.

Consistent with section 301(k) of the FD&C Act's purpose, courts have held that devices used in the diagnosis or treatment of patients may properly be considered ''held for sale'' within the meaning of the FD&C Act, even where the device itself is not delivered or transferred to a patient. *See, e.g., United States* v. *Diapulse Corp. of Am.,* 514 F.2d 1097, 1098 (2d Cir. 1975) (the Diapulse machine, which was held by practitioners and ''used in the treatment of patients, may properly be considered 'held for sale' within the meaning of the [FD&C Act], 21 U.S.C. 331(k).'' (citations omitted)); *United States* v. *Articles of Device (Acuflex; Pro-Med),* 426 F. Supp. 366, 368 n.3 (W.D. Pa. 1977) (''Therefore, by their use in diagnosis [the electric acupuncture devices] were

held for sale after interstate shipment.''); *United States* v. *Device Labeled* ''*Cameron Spitler Amblyo-Syntonizer,*'' *etc.,* 261 F. Supp. 243, 246 (D. Neb. 1966) (''The court is also of the opinion that the devices were misbranded while being held for sale. Although the claimant never sold the devices in the commercial sense, the device was used in the claimant's treatment of patients.''). This interpretation of section 301(k) of the FD&C Act by the courts is consistent with the FD&C Act's intent to supply protection ''all the way to the consumer.'' The view asserted by the comment is not only inconsistent with the case law, but also would leave a serious gap in protecting patients under the FD&C Act. For example, under the comment's view, devices such as x-ray systems, MRI systems, excimer lasers, and proton therapy beams could never fall within section 301(k) of the FD&C Act because these devices are not delivered or transferred to a patient, even though they are used on patients. Whether a device is physically transferred/delivered to a patient or used on a patient without physical transfer/delivery, the public health interest in safe and effective devices is the same.

Although some of the cases discussing section 301(k) of the FD&C Act involved a product that was delivered or transferred to a patient, that does not mean that these cases stand for the proposition that delivery or transfer to a patient must occur in order for section 301(k) to apply. For example, in *United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314 (D.C. Cir. 2014), cited in one of the comments, the D.C. Circuit did not state that an article is held for sale only if there is physical delivery or transfer to a patient. Indeed, it did not address the ''held for sale'' requirement at all. On appeal the issue concerning section 301(k) of the FD&C Act was whether the defendant's entire Mixture product had to be shipped in interstate commerce in order to fall within section 301(k), which applies ''after shipment in interstate commerce.'' Id. at 1320. The court held ''that, by virtue of its use of doxycycline, [a component shipped in interstate commerce,] the Mixture is within the scope of drugs—and, by extension, biological products, see 42 U.S.C. 262(j)—regulated by [21 U.S.C.] § 331(k).'' Id. at 1321. Contrary to the comment's assertion, the D.C. Circuit's holding applies to LDTs because, among other things, LDTs are generally manufactured with components that are shipped in interstate commerce. Additionally, the district court's opinion in the same case *did* address the ''held for sale'' requirement, and endorsed FDA's interpretation. The district court stated: ''Defendants create the cell product, the 'drug' in this case, and use it to treat their patients. Such conduct satisfies the 'held for sale' requirement of the statute.'' *United States* v. *Regenerative Scis., LLC,* 878 F. Supp. 2d 248, 258. Both courts determined that the defendants who manufactured the Mixture fell within the scope of section 301(k) of the FD&C Act, because the Mixture was made with doxycycline that had been shipped in interstate commerce and the defendants used the Mixture to treat patients. Similarly, laboratories that manufacture LDTs with any component that has been shipped in interstate commerce and use their LDTs in the diagnosis or treatment of patients fall within the scope of section 301(k). 21 U.S.C. 331(k).

Additionally, the comment misconstrues *Shahinian* v. *Kimberly-Clark Corp.,* No. 14–CV–8390, 2017 WL 11595343 (C.D. Cal. March 7, 2017). Although not explicitly stated, it appears that the court considered the surgical gowns not to be ''held for sale'' by the surgery center because the surgery center purchased the surgical gowns for its own personal consumption.

In contrast, laboratories are not manufacturing LDTs solely for their own personal consumption. Rather, laboratories manufacture LDTs for healthcare providers and patients. Consistent with the case law discussed above, LDTs are generally held for sale under section 301(k) because LDTs are generally sold and used on patients, specifically their specimens (as is the nature of in vitro diagnostic products), and the LDT output—the test results—are provided to healthcare professionals and/or patients for use in diagnosing or treating patients.

(Comment 59) A comment argued that even if LDTs were ''held for sale,'' section 301(k) of the FD&C Act only applies while LDTs are held for sale ''after shipment'' in interstate commerce, and LDTs are never shipped in interstate commerce, but rather performed only within the laboratory in which they are developed.

(Response 59) FDA disagrees with the comment. The comment's assertion—that section 301(k) of the FD&C Act only applies while LDTs are held for sale after the LDT is shipped in interstate commerce—is contrary to the case law. For example, as discussed in response to comment 58, the appellants in *United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314, raised this issue, arguing that section 301(k) did not apply because the entire Mixture product was not shipped in interstate commerce. Id. at 1320. The court disagreed, holding ''that, by virtue of its use of doxycycline''—a component shipped in interstate commerce—''the Mixture is within the scope of drugs—and, by extension, biological products, see 42 U.S.C. 262(j)—regulated by [21 U.S.C.] § 331(k).'' Id. at 1321. The court noted that other circuits had come to the same conclusion, citing *Baker* v. *United States,* 932 F.2d 813, 814 (9th Cir. 1991) (holding that section 301(k) of the FD&C Act's '' 'shipment in interstate commerce' requirement is satisfied even when only an ingredient is transported interstate.''); and *United States* v. *Dianovin Pharmaceuticals, Inc.,* 475 F.2d 100, 103 (1st Cir. 1973) (holding that the company's ''use of components shipped in interstate commerce to make vitamin K for injection brought their activities within [21 U.S.C.] § 331(k).''). Thus, even if the LDT itself is not shipped in interstate commerce, LDTs generally are manufactured with components (*e.g.,* reagents and instruments) that are shipped in interstate commerce, and as discussed in response to comment 58, generally LDTs are held for sale under section 301(k) of the FD&C Act.

4. Commercial Distribution

(Comment 60) Some comments asserted that FDA lacks authority to regulate LDTs under the FD&C Act because certain device provisions under the FD&C Act, such as the premarket notification provision in section 510(k) of the FD&C Act, require ''commercial distribution'' and that LDTs do not meet this element. For example, several comments argued that LDTs are not in commercial distribution because there is no transfer of title with an LDT, and the test is not distributed to the clinician or the patient. A comment further argued that ''commerce'' refers to ''the exchange or buying and selling of commodities especially on a large scale and involving transportation from place to place'' and that ''distribution'' requires a ''delivery'' or ''conveyance'' of a good from a main source. Additionally, the comment alleged that the preamble to part 807 took pains to emphasize that commercial distribution is satisfied only where the product at issue is transferred to an unaffiliated third party, claiming that this is the reason why § 807.3(b)(1) specifically exempts the ''[i]nternal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company,'' and that this is also the reason why the preamble to the analyte specific reagent (ASR) rule expressly distinguished between ''ASR's that move in

commerce'' and ''tests developed in-house by clinical laboratories or ASR's created in-house and used exclusively by that laboratory for testing services.'' (62 FR 62243 at 62249, November 21, 1997). Additionally, a comment argued that in Compliance Policy Guide (CPG) § 300.600 (Commercial Distribution with Regard to Premarket Notification (Section 510(k))) (1978, reissued 1987) (Ref. 133), FDA interpreted commercial distribution to require actual or anticipated delivery of the device to purchasers or consignees and that in *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, 993–95 (W.D. Mich. 1985), a court upheld this interpretation.

(Response 60) FDA disagrees with these comments. As discussed in the NPRM, LDTs generally are in commercial distribution (88 FR 68006 at 68020–21). Under our longstanding interpretation, ''commercial distribution'' does not require the physical transfer of an object, nor does it require transfer of title. Instead, the legislative history of the MDA, FDA's near contemporaneous regulation, and at least one judicial decision reflect that the phrase ''commercial distribution'' means ''on the market.'' *See* H.R. Rep. No. 94–853 at 36 (Feb. 29, 1976) (''`Commercial distribution' is the functional equivalent of the popular phrase `on the market.' ''); 41 FR 37458 at 37459, September 3, 1976 (in the preamble to proposed part 807, FDA equated ''commercial distribution'' with the phrase ''on the market''); and *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, 994–95 (upholding as reasonable FDA's interpretation of ''commercial distribution'' to mean, ''in its popular sense, `on the market' ''). For further discussion, see the NPRM (88 FR 68006 at 68020). Because LDTs generally are ''on the market,'' they are for commercial distribution. For example, like manufacturers of other IVDs do, laboratories often promote their LDTs on their websites and hold or offer them for sale.

Additionally, the dictionary definitions of ''commercial,'' ''distribute'' and ''distribution'' are not limited to physical transfer of an object. The dictionary defines ''commercial'' to mean ''of or relating to commerce,'' providing examples of ''commercial regulations'' and ''commercial services,'' thus making it clear that the term ''commercial'' is not limited to ''the exchange or buying and selling of commodities especially on a large scale and involving transportation from place to place'' as suggested in the comment (Ref. 134). Regardless, the manufacture of LDTs generally involves components, such as reagents and instruments, that are purchased by and transported to the laboratory, and thus, involves commerce even under the more limited definition described in the comment. Moreover, the dictionary definitions of ''distribute'' and ''distribution'' include ''supply for sale'' and ''the marketing or merchandising of commodities'' (Refs. 135 and 136).[57] Thus, the plain meanings of ''commercial,'' ''distribute,'' and ''distribution'' are not limited to physical transfer of an object, and are consistent with FDA's longstanding interpretation of ''commercial distribution.''

FDA's interpretation of ''commercial distribution'' is also consistent with the FD&C Act's overriding purpose to ''protect the public health by ensuring that . . . there is reasonable assurance of the safety and effectiveness of devices intended for human use.'' Section 1003(b)(2)(C) of the FD&C Act (21 U.S.C. 393(b)(2)(C)). Moreover, FDA's interpretation of ''commercial distribution'' is consistent with section 301(k) of the FD&C Act which is intended to supply protection all the way to the consumer. As discussed in our responses to comments in section VI.D.3, the case law on section 301(k) of the FD&C Act supports FDA's jurisdiction over medical products that never leave a physician's office, and that are used in the diagnosis or treatment of patients even where the product itself is not delivered or transferred to a patient. *See, e.g., United States* v. *Diapulse Corp. of Am.,* 514 F.2d 1097, 1098 (the Diapulse machine, which was held by practitioners and ''used in the treatment of patients, may properly be considered `held for sale' within the meaning of the [FD&C Act], 21 U.S.C. 331(k).'' (citations omitted)); *United States* v. *Articles of Device (Acuflex; Pro-Med),* 426 F. Supp. 366, 368 n.3 (''Therefore, by their use in diagnosis [the electric acupuncture devices] were held for sale after interstate shipment.''); *United States* v. *Device Labeled ''Cameron Spitler Amblyo-Syntonizer,'' etc.,* 261 F. Supp. 243, 246 (''The court is also of the opinion that the devices were misbranded while being held for sale. Although the claimant never sold the devices in the commercial sense, the device was used in the claimant's treatment of patients.'').

However, even assuming LDTs were not in commercial distribution, this would not preclude FDA jurisdiction over these devices. As an initial matter, even assuming that certain provisions in the FD&C Act do not apply to a particular device, that does not mean FDA lacks authority to regulate the device under the FD&C Act. As discussed in the NPRM, ''commercial distribution'' appears in certain device provisions of the FD&C Act, including section 510(k), but as with ''interstate commerce,'' the presence of this term in certain device provisions does not bear on the Agency's overall jurisdiction (88 FR 68006 at 68019–21). For example, ''commercial distribution'' is not needed to trigger or enforce the PMA requirements. Specifically, section 515(a)(2) of the FD&C Act requires, without reference to commercial distribution, an approved PMA for any device that is class III under section 513(f) of the FD&C Act (which applies to all postamendments devices) unless it is exempt under section 520(g) of the FD&C Act, and section 501(f)(1)(B) of the FD&C Act deems adulterated, without reference to commercial distribution, any device that is classified into class III under section 513(f) of the FD&C Act and is required to have an approved PMA under section 515(a) of the FD&C Act, unless it is exempt under section 520(g) of the FD&C Act. Simply put, any requirement of commercial distribution is conspicuously absent from the statutory provisions that require an approved PMA for a postamendments class III device and that render the device adulterated in its absence. Further, FDA may initiate seizure of an adulterated device regardless of whether the device is in commercial distribution (21 U.S.C. 334(a)(2)(D) (stating that any adulterated device ''shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States . . . within the jurisdiction of which they are found,'' without reference to ''commercial distribution'')).

The fact that Congress chose to include commercial distribution as an element only in certain device provisions but omitted it in others further supports that Congress did not intend for commercial distribution to be a prerequisite for device jurisdiction under the FD&C Act. ''[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'' *See, e.g., Russello* v. *United States,* 464 U.S. 16, 23 (quoting *United States* v. *Wong Kim Bo,* 472 F.2d 720, 722). When

[57] The definition of ''commodity'' includes ''an economic good'' and ''something useful or valued'' (Ref. 137).

Congress enacted the MDA, it could have made commercial distribution an overarching element for device jurisdiction, but instead Congress chose to include this element only in a limited number of device provisions.

Regarding the regulatory exclusion from commercial distribution in § 807.3(b)(1) for ''[i]nternal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company,'' the preambles to the regulation support that this was intended to exclude such transfers as such devices were not on the market at that point. In the preamble to proposed part 807, FDA explicitly equated ''commercial distribution'' with ''on the market.'' 41 FR 37458 at 37459 (''The Amendments contain special provisions relating to the classification of devices not in commercial distribution (*i.e.,* not actually on the market) prior to May 28, 1976''). Further, commenters understood ''commercial distribution'' to mean ''on the market.'' *See* 42 FR 42520 (with regard to the internal/interplant transfer exclusion in the ''commercial distribution'' definition, commenters recommended that transfers between a foreign subsidiary and domestic parent also be excluded as ''premarket notification in such a situation would not serve any useful purpose since the device will not go 'on the market' at that point.''). Thus, the exclusion in § 807.3(b)(1) is consistent with FDA's longstanding interpretation of ''commercial distribution.''

Regarding the CPG on commercial distribution and *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, neither the CPG nor the court in this case limited ''commercial distribution'' to delivery. The CPG is clearly directed to devices that were not delivered. Specifically, the CPG identifies certain factors that FDA considers in determining whether a device is in commercial distribution before May 28, 1976, ''even though no units of the device had been delivered to purchasers or consignees.'' (Ref. 133). The factor in the CPG that the manufacturer had, before May 28, 1976, accepted or been prepared to accept at least one purchase order ''*generally* with delivery to occur immediately or at a promised future date'' indicates that delivery is typical but not necessary. Id. (emphasis added). Regardless, given that the CPG clearly covers devices that were not delivered, it reflects FDA's view that delivery is not required for commercial distribution. Additionally, in *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, 993–95, the court upheld FDA's interpretation of commercial distribution, stating ''This explanation, together with the agency's compliance policy guide . . . is a reasonable interpretation of the phrase 'commercial distribution'.'' The court was referring to the explanation in FDA's letter to the firm that, among other things, ''indicated that the agency views 'commercial distribution' to mean, in its popular sense, 'on the market', pursuant to H.R. 94–853, 94th Cong. 2d Sess. 36 (1976).'' Id. at 994.

Regarding the preamble to the ASR rule, FDA's limitation of the scope of the ASR rule to ''the classification and regulation of ASR's that move in commerce, not tests developed in-house by clinical laboratories,'' was a statement that those products were outside the scope of the rule and not a statement that there was no commercial distribution or that they were outside of FDA's jurisdiction or authority to regulate. 62 FR 62243 at 62249 (''The focus of this rule is the classification and regulation of ASR's that move in commerce, not tests developed in-house by clinical laboratories. . . .''). In fact, FDA made clear in the preamble to the ASR rule that ''FDA believes that clinical laboratories that develop [in-house] tests are acting as manufacturers of medical devices and are subject to FDA jurisdiction under the act.'' Id.

(Comment 61) A comment argued that neither the FD&C Act nor FDA's own interpretation of the statute supports an interpretation that a device not subject to section 510(k) may be independently subject to the PMA requirements in section 515 or the De Novo provisions in section 513(f)(2) of the FD&C Act. The comment argued that this is because submission of a PMA under section 515 or a De Novo request under section 513(f)(2) satisfies the requirement to submit a 510(k) premarket notification, which generally applies to all devices unless subject to a specific exemption. As support, the comment points to § 807.81, which states that a premarket notification is not required for a device for which a PMA, or for which a reclassification petition under section 513(f)(2) of the FD&C Act, is pending before FDA. The comment also refers to the preamble to proposed part 807 in which the Agency stated that ''[a] premarket notification under § 807.81 is not required for a device for which a premarket application under section 515 of the act, or for which a petition to reclassify from class III to class I or II under section 513(f)(2) of the act, is pending before FDA. For such devices, the other submissions will serve the purpose of a notification under section 510(k) of the act.'' 41 FR 37458 at 37460. Additionally, the comment refers to the preamble to the final rule setting out part 807 in which FDA explained ''[i]f a premarket approval application has been submitted, a premarket notification submission would not be required since FDA would already be advised of the intent to market.'' 42 FR 42520 at 42523. Another comment also argued that it ''defies logic that Congress would create a system to regulate LDTs where foundational provisions would not apply.'' The comment also alleged that the principal pathway to market for devices would be unavailable to LDTs, and claimed that the tens of thousands of LDTs that FDA estimated to be eligible for the 510(k) pathway in the PRIA would be subject to the lengthier, more expensive PMA and De Novo pathways.

(Response 61) The comment suggests that the fact that there are exemptions from the 510(k) requirements in the FD&C Act and in FDA regulations supports the conclusion that a device must be subject to the 510(k) requirements in order to be subject to the PMA requirements. FDA disagrees. Exemptions from the 510(k) requirements in the FD&C Act and FDA regulations are provided for various reasons, *e.g.,* because a 510(k) submission is not necessary to provide for reasonable assurance of safety and effectiveness as reflected in section 510(m) of the FD&C Act or because a 510(k) submission is not necessary where another submission informs the Agency of the intent to market the device as reflected in § 807.81(b)(1) and the accompanying preambles. The fact that these exemptions from 510(k) requirements exist do not signify that a device must be intended for ''introduction or delivery for introduction into interstate commerce for commercial distribution'' under section 510(k) of the FD&C Act in order for FDA to have jurisdiction over the device or for the PMA requirements to apply. This is supported by the device framework in the FD&C Act where all postamendments devices are class III by operation of law and subject to the PMA requirements, without satisfying any particular interstate commerce or commercial distribution element, unless one of the criteria under section 513(f)(1) of the FD&C Act is met or the device is exempt under section 520(g) of the FD&C Act (section 513(f)(1) of the FD&C Act). This is also supported by the numerous other provisions applicable to devices that do not require these elements, including the seizure

provision in section 304(a)(2) which was amended through the MDA. The legislative history of the MDA reinforces that under section 304(a)(2) of the FD&C Act, FDA has the authority to seize adulterated and misbranded devices without satisfying any particular interstate commerce element (see H.R. Rep. 94–853 at 15 (Congress made clear that it was amending this seizure provision to ''permit seizure of devices without reference to interstate commerce'' because ''whether or not a medical device actually crosses state lines has nothing to do with the principal intent of this proposal: to assure the safety and effectiveness of medical devices.'')).

Further, the 510(k) and PMA requirements are separate and distinct as reflected by the different charges under the FD&C Act. Specifically, the failure to provide a premarket notification as required under section 510(k) of the FD&C Act misbrands the device (section 502(o) of the FD&C Act), and the failure to obtain approval of a PMA as required under section 515 of the FD&C Act adulterates the device (section 501(f)(1) of the FD&C Act). Indeed, FDA routinely cites both charges in warning letters issued to manufacturers that appear to be marketing a device that FDA did not review (see *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters*). Thus, the FD&C Act supports that a device may be subject to the PMA requirements regardless of whether the device is subject to the 510(k) requirements and the fact that there are exemptions from 510(k) requirements do not lead to a contrary conclusion.

We note that the De Novo provisions in section 513(f)(2) of the FD&C Act exist simply to provide another pathway to classify a postamendments device (which is class III by operation of law under section 513(f)(1) of the FD&C Act) into class I or II. A manufacturer is not required to follow the De Novo pathway but may instead submit a reclassification petition under section 513(f)(3) of the FD&C Act.

Regarding the comment claiming that it ''defies logic that Congress would create a system to regulate LDTs where foundational provisions would not apply,'' we assume the comment is referring to the 510(k) requirements as this comment was made in the context of referring to other premarket pathways. We addressed this above and in other responses in this preamble.

Regarding the comment alleging that the principal pathway to market for devices would be unavailable to LDTs, we assume the comment is referring to the 510(k) pathway. As we explained in the NPRM (88 FR 68006 at 68020), section 510(k) of the FD&C Act does not preclude regulated entities from submitting premarket notifications even assuming their devices are not introduced or delivered for introduction into interstate commerce for commercial distribution. Thus, such regulated entities may still obtain a substantial equivalence determination through the submission of a 510(k) as a substantial equivalence determination is one way for a device that is otherwise class III by operation of law to be classified into class I or II (section 513(f)(1) of the FD&C Act).

Regarding the comment claiming that the tens of thousands of LDTs that FDA estimated to be eligible for the 510(k) pathway in the PRIA would be subject to the lengthier, more expensive PMA and De Novo pathways, as discussed in the paragraph above, LDTs may be eligible for the 510(k) pathway. Further, given that a substantial equivalence determination through a 510(k) submission is less burdensome than a PMA or De Novo submission, such regulated entities have an incentive to follow this less burdensome path to market (see 88 FR 68006 at 68020). Thus, the 510(k) pathway should play the same role in device reclassification regardless (88 FR 68006 at 68020).

(Comment 62) One comment argued that the presence of ''commercial distribution'' in the 510(k) and certain other specific device provisions of the FD&C Act bears on FDA's overall jurisdiction because statutes must be read as a whole, citing *Territory of Guam* v. *United States,* 141 S. Ct. 1608, 1613 (2021), and that a statute's language has meaning only in context, citing *Graham Cnty. Soil & Water Conservation Dist.* v. *United States ex rel. Wilson,* 545 U.S. 409, 415 (2005). The comment further stated that consequently, the words of a statute must be read in their context and with a view to their place in the overall statutory scheme, citing *Sturgeon* v. *Frost,* 577 U.S. 424, 438 (2016).

(Response 62) As explained in more detail in response to comment 60, FDA disagrees that the inclusion of commercial distribution as an element in certain device provisions in the FD&C Act bears on FDA's overall jurisdiction of devices or on the applicability of those provisions in the FD&C Act in which Congress did not include commercial distribution as an element. However, even assuming ''commercial distribution'' were necessary for a device to be within FDA's jurisdiction under the FD&C Act, this would not affect FDA's jurisdiction over LDTs because LDTs are generally in commercial distribution, and therefore, LDTs generally would meet such an element. *See* NPRM (88 FR 68006 at 68021) and response to comment 60.

(Comment 63) A comment asserted that there is not much support for ''commercial distribution'' meaning ''on the market.'' Specifically, the comment argued that the cited legislative history is a statement in one committee report, and that an isolated statement in a committee report does not represent an authoritative interpretation of a congressional enactment, citing *NLRB* v. *Health Care & Retirement Corp. of Am.,* 511 U.S. 571, 582 (1994). The comment also argued that the case cited in the NPRM, *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, deferred to an FDA letter citing the committee report in the course of improperly deciding a genuine issue of material fact on summary judgment. Another comment argued that the aforementioned case arose from a traditional device manufacturer's introduction without premarket notification of a prosthetic ligament device, and that the parties' only dispute turned on whether the defendant's product was the same or different from a pre-1976 version of the product. The comment further alleged that the government itself ''argue[d] that the FDA's definition of 'commercial distribution' has only minor relevance to this action . . . since the device in question did not exist prior to enactment of the [MDA],'' and the district court fully agreed. Another comment argued that the case cited in the NPRM, *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990, 994–95, fails to support that no transfer, movement, transportation, or exchange of title between unaffiliated parties is required to trigger statutory provisions requiring commercial distribution.

(Response 63) FDA disagrees with the comments. As discussed in response to comment 60, the plain meanings of ''commercial,'' ''distribute,'' and ''distribution'' support FDA's interpretation that ''commercial distribution'' in the relevant provisions of the FD&C Act means ''on the market.'' This interpretation has been endorsed by at least one judicial decision, as explained in more detail below, and is reinforced by a House Report issued 3 months before the MDA that contained an unusually clear statement on the intended meaning of commercial distribution. H.R. Rep. No. 94–853 at 36 ('''Commercial distribution' is the

functional equivalent of the popular phrase 'on the market.' '). *See also Garcia* v. *United States,* 469 U.S. 70, 76 (1984) (the Court has ''repeatedly stated that the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which '[represent] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.' '') (citation omitted).

FDA's interpretation of ''commercial distribution'' is also consistent with the FD&C Act's overriding purpose to ''protect the public health by ensuring that . . . there is reasonable assurance of the safety and effectiveness of devices intended for human use.'' Section 1003(b)(2)(C) of the FD&C Act. Moreover, as discussed in response to comment 60, FDA's interpretation is consistent with section 301(k) of the FD&C Act which is intended to supply protection all the way to the consumer, and under which courts have upheld FDA's jurisdiction over medical products that never leave a physician's office, and that are used in the diagnosis or treatment of patients even where the product itself is not delivered or transferred to a patient. *See, e.g., United States* v. *Diapulse Corp. of Am.,* 514 F.2d 1097, 1098 (the Diapulse machine, which was held by practitioners and ''used in the treatment of patients, may properly be considered 'held for sale' within the meaning of the [FD&C Act], 21 U.S.C. 331(k).'' (citations omitted)); *United States* v. *Articles of Device (Acuflex; Pro-Med),* 426 F. Supp. 366, 368 n.3 (''Therefore, by their use in diagnosis [the electric acupuncture devices] were held for sale after interstate shipment.''); *United States* v. *Device Labeled ''Cameron Spitler Amblyo-Syntonizer,'' etc.,* 261 F. Supp. 243, 246 (''The court is also of the opinion that the devices were misbranded while being held for sale. Although the claimant never sold the devices in the commercial sense, the device was used in the claimant's treatment of patients.'').

The case cited by the comment to support the assertion that a committee report does not represent an authoritative interpretation of a congressional enactment is inapposite. In that case, which involved the interpretation of a phrase in the definition of ''supervisor'' in the National Labor Relations Act, the Court found the legislative history to be unpersuasive where the interpretation asserted by the National Labor Relations Board (NLRB) was inconsistent with the plain meaning of the phrase and court precedent. *NLRB* v. *Health Care & Ret. Corp. of Am.,* 511 U.S. 571, 578–79 (1994). Additionally, the Court noted that the legislative history relied on by the Board was not contemporaneous as it related to the 1974 amendments to the National Labor Relations Act that amended other sections of the statute but not the provision at issue which was enacted in 1947. Id. at 581–82. Thus, the Court stated: ''the isolated statement in the 1974 Committee Report does not represent an authoritative interpretation of the phrase 'in the interest of the employer,' which was enacted by Congress in 1947.'' Id. at 582. In contrast, FDA's interpretation of commercial distribution is consistent with the plain meaning of the terms. Moreover, the legislative history that provides additional support for the Agency's interpretation is contemporaneous to the enactment of the relevant statutory language.

Additionally, FDA maintains that *United States* v. *An Article of Device Consisting of 1,217 Cardboard Boxes,* 607 F. Supp. 990 supports the Agency's reasonable interpretation of ''commercial distribution.'' In this case, which involved summary judgment motions filed by both the government and claimant, one of the charges was that the device was misbranded under section 502(o) of the FD&C Act because the claimant did not submit a 510(k) for the device. Id. at 992–97. The court stated that ''[w]hether the device was in commercial distribution before May 28, 1976, was a factual issue'' because it pertained to whether an exemption from the 510(k) requirements would apply. Id. at 993–94. This factual issue was ''hotly debated'' by the parties and given that ''commercial distribution'' was a key element of the exemption, the court considered the Agency's interpretation of the term and the relevant CPG in deciding the issue. Id. at 994–95. Ultimately, the court agreed with the government that the seized device was not in commercial distribution prior to May 28, 1976, because it was not the same as the device that was manufactured prior to May 28, 1976. Id. at 995 (''I find myself in agreement with the Government that the device which it has seized is not the same device manufactured by Meadox prior to enactment of the amendments.''). The court did not address the argument that the definition of ''commercial distribution'' has only minor relevance but regardless, the meaning of ''commercial distribution'' was still relevant given that ''commercial distribution'' was an element of the exemption; therefore, it was appropriate for the court to consider the meaning of the term and to uphold FDA's interpretation.

Although *An Article of Device Consisting of 1,217 Cardboard Boxes* was not specifically about transfer, movement, transportation, or exchange of title between unaffiliated parties, FDA referenced this case to support its longstanding interpretation of ''commercial distribution'' to mean ''on the market.'' It is clear in this case that the court upheld this interpretation.

(Comment 64) One comment argued that clinical laboratories cannot be considered manufacturers within the scope of the FD&C Act or key regulatory requirements because ''distribution'' of a device in interstate commerce is a threshold requirement for the applicability of many of the key regulatory requirements applicable to device manufacturers, including the requirements for medical device reporting, correction and removal reporting, and registration and listing, citing as an example, the definition of ''manufacturer'' in part 806 which includes ''distribution'' or ''commercial distribution.''

(Response 64) FDA disagrees with the comment. Although the definition of ''manufacturer'' in various regulations includes ''distribution,'' ''distribution'' is not a required element of the definition. For example, § 806.2(h) defines ''manufacturer'' to mean ''any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term *includes* any person who: (1) [r]epackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer; (2) [i]nitiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or (3) [m]anufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient'' (emphasis added). Although the definition lists three specific types of persons, the term ''includes'' indicates that the list is not intended to be exhaustive or limit the first part of the definition. The term ''includes'' means, among other things, ''to take in or comprise as a part of a whole or group.'' (Ref. 138). Thus, the

specific list is intended to be part of the whole or group described in the prior sentence of the ''manufacturer'' definition, *i.e.,* ''any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.'' In other words, any person who engages in any of these activities is a manufacturer under part 806 and subject to the requirements therein.

(Comment 65) A comment claimed that the use of ''distributed'' in section VI.B.3 (''distributed outside that laboratory'') of the NPRM, which describes certain settings where limited QS requirements may be implemented, is inconsistent and illogical, and asserted that the Agency uses expansive definitions only when it supports its own claims for increased regulatory authority.

(Response 65) FDA disagrees with the comment. Words can have different meanings depending on their context. For example, the dictionary provides multiple definitions of ''distribute'' and ''distribution.'' (Refs. 135 and 136). As explained in response to comment 60, ''distribute'' and ''distribution'' in the context of the term ''commercial distribution'' include ''supply for sale'' and ''the marketing or merchandising of commodities,'' consistent with FDA's interpretation of ''commercial distribution'' to mean ''on the market.'' However, in other contexts, ''distribute'' and ''distribution'' can have different meanings. In section VI.B.3 of the NPRM (88 FR 68006 at 68025), FDA was using ''distributed'' consistent with the meaning ''to give out or deliver. . . .'' (Ref. 139). FDA believes it was obvious the Agency was not using the term consistent with commercial distribution as FDA was not saying that the IVD could not be on the market. However, to avoid potential confusion about this subset of IVDs for which FDA intends to enforce only certain QS requirements, FDA has decided to use ''transferred'' instead of ''distributed'' in section V.C of this preamble.

5. Asserted Distinctions From Devices

A number of comments argued that laboratory activities, tests, or both have unique characteristics that distinguish them from devices and device manufacturers. Many comments argued that these characteristics mean that LDTs are ''services'' or ''processes'' not subject to FDA jurisdiction.

(Comment 66) A number of comments argued that laboratory tests should not be understood to be devices because there is a strong human professional component to the performance of these tests. One comment stated, for example, that ''[t]he quality of [an LDT] procedure depends not only on the tangible components of a cancer genomics assay such as the reagents, and platforms and software but quite heavily on the qualifications, expertise, and experience of the operator both at the level of test performance and interpretation.'' Several comments stated that ''LDTs are comprised of not only medical products, but also analytic processes.'' Many comments emphasized the expertise and training of laboratory professionals who perform tests, including that they may be ''doctoral-level'' and ''board-certified,'' and may have ''specialty training to implement and run assays, interpret results, and ensure that clinicians understand them.'' One comment distinguished between laboratory tests that, in the commenter's view, are subject to FDA's jurisdiction—tests in which the device ''does all the work''—and those that are not, such as tests that involve a ''complex interplay between highly trained personnel, at multiple steps throughout the process.'' One comment suggested that LDT system components do not make up a system at all, stating that an LDT ''is a protocol or process by which a laboratory uses various tools—some of which are individually regulated as devices—to derive a test result for a patient,'' similar to ''a surgery'' that is ''performed by a physician using various tools (scalpels, sutures, etc.).'' The comment stated that LDTs ''do not become devices because they use devices.''

(Response 66) FDA does not agree that the involvement of qualified personnel in the administration of laboratory tests eliminates FDA's jurisdiction over IVDs, including LDTs.

The comments argue that test systems manufactured by laboratories are distinct from ''devices'' because professional users play a significant role in the achievement of the systems' intended uses, but that fact is not unusual or unexpected for devices. Devices are often complex and difficult to use; many contain a range of features, parts, and accessories, and functions that necessitate extensive user instructions to enable healthcare professionals to administer the device safely and effectively. Some devices are so difficult to use that FDA requires manufacturers to provide end-user training for them. *See, e.g.,* 21 CFR 870.5700(b)(5); 876.4340(b)(9); 884.4050(b)(5); 892.5725(b)(2). For this reason, human factors testing can be a core element of device design and important area of review during device premarket review. *See, e.g.,* Ref. 140.

The devices that require sophisticated user involvement regularly consist of disparate components that must be organized, manipulated, and evaluated by healthcare professionals, just like the complex laboratory test systems described in the comments. Sometimes, healthcare professionals must use the disparate components to build the device in accordance with the manufacturer's instructions for use. For example, FDA regulates a type of device known as a ''thoracolumbosacral pedicle screw system'' consisting of ''multiple components,'' such as screws, plates, rods, and connectors, that ''allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements.'' 21 CFR 888.3070(a); *see also* 21 CFR 870.1350(a) (identifying as a device a ''catheter balloon repair kit,'' which includes the materials, such as glue and balloons, necessary to repair or replace a catheter balloon). These systems are still ''devices'' even though significant healthcare practitioner involvement is required to effectuate their intended use.

FDA regulation of such devices is important—even in the context of use by highly trained and expert users—because, among other things, FDA regulation helps assure the safe and effective design of the device, which is separate from the safe and effective use of a device. For example, if a stent has a serious design defect, a cardiologist implanting the stent cannot necessarily assure the safety and effectiveness of the procedure no matter how great her stent implantation expertise. Similarly, if a laboratory test system lacks clinical validity (for example, it identifies a gene that has no clinical meaning), the test will not provide meaningful diagnostic information no matter how great the expertise or experience of the professionals performing the test.

Taken to its logical conclusion, commenters' argument would mean that few or no test systems intended for laboratory use (even those made by non-laboratories) would be devices, because most such systems consist of different components that must be organized and managed by expert personnel performing the test, in accordance with a manufacturer's instructions for use. No comments appeared to embrace the conclusion that even these sorts of systems are not devices, which would run counter to 50 years of established IVD regulation and enforcement. It would also mean that none of the device types described earlier in this comment response are actually ''devices,'' contrary to decades of FDA regulation of those articles.

FDA also emphasizes that the fact that these systems are devices does not mean that the use of the devices—*i.e.,* the performance of a test—in accordance with a manufacturer's instructions for use is a ''device.'' Those two things are distinct. *See, e.g., United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314, 1319 (distinguishing FDA regulation of a defendant's ''Mixture'' product from ''the procedures used to administer the Mixture'') (citation omitted).

FDA recognizes that extensive training and clinical knowledge can be required to perform laboratory tests, and does not seek in any way to diminish that expertise required for, or the important public-health contributions associated with, laboratorians performing testing. The fact that an entire statute was enacted to govern laboratory operations and laboratory personnel—CLIA—is evidence of the degree of complexity, technical skill, and experience required to perform many laboratory tests. But FDA believes that expertise in performing tests is not the same thing as expertise in designing and developing tests. For example, the set of skills required to develop a test that accurately detects COVID–19 is not the same as the set of skills required to correctly perform a test that accurately detects COVID–19. FDA's responsibility under the FD&C Act is to help ensure that such tests are designed in a way that, when they are performed as the manufacturer intends, they can produce accurate and reliable results, and that responsibility exists whether or not the test is designed by a laboratory.

(Comment 67) Various comments argued that design and development by laboratories should be viewed as distinct from design and development by other IVD manufacturers because laboratories provide medical care or employ medical experts. For example, one comment argued that LDTs are neither ''products'' nor ''manufactured'' because they may be developed in medical care settings. Another comment stated that LDTs ''do not fit into the category of medical devices'' because ''[t]he development and usage of LDTs are heavily reliant on the expertise of professional laboratory personnel.''

(Response 67) As an initial matter, FDA does not agree that IVDs offered as LDTs are necessarily designed and manufactured under circumstances that are distinct from other IVDs. As explained in the NPRM, FDA's understanding is that many test systems offered as LDTs are designed at Fortune 500 and other large companies by a ''development team,'' similar to how systems from conventional IVD manufacturers are designed (88 FR 68006 at 68018) (see also Ref. 141). And in FDA's experience, the individuals on these development teams (as well as individuals developing laboratory test systems at smaller laboratories) generally have the same training and expertise as those employed by a conventional manufacturer. Usually, this training is scientific or technical in nature rather than medical in nature. Therefore, FDA disagrees that the background and training of the individuals who develop LDTs is necessarily a distinguishing feature of these devices.

In any event, whether an article meets the definition of a ''device'' in the FD&C Act does not turn on who manufactures the article or where it is manufactured. Thus, even assuming that LDTs were always designed by healthcare professionals in medical care settings, those facts would not affect whether the LDT is a device under the plain language of the statutory definition. Other provisions in the FD&C Act confirm this fact because they exempt healthcare professionals who manufacture devices solely for use in the course of their professional practice from certain requirements. *See, e.g.,* 21 U.S.C. 360(g)(2). These exemptions would be superfluous if licensed healthcare professionals operating in medical care settings could not ''manufacture'' ''devices'' in the first place. For additional discussion of these exemptions, see our response to comment 77.

(Comment 68) Various comments took the position that LDTs are services and not devices because they are tailored to patients. For example, comments stated that LDTs ''are informed by the clinical needs of the individuals we treat,'' address patients' ''unique needs,'' and ''can be adjusted to the specific needs of the patient.''

(Response 68) FDA does not agree that the fact that LDTs can be customized to patients is a reason to conclude that they are not devices. The FD&C Act does not require mass production, marketing, or use in order for an article to be a ''device.'' On the contrary, the FD&C Act contains special provisions for ''custom devices,'' thus recognizing that an article can be tailored to patients and still be a device. *See* 21 U.S.C. 360j(b) (exempting devices that have been designed and manufactured to suit the unique needs of a physician or patient from certain requirements). The legislative history for these provisions reinforces that they were intended to cover the circumstances in which devices are ''ordered from manufacturers by members of the health professions to conform to their own special needs or to those of their patients'' as well as when ''health professionals themselves develop or alter devices to serve such needs.'' H.R. Rep. 94–853 at 44. Thus, the provisions were designed for exactly the types of circumstances asserted to exist with certain LDTs. Furthermore, Congress limited the applicability of the exemptions to premarket approval and performance standards, meaning that custom devices are not entirely exempt from the FD&C Act. Id. (explaining that ''[custom] devices are not exempt from otherwise applicable provisions . . . such as provisions with respect to investigational use, banning, restriction, adulteration or misbranding''). Reading the definition of ''device'' to exclude customized devices would render these provisions superfluous.

(Comment 69) One comment stated that LDTs are distinct from other IVDs because they ''are not produced or marketed for use outside of the originating laboratory.'' The comment stated that ''[t]he lack of marketing and sales to other laboratories further differentiates LDTs from IVDs—a distinction that is crucial to understanding why LDTs do not fit into the category of medical devices.''

(Response 69) FDA recognizes that LDTs are designed, manufactured, and used within a single laboratory (without being sold for use outside that laboratory), but that fact does not mean these IVDs are not devices. The statute defines a ''device,'' in relevant part, as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.'' 21 U.S.C. 321(h)(1). The definition does not exclude an article produced, sold, and used in a single location, and reading in such a limitation would undermine Congress's purpose in the MDA to assure the safety and effectiveness of devices (see response to comment 53).

(Comment 70) One comment suggested that LDTs are not devices because they have purposes that are distinct from other IVDs. The comment stated that the ''primary role of LDTs is to detect and/or quantify substances within the human body, aiding in disease detection, health condition assessment, monitoring of drug treatments and other testing processes'' and that ''over 83 percent of LDTs offered by NILA [National Independent Laboratory Association] and AAB [American Association of Bioanalysts]-

member laboratories serve these purposes.''

(Response 70) FDA disagrees that LDTs have purposes that are distinct from other IVDs. The detection and/or quantification of substances within the human body to aid in ''disease detection, health condition assessment, monitoring of drug treatments and other testing processes'' is consistent with the intended uses of non-LDT IVDs, and articles intended for such uses generally fall within the device definition because they are intended for use in ''the diagnosis of disease or other conditions'' and/or ''the cure, mitigation, treatment, or prevention of disease.'' Many FDA-authorized IVDs are indicated for use in conjunction with clinical assessments and not as the sole basis for clinical decisions, and IVDs offered as LDTs are not unique in that respect (see our response to comment 196 for examples of IVDs that fit this description). Therefore, even assuming the comment's factual assertions are correct that these are the primary intended uses of LDTs, these uses are not distinct from the intended uses of other IVDs, and they do not distinguish LDTs from devices.

(Comment 71) Several comments argued that test development activities occurring in a laboratory are distinct from conventional IVD manufacturing. One comment asserted, for example, that the laboratory validation is distinct because ''[v]alidation of each clinical test requires specific equipment and personnel that is unique to the lab and test being performed.'' Another comment stated that ''LDTs are developed specifically for use by the laboratory that created them, or laboratories under the same ownership/control,'' which promotes ''great consistency in performance'' and more limited ''potential for user error'' compared with manufacturing by non-laboratories. A separate comment argued that ''Quality Management applied to procedures have to be inherently different from those applied to products and need to consider the entire laboratory and not just individual procedures.'' The same comment stated that LDT development is unique because ''the primary output of a test development process is a standard operating procedure document, which is essentially a set of instructions to appropriately qualified individuals.''

(Response 71) With respect to comments' factual assertions about laboratory test development, FDA does not necessarily agree[58], but even assuming those assertions are correct, FDA disagrees that they would mean that laboratory test development is distinct from device manufacturing. As explained in the NPRM and elsewhere in this preamble, IVDs manufactured by laboratories are devices. Under FDA regulations, any ''person who designs, manufactures, fabricates, assembles, or processes a finished device'' is a manufacturer (§ 820.3(o)). Thus, laboratories that design, manufacture, fabricate, assemble, or process IVDs are manufacturers subject to FDA requirements.

Furthermore, laboratory IVD development is fully amenable to regulation under FDA's CGMP requirements for devices (the QSR) even if that development occurs in a single laboratory. These requirements are flexible and recognize that manufacturing circumstances may vary. For example, the QSR requires design validation that ''ensure[s] that devices conform to defined user needs and intended uses'' and ''include[s] testing of production units under actual or simulated use conditions'' for most devices (§ 820.30(g)). This requirement does not prescribe a single, rigid approach to validation; instead, under the QSR, a manufacturer's design validation obligations vary based on specific user needs and actual or simulated use conditions. In addition, the FD&C Act and FDA regulations provide for the issuance of ''exemption[s]'' and ''variance[s]'' from the QSR to account for unique circumstances in manufacturing. 21 U.S.C. 360j(f)(2)(A); § 820.1(e).

With respect to one comment's statement that laboratories primarily produce ''standard operating procedure document[s]''—and to the extent that the comment was suggesting that such documents are incongruous with FDA manufacturing requirements—FDA disagrees. First, we disagree that laboratories only produce standard operating procedure documents; laboratories produce test systems, which are the devices that generate results and implicate patient health and safety. For example, when a laboratory develops a test for measurement of hormone levels using mass spectrometry, they must source or manufacture calibrators and qualify a mass spectrometry instrument in order to perform that test. These calibrators and instrument, along with other components, comprise a test system. Second, the QSR specifically requires the development of documents, including procedures, laying out the design of a test (§ 820.30(d) (requiring device design output to be documented, reviewed, and approved before release)). Thus, this type of work is directly contemplated under the QSR. We note that even if laboratories were only engaged in design activity, they would still be manufacturers under the QSR (§ 820.3(o) (''manufacturer'' includes those ''perform[ing] the function[ ] of . . . specification development'')).

(Comment 72) One comment stated that an individual laboratory should not be considered a manufacturer because the instruments, software, and many reagents used in IVD testing are not manufactured by the laboratory. In addition, the comment stated that ''the term manufacture doesn't necessarily apply to the process individual laboratories use to assemble reagents for use in running an IVD test'' because they ''are not sold to other entities, do not leave the laboratory, take no part in interstate commerce, and may be individually labeled for their many uses within the laboratory environment.''

(Response 72) If a laboratory manufactures a test system, it is a manufacturer, even if it does not manufacture the components of that system (such as instruments, software, and reagents). In addition, FDA notes that entities who ''assemble[ ]'' devices constitute manufacturers (§ 820.3(o)). Laboratories do this by sourcing individual components and combining them to assemble a single test system with a specific intended use. For example, a laboratory that develops a PCR-based, targeted genetic test for Factor V Leiden thrombophilia must source or manufacture primers and probes and validate a PCR instrument to assemble their test. These primers, probes and instrument together, along with other components, comprise a test system with a specific intended use that is independent of each individual component's intended use. Under the FD&C Act and FDA regulations, manufacturing is not limited to devices that are sold to other entities, leave a laboratory, take part in interstate

[58] In particular, FDA disagrees that the need for specific equipment and personnel for validation is unique to laboratory manufacturers. Validation of each clinical test, regardless of whether that test is manufactured by a laboratory or a non-laboratory manufacturer, may require equipment and personnel to perform the validation that is specific or unique to the type of test being performed. FDA also disagrees that developing a test for use in a single laboratory or laboratories under common ownership/control necessarily promotes ''great consistency in performance'' or more limited ''potential for user error.'' Elsewhere in this preamble, FDA has described examples of problematic tests that were designed or used in a single laboratory. In addition, standard operating procedures for LDTs must include instructions that specify the components for use (this may include specifically naming components that are procured or specifications for components that may be otherwise procured). This is no different from IVD kit instructions that list components that are necessary but not provided.

commerce, or are labeled for different uses. *See generally* 21 U.S.C. 360j(f); part 820. FDA addresses interstate-commerce arguments in more detail in section VI.D.3 of this preamble.

(Comment 73) One comment argued that FDA regulations recognize that laboratories are performing services, and not manufacturing devices, based on the language in § 807.65(i) that exempts clinical laboratories from registration and listing under certain circumstances.

(Response 73) This comment misunderstands the legal framework behind the exemption at § 807.65(i). Contrary to the comment's suggestion, § 807.65(i) is premised on the position that laboratories are device manufacturers. If they were not device manufacturers, there would have been no need to exempt them from the registration and listing requirements because those requirements only apply to those who own or operate establishments engaged in the ''manufacture, preparation, propagation, compounding, or processing'' of a device. *See* 21 U.S.C. 360(b)(2), (c), (i), and (j). In other words, FDA issued § 807.65(i) because it understood laboratories to be engaged in the ''manufacture, preparation, propagation, compounding, or processing'' of a device and concluded laboratories engaged in limited activities falling within that description should be exempt from the registration and listing requirements. Specifically, FDA decided that laboratories ''whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device'' should not have to register and list.

As noted in response to comment 45, this exemption means not only that FDA considers clinical laboratories to manufacture devices, as just explained, but also that only certain laboratories should be exempt from registration (*i.e.,* those ''whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device''). Laboratories who go beyond that do not fall within the exemption. Furthermore, even for those laboratories who fall within § 807.65(i), the exemption does not confer broad immunity on laboratories or suggest they are not manufacturing devices. In the preamble to the registration and listing rule, for example, FDA emphasized (in the context of a different exemption) that ''exemption from registration does not relieve such persons from their obligation to comply with other provisions of the act or regulations'' (42 FR 42521, August 23, 1977). Although FDA acknowledges that the exemption implicates listing and the 510(k) premarket notification requirements because those requirements are tied to registration, it does not implicate the premarket approval or investigational use requirements, for example.

Thus, § 807.65(i) confirms, rather than undermines, the position that laboratories are manufacturers and that they are subject to a variety of requirements under the FD&C Act.

6. Practice of Medicine

(Comment 74) Several comments asserted that FDA cannot regulate the ''practice of medicine,'' which (in the commenters' view) includes all laboratory testing activities, but did not cite a specific source of authority for either the general assertion about FDA authority or the specific assertion about laboratory testing activities. To support the position that laboratory development falls within the ''practice of medicine,'' comments emphasized: (1) the training, board certifications, technological expertise, and medical judgment required for these activities, (2) that medical specialties associated with laboratory testing are sometimes defined to include the ''develop[ment of] new testing methods,'' (3) that the focus of laboratorians is on patient care, and (4) the involvement of a treating physician in ordering a test and receiving results. Some comments explained why, in the commenters' opinion, this type of ''practice of medicine'' limitation on FDA's authority is justified, including the fact that laboratories consider many factors in developing an LDT, such as clinical need, accuracy, and cost-effectiveness to the patient, and ensure ''quality'' in a more comprehensive sense than does FDA.

(Response 74) FDA does not agree that an atextual ''practice of medicine'' limitation precludes FDA regulation of all laboratory testing activities. The statute does not contain such a limitation, and FDA ''assume[s] that Congress meant what it said, and said what it meant.'' *See Aqualliance* v. *U.S. Bureau of Reclamation,* 856 F.3d 101 at 105. Instead, Congress enacted a narrower provision, entitled ''Practice of Medicine,'' that spells out in clear terms what conduct within the practice of medicine falls outside FDA's statutory authority. That provision states, in relevant part: ''Nothing in this [Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship,'' with several explicit limitations (21 U.S.C. 396).[59] In general, the provision codifies FDA's longstanding recognition of the fact that healthcare providers prescribe and use medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their particular patients.[60] It thus limits FDA's oversight of certain practitioners' ''prescrib[ing] or administer[ing]'' of a ''legally marketed device,'' but it does not reach all the activities that fall within commenters' broad conception of the practice of medicine—including, notably, the manufacturing of a device. The fact that Congress assigned specific meaning to the ''practice of medicine'' and laid out, in statutory text, exactly how that concept should apply in the context of FDA regulation belies the notion that there is some additional ''practice of medicine'' limitation on the Agency.

Other statutory provisions confirm that understanding. In particular, if there were some generalized ''practice of medicine'' limitation that foreclosed FDA regulation of activities in a medical context, Congress would not have needed to issue exemptions specific to physician manufacturing. But the FD&C Act does contain exemptions for licensed practitioners who manufacture devices ''solely for use in the course of their professional practice.'' *See, e.g.,* 21 U.S.C. 360(g)(2). A generalized ''practice of medicine'' limitation would render these provisions superfluous. The exemptions are also limited in scope and do not, by their express terms, apply to all manufacturing by licensed practitioners. Id. (limiting exemption to ''use in the course of [the practitioner's] professional practice''); *see also* H.R. Rpt. 94–853 at 24 (stating, with respect to the adverse-event reporting exemption, that ''[o]bviously, physicians and other licensed practitioners are not exempt from these requirements if their use of a device extends beyond ordinary professional practice into commercial activity''). A generalized ''practice of medicine''

[59] The rest of 21 U.S.C. 396 provides: ''This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.'' These limitations show that this provision does not operate as an across-the-board bar on FDA regulation of the prescribing or administration of legally marketed devices.

[60] See Ref. 17 at 17 (''January 2017 Memorandum'').

prohibition would read out those limitations.

As explained in response to comment 66, FDA recognizes that laboratories employ expert, trained personnel. We also recognize that laboratories prioritize the care of patients, may specialize in the development of testing methods, and may work closely with treating physicians. But these facts do not mean that, as a legal matter, FDA lacks authority over the IVDs manufactured by laboratories. The FD&C Act by its very nature affects medical practice. Cf. *United States* v. *9/1 Kg. Containers,* 854 F.2d 173, 176 (7th Cir. 1988) (''Congress gave the FDA comprehensive powers to license the manufacture of drugs and limit their sales. To regulate drugs is to be 'involved' in the 'practice of the healing arts.' ''). Thus, the fundamental question is the scope of authority Congress delegated, and the limitations it enacted, relevant to medical practice. As already explained, the FD&C Act contains no generalized limitation on FDA regulation of devices in a medical context. *Cf. United States* v. *Regenerative Scis.,* 741 F.3d 1314, 1320 (construing the FD&C Act not to apply to otherwise prohibited activities, because they were undertaken by doctors, would ''create an enormous gap in the FDCA's coverage'').

(Comment 75) One comment stated that Congress did not intend for FDA to regulate the ''practice of medicine,'' which (in the commenter's view) included all laboratory testing activities, as shown by: (1) legislative history for the FD&C Act, including legislative history associated with the 1938 Act and the 1962 Kefauver-Harris Amendments, (2) section 214 of the Food and Drug Administration Modernization Act (FDAMA), and (3) section 1111 of the Food and Drug Administration Amendments Act (FDAAA).

(Response 75) As explained in response to comment 74, FDA does not agree that there is a generalized, atextual ''practice of medicine'' limitation on FDA's authority in ways other than those enumerated in the statute. The statute contains specific provisions related to healthcare practitioners' ''prescrib[ing] or administer[ing]'' a legally marketed device and ''manufactur[ing]'' a device ''solely for use in the course of their professional practice,'' and those provisions represent Congress's considered judgment about the scope of conduct that falls outside FDA authority. *See West Virginia Univ. Hospitals, Inc.* v. *Casey,* 499 U.S. 83, 98 (1991) (''The best evidence of [Congress's] purpose is the statutory text adopted by both Houses of Congress and submitted to the President.'').

Comments cite statements in the legislative history related to the 1938 Act and the 1962 Kefauver-Harris Amendments, but (among other things) those sources predate the MDA and FDAMA, when Congress specifically considered the practice of medicine in the device context and translated those considerations into legislative text. *See* 21 U.S.C. 360(g)(2), 360i(c)(1), 374(a)(2)(B), 396.

FDA agrees that section 214 of FDAMA, codified at 21 U.S.C. 396, reflects Congress's intent to protect certain practitioner prescribing and administration activities, but the provision does not extend to laboratory manufacturing of IVDs, including LDTs. The purpose of the provision is to ''ensure[ ] that once the FDA permits a device to be marketed for one use, health care practitioners have the flexibility to draw on their expertise to prescribe or administer the device'' for other uses for a specific patient. *Judge Rotenberg Educ. Ctr., Inc.* v. *United States,* 3 F.4th 390, 395 (D.C. Cir. 2021); *see also* Conf. Rep. 105–399 at 97 (November 9, 1997) (provision intended to cover ''off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient''). It applies only in the context of use of a ''legally marketed device''—that is, a device that is already manufactured and lawfully on the market—and only applies to ''prescrib[ing] or administer[ing] . . . within a legitimate health care practitioner-patient relationship.''

The comment also cites section 1111 of FDAAA, 42 U.S.C. 247d–5a (2007), but that provision was repealed in 2016 by the Cures Act (Pub. L. 114–255, 130 Stat 1033 at 1121 ''Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d–5a), relating to identification of clinically susceptible concentrations of antimicrobials, is repealed.''). In any event, that provision directed FDA to identify and periodically update ''clinically susceptible concentrations'' of antimicrobial drugs and did not address FDA's regulation of IVDs.

(Comment 76) Various comments cited the role of state authorities, such as State laws and medical boards, in support of their conclusion that FDA cannot regulate the ''practice of medicine,'' which (in the commenters' view) included all laboratory testing activities. Several commenters asserted, for example, that the practice of medicine is regulated by state medical boards rather than FDA. Comments also argued that the proposed rule is inconsistent with existing state medical practice acts, such as a Utah law's definition of the practice of medicine. One commenter indicated that state law definitions of the practice of medicine should inform the applicability of 21 U.S.C. 396. Finally, one comment suggested that state tort law provides adequate oversight, noting that certain pathologists ''bear legal responsibility for the design and performance of LDTs'' and ''purchase medical malpractice insurance to cover these activities.''

(Response 76) The scope of FDA's authority is defined by Federal law. *See, e.g., City of Arlington* v. *Fed. Commc'ns Comm'n,* 569 U.S. 290, 297 (2013) (Agencies' ''power to act and how they are to act are authoritatively prescribed by Congress.''). Thus, the FD&C Act vests FDA with authority and dictates how that authority intersects with the ''practice of medicine'' (see our response to comment 52 for a discussion of FDA's authority and our response to comment 74 for a description of this intersection). To the extent that comments were suggesting that State law defines those authorities and limitations, FDA disagrees.

Comments appear to take the view that State law controls based on an assumption that state and Federal authorities cannot share jurisdiction, but that is not the case. Congress regularly enacts laws governing entities or activities that are also regulated under State law, and when it does so, the two regimes can coexist. *See Wyeth* v. *Levine,* 555 U.S. 555, 579 (2009) (''FDA [has] long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.''). At least one comment indicated that there is a ''conflict'' between the State laws cited in the comments and this rulemaking, but the comment did not give any basis for the alleged conflict. State medical boards can perform their oversight function—and State law definitions of the ''practice of medicine'' can inform the application of State law—concurrent with FDA's exercise of its own authority under Federal law. Several comments inferred conflict from State law definitions, but if a State law defines particular activities to fall within the practice of medicine, that does not mean that FDA oversight of those same activities is impermissible, just as CMS's administration of CLIA with respect to laboratory activities that fall within the State's ''practice of medicine'' is not impermissible. *See*

Pharm. Mfrs. Ass'n v. *FDA,* 484 F. Supp. 1179, 1187–88 (D. Del.), aff'd, 634 F.2d 106 (3d Cir. 1980) (''The fact that the practice of medicine is an area traditionally regulated by the states does not invalidate those provisions of the [statute] which may at times impinge on some aspect of a doctor's practice.''). Even assuming there were a conflict, it is Federal law, not State law, that would trump. Const. Art. VI, Cl. 2 (''[T]he Laws of the United States . . . shall be the supreme Law of the land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'').

FDA also does not agree that it should read State law definitions of the ''practice of medicine'' into 21 U.S.C. 396. Section 396 does not prohibit regulation of the ''practice of medicine'' in general terms, nor does it explicitly or implicitly incorporate State law to define the scope of FDA authority. Instead, that provision carves out a specific and defined scope of physician conduct that falls outside FDA's statutory authority. *See* Lars Noah, Ambivalent Commitments to Federalism in Controlling the Practice of Medicine (February 21, 2004) (Provisions such as 21 U.S.C. 396 ''endorse deference to professional autonomy rather than the primacy of state regulation.'') (Ref. 142). Under the statute's plain language, State law does not control the analysis of FDA authority—nor would it be sensible to apply State law in this way given differences in definitions of the ''practice of medicine'' across the states. See *United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314, 1319 (''[A]ppellants are wrong to suggest that the scope of the FDCA depends on state-by-state definitions of the 'practice of medicine.' '').

Finally, the presence of State tort law is not a reason to conclude that FDA lacks authority over IVDs manufactured by laboratories. The FD&C Act was enacted against the backdrop of State regulation and common-law liability. *Wyeth* v. *Levine,* 555 U.S. 555 at 566. Congress delegated power to FDA based on a view that the then-existing controls, including state controls, were not adequate to protect the public from dangerous products. Id. As explained in response to comment 53, Congress then increased FDA's powers over devices in the MDA based on concerns about unsafe and ineffective devices on the market, all while state tort liability continued. *See Medtronic, Inc.* v. *Lohr,* 518 U.S. 470, 475–76 (1996). These facts show that the FD&C Act is not constrained by, but rather provides an extra layer of public-health protection over, state tort law.

(Comment 77) Two comments argued that the statutory exemptions for licensed practitioners who manufacture products solely for use in the course of their professional practice apply for laboratories, or some subset of laboratories. One comment asserted that the exemptions apply to corporate and hospital laboratories that employ licensed practitioners, because construing the exemption to exclude corporate entities would impose liability on a solo practitioner's personal service corporation and would ''conflict[ ] with baseline common-law principles'' related to vicarious immunity. The same comment suggested that these statutory exemptions also should be construed to constitute an exemption from other ''more burdensome and costly provisions'' under the FD&C Act and FDA regulations.

(Response 77) The statutory exemptions cited by comments exempt covered practitioners from several specific requirements: (1) establishment registration requirements (this exemption, by operation of law, also constitutes an exemption from listing and 510(k) requirements); (2) adverse-event reporting requirements; and (3) an expansive FDA inspection that ''extend[s] to all things'' within a relevant factory, warehouse, establishment, or consulting laboratory. 21 U.S.C. 360(g)(2), 360i(c)(1), 374(a)(2)(B). These exemptions apply when a ''practitioner[ ]'' (1) is ''licensed by law to prescribe or administer'' a device, such as an IVD, (2) ''manufacture[s]'' that device, and (3) does so ''solely for use in the course of their [or his] professional practice.'' The exemptions are only relevant when a particular individual meets all three criteria. The language is precise and limited in scope; the possessive terms ''their'' and ''his,'' for example, make clear that the exemption applies only to specific individuals, not institutions. Thus, to the extent that comments are arguing that the exemptions apply to: (1) all activities of a laboratory that employs such an individual or (2) any laboratory activities in which personnel collectively meet the criteria (*e.g.,* one individual is licensed to administer the device and others manufacture the device), FDA disagrees. By their plain terms, the exemptions do not apply to an institution or an entity; they apply only to an individual practitioner who meets all criteria. And construing the exemptions to apply more broadly would create a significant loophole: every device manufacturer could escape the relevant requirements simply by hiring the right personnel. That is not a rational understanding of Congress's intent: as one committee report made clear, the exemption was not intended to apply to ''commercial activity.'' H.R. Rpt. 94–853 at 24. This evidence of congressional purpose underscores the plain language of the statute.

FDA also disagrees that exemptions from certain requirements in the FD&C Act should be read as exemptions from all, or any other, requirements of the FD&C Act. Congress included the licensed-practitioner exemption for certain requirements and excluded it from others. This means that Congress knew how to apply the exemption when it wanted to, and did so only in particular circumstances. Interpreting the exemption to apply to other requirements, not specified by Congress, would directly conflict with Congress's intent as expressed through the statutory text. Courts have come to the same conclusion. *See Cowan* v. *United States*, 5 F. Supp. 2d 1235, 1240 (N.D. Okla. 1998) (''[T]he 'medical practice exemption' referenced by Plaintiff is a very limited exemption from the registration requirements of the FDCA. Plaintiff's assertion that this exception provides a broad-based exemption to all physicians from the requirements of the Food, Drug, and Cosmetic Act is incorrect.''); *cf. United States* v. *Algon Chem., Inc.,* 879 F.2d 1154, 1160 (3d Cir. 1989) (''the medical practitioner exemptions by their terms afford no more than the right to be free from inspection and registration requirements when veterinarians and other practitioners compound medicine with legally acquired materials, not the right to acquire unapproved drug substances'').

One comment argued that it is not reasonable to say that a licensed practitioner acting within the scope of the exemption is exempt from ''basic'' requirements such as registration, listing, and adverse-event reporting but still subject to ''more burdensome'' requirements, like De Novo review and premarket approval. FDA disagrees. De Novo review generally applies when FDA lacks experience with a device type, and premarket approval applies to class III devices, the highest-risk devices regulated by FDA. It is entirely reasonable for Congress to conclude that an exemption should apply with respect to some FD&C Act requirements but not with respect to FDA's premarket review of devices that are unknown or ''present[ ] a potential unreasonable risk of illness or injury,'' for example. *See* 21 U.S.C. 360c(a)(1)(C). FDA also notes that although the comment suggested that

the FD&C Act exempts licensed practitioners who are manufacturing solely within the course of their professional practice from ''inspection[s],'' that is not the case. The licensed-practitioner inspection provision limits the scope of FDA's inspection—so that the inspection does not ''extend to all things therein''—but it does not eliminate FDA's authority to inspect (21 U.S.C. 374(a)(1)–(2)). In any event, reading these exemptions into other provisions of the FD&C Act would amount to rewriting the FD&C Act, which FDA cannot do.

(Comment 78) Several comments argued that activities regulated under CLIA constitute the ''practice of medicine,'' implying that they are outside the scope of FDA's authority.

(Response 78) CLIA does not constrain FDA's authority over devices, including LDTs, and that fact is true regardless of whether the activities regulated under CLIA are described as ''the practice of medicine.'' For further discussion of CLIA, please see section VI.D.8 of this preamble.

7. Right of Healthcare Providers To Practice Medicine

(Comment 79) One comment asserted that there is a right—based on several provisions of the Constitution—of healthcare providers to practice their profession without unwarranted interference. Specifically, the comment asserted that: the First Amendment guarantees the freedom of expression and the right to petition, which implicitly supports healthcare providers' rights to advocate for their patients and express concerns about regulations they view as capricious; the Fourth Amendment guards against unreasonable searches and seizures, which can be related to the privacy of patient records and the autonomy of healthcare providers in their practice; and the 14th Amendment ensures that no state may deprive any person of life, liberty, or property without due process of law. The comment asserted that, because the right to practice medicine is constitutionally protected, any limitation on that right must withstand strict scrutiny. The comment asserted that the LDT rule fails strict scrutiny because there is ''nothing narrow'' in FDA's approach to LDTs.

(Response 79) We disagree with this comment. First, this rule does not purport to regulate healthcare providers' practice of their profession. As the phaseout of the general enforcement discretion approach is implemented, laboratories that manufacture IVDs offered as LDTs generally will be expected to comply with several pre- and post-market submission and reporting requirements applicable to devices for humans (including premarket notification/PMA requirements (as applicable), registration and listing, labeling requirements, reporting requirements regarding adverse events and corrections and removals, QS requirements, and certain IDE regulations), but this phaseout policy relates to statutory and regulatory requirements applicable to medical devices and the conduct of manufacturers and distributors, not healthcare providers. The medical profession is, of course, regulated, particularly under state law, but neither the amendment to § 809.3 nor the phaseout policy regulates healthcare providers acting in that capacity.

Second, we disagree with the assertion that there is a constitutional right to practice medicine subject to regulation only under strict scrutiny. The comment did not support its conclusory assertion of a constitutional right to practice medicine with any case law citations, and we are not aware of any. *See, e.g.,* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine,* 53 U. Kan. L. Rev. 149, 192 (2004) (''[F]ederal expressions of deference to professional medical autonomy are rooted in politics rather than constitutional law.'') (Ref. 142). The comment's citation to various rights protected by the Constitution does not help bolster the argument. The right to petition, like other parts of the First Amendment, provides an ''assurance of a particular freedom of expression.'' *McDonald* v. *Smith,* 472 U.S. 479, 482 (1985). Nothing in this rule limits healthcare providers' ability to advocate for their patients and express concerns about regulations they view as capricious—in fact, that is just what the commenter did in submitting a comment on the proposed rule. Similarly, although ''private medical records warrant some privacy protection under the Fourth Amendment,'' *Big Ridge, Inc.* v. *Fed. Mine Safety & Health Review Comm'n,* 715 F.3d 631, 648 (7th Cir. 2013), the comment failed to identify anything in the rule that constitutes a search or seizure of medical records or impinges on patients' privacy.

Procedural due process guarantees ''the opportunity to be heard at a meaningful time and in a meaningful manner'' ''before an individual is finally deprived of a property interest.'' *Mathews* v. *Eldridge,* 424 U.S. 319, 333 (1976) (cleaned up). Substantive due process protects rights that are ''deeply rooted in this Nation's history and tradition'' and ''implicit in the concept of ordered liberty'' ''such that neither liberty nor justice would exist if they were sacrificed.'' *Washington* v. *Glucksberg,* 521 U.S. 702, 721 (1997) (cleaned up). Nothing in this rule implicates either doctrine; the comment did not identify anything in the rule that would cause a deprivation of life, liberty, or property without notice and opportunity for hearing or any infringement on a fundamental right.

Third, even if strict scrutiny were applied, that test would be satisfied here because the government has a compelling interest in protecting the public health, and premarket review and related requirements are narrowly tailored to achieve that result, as further explained elsewhere (see response to comment 93). The comment did not support its conclusory assertion to the contrary.

8. CMS/CLIA

(Comment 80) Several comments argued that Congress delegated the regulation of IVDs offered as LDTs not to FDA but to CMS, and that the enactment of CLIA is evidence that Congress did not intend for such IVDs to be subject to the device authorities of the FD&C Act. Some argued that the FD&C Act's failure to specifically call out IVDs offered as LDTs, in contrast with CLIA's specific provisions regarding the regulation of laboratories, demonstrates that Congress intended IVDs offered as LDTs to be solely regulated by CMS under CLIA.

(Response 80) FDA does not agree that Congress intended for IVDs offered as LDTs to be regulated solely by CMS under CLIA. CMS's CLIA authorities complement, rather than replace, FDA's regulation of laboratory-manufactured IVDs as devices under the FD&C Act. CMS determines whether a laboratory meets CLIA requirements, which is a specific role distinct from FDA's statutory responsibilities. FDA's device authorities under the FD&C Act are intended to help ensure that devices, including IVDs offered as LDTs, have appropriate assurance of safety and effectiveness. CMS's authorities under CLIA, by contrast, focus on the proficiency with which laboratories perform the testing activities. Unlike FDA can do under the FD&C Act, CMS does not regulate critical aspects of laboratory test development; does not evaluate the performance of a test before it is offered to patients and healthcare providers; does not assess clinical validity (*i.e.,* the accuracy with which a test identifies, measures, or predicts the presence or absence of a clinical

condition or predisposition in a patient); does not regulate certain manufacturing activities, such as design controls and acceptance activities; does not provide human subject protections for patients who participate in clinical trials of tests; and does not require adverse event reporting.

The lack of language in the FD&C Act specifically mentioning IVDs offered as LDTs does not change this conclusion. Congress did not define the scope of FDA's device authority by enumerating every device type subject to that authority; instead, it wrote a broad device definition at 21 U.S.C. 321(h)(1), which captures a wide range of articles without listing each one. FDA's device authorities thus are not limited to those few device types specifically mentioned in the FD&C Act. To the contrary FDA can, and does, regulate hundreds of device types that are not specifically mentioned in the FD&C Act. The controlling question is whether a product meets the FD&C Act's definition of device, and under the plain language of the statute as well as FDA's long-standing position this inquiry is resolved in the affirmative for IVDs offered as LDTs.

As explained in the NPRM, CLIA does not expressly repeal FDA's authority, nor was FDA's authority repealed by implication, and the comments do not demonstrate otherwise (88 FR 68006 at 68019). ''An implied repeal will only be found where provisions in two statutes are in irreconcilable conflict, or where the latter Act covers the whole subject of the earlier one and is clearly intended as a substitute.'' *Branch* v. *Smith,* 538 U.S. 254, 273 (2003) (cleaned up). Here, as CMS itself has explained, ''the regulatory schemes of the two agencies are different in focus, scope and purpose'' and ''are intended to be complementary'' (Ref. 26). As explained above, CLIA puts a focus on the proficiency with which laboratories perform clinical testing, and the FD&C Act puts a focus on the tests themselves. CMS and FDA have different areas of expertise, and CLIA does not address a wide range of activities regulated under the FD&C Act, such as clinical validation and design activities. Thus, ''CLIA does not preempt the FDA's authority to regulate facilities like [Clinical Reference Laboratory]. When two statutes are 'capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intent to the contrary, to regard each as effective.' '' *Clinical Reference Lab.,* 791 F. Supp. at 1509 (quoting *Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1018, (1984)), aff'd in part and rev'd in part on other grounds sub nom. *United States* v. *Undetermined No. of Unlabeled Cases,* 21 F.3d 1026 (10th Cir. 1994).

(Comment 81) Some comments stated that CLIA's legislative history does not mention FDA jurisdiction over LDTs, or that it characterized CLIA as directing HHS ''to regulate all laboratories under a single statute,'' arguing that this is evidence that Congress did not intend for LDTs to be subject to the device authorities of the FD&C Act.

(Response 81) FDA disagrees with the comments' characterization of CLIA's legislative history. As FDA has noted, CLIA serves a distinct role from FDA oversight and establishes requirements for laboratories and laboratory personnel pertaining to operations, inspections, and certification, with a focus on the proficiency with which laboratories conduct clinical testing, rather than on the test systems themselves, and its legislative history reflects this. The full context surrounding the enactment of CLIA reveals that Congress was not focused on the oversight of test systems themselves but rather on whether laboratory personnel were performing their jobs in a setting and in a manner that helped ensure accurate, reliable, and timely patient test results. CLIA's enactment was prompted in large part by Congress's concern with the low quality of cytology services associated with Pap testing for cervical cancer. For example, the Senate Report accompanying the bill noted: ''In too many instances, such errors [in pap smear testing] are the result of overworked and under-supervised cytotechnologists charged with the crucial responsibility of examining and categorizing cervical slides.'' S. Rep. No. 100–561, at 27 (1988). This concern led Congress to conclude that ''lack of quality assurance and quality control in the medical testing industry is pervasive.'' Id. at 20. Congress reaffirmed this intent in 1997 when it noted that ''[t]he purpose of CLIA quality control, proficiency testing, and personnel requirements is to ensure consistent, reliable, and appropriate *use* of a test system [61] by users of the test.'' H.R. Rep. No. 105–310, at 76 (1997) (emphasis added). CMS has interpreted its authority consistent with this congressional intent, stating in the preamble to the final rule implementing the 1988 CLIA: ''CLIA specifically requires the regulation of the provision of laboratory services. On the other hand, CLIA and those implementing regulations are not intended to affect FDA's existing jurisdiction under the [FD&C Act] to regulate as devices, products used by providers of laboratory services.'' (57 FR 7002 at 7010). CLIA's legislative history thus reflects a distinct and complementary role for CMS in the regulation of IVDs offered as LDTs.

(Comment 82) Some comments argued that CLIA's quality control and assurance provisions are incompatible with or duplicative of, or were intended to apply to laboratories in place of, FDA's QS requirements, and therefore IVDs offered as LDTs cannot be regulated as devices.

(Response 82) FDA disagrees. CLIA's quality control and assurance provisions do not supplant FDA's QS requirements, because FDA and CMS regulation, including these requirements, are complementary. Although the phaseout policy described in section V.C acknowledges that compliance with CLIA requirements provides certain quality assurances, FDA's QS requirements are neither duplicative of, nor incompatible with, CLIA. As noted in response to comment 12, the portion of CLIA that addresses quality systems relates to laboratory operations, laboratory personnel, and requirements for laboratory procedures relevant to testing. FDA's QS requirements are focused on the IVD offered as an LDT, including design control and validation, complaint handling, and other requirements intended to ensure that the IVD has appropriate assurance of safety and effectiveness for its intended use.

Moreover, nothing in CLIA suggests that Congress intended it to supersede FDA's ability to apply its QSR to IVDs offered as LDTs. As described in more detail in response to comment 80 and in the NPRM, CLIA does not expressly repeal FDA's authority, nor was FDA's authority repealed by implication (88 FR 68006 at 68019).

(Comment 83) FDA received comments asserting that IVDs offered as LDTs cannot be regulated under FDA's device authorities, because the application of FDA labeling requirements and prohibitions to these test systems would prevent manufacturers from complying with CMS's CLIA regulations requiring laboratories to offer consultation on interpreting test results and to provide pertinent updates on testing information that affect test results or their interpretation.

[61] It is our understanding that CMS's role is, in part, to determine and ensure that a laboratory is following the manufacturer's instructions for a test (including how the test kit is stored, what specimens are used, how the specimens are stored, how the test is interpreted, and other aspects of the manufacturer's instructions). This is distinct from regulation by FDA, which focuses on the test itself and its manufacture.

(Response 83) FDA disagrees that these policies are in conflict. CMS's CLIA consultation regulations, 42 CFR 493.1445(e)(9) and 493.1457(d), provide that laboratory directors and clinical consultants must ''[e]nsure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.'' As noted in more detail in response to comment 93, a laboratory director or clinical consultant's ability to comply with the cited regulatory requirements is unaffected by FDA's oversight of LDTs. Premarket review for LDTs is intended to help assure that LDTs generate accurate and reliable test results. As noted in response to comment 93, FDA does not generally consider professional advice regarding a patient's results as evidence of a new intended use, and nothing in this rule is intended to change this practice.[62] FDA recognizes that laboratory directors and clinical consultants help with interpretation and consulting to the healthcare provider, and they can and do give recommendations that are not limited to the content of FDA-required labeling.[63]

CMS's CLIA test report requirements provide, in relevant part, that ''[p]ertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.'' 42 CFR 493.1291(e). As further explained in CMS's interpretive guidelines: ''When the laboratory changes methods, establishes a new procedure or refers tests to another laboratory, the laboratory must make the updated information concerning parameters such as patient preparation, preservation of specimens, specimen collection, or new 'normal' ranges or units of measure available to its clients.'' CMS Manual Pub. 100–07. (Ref. 143). This requirement would not conflict with FDA requirements associated with certain labeling changes as the comment asserts. As noted above, interpretations and recommendations are not limited to the content of FDA-required labeling.

(Comment 84) Some comments argued that IVDs offered as LDTs are not devices because the CLIA regulatory requirement for the establishment of performance specifications for tests that are not cleared or approved by FDA, 42 CFR 493.1253, indicates that such test systems are not intended to be regulated by FDA.

(Response 84) FDA disagrees that the regulation of LDTs as devices is inconsistent with the CLIA regulatory requirements for the establishment of performance specifications for tests that are not FDA-approved or -cleared. The CLIA regulation provides, ''[e]ach laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval'' must establish performance specifications for certain performance characteristics specified in the regulation. *See* 42 CFR 493.1253(b)(2). Although the regulation uses the term ''not subject to FDA clearance or approval,'' the purpose of the regulation is not to state what tests are and are not devices that are required to undergo FDA premarket review (which would not be within CMS's expertise). It merely differentiates those tests that have not undergone FDA premarket review and thus must adhere to certain additional CLIA requirements. The regulation was issued in 2003—long after FDA had publicly stated that IVDs offered as LDTs fall within the device authorities of the FD&C Act—but its preamble does not discuss any intent to overrule FDA on this issue (see 68 FR 3640 at 3707). Instead, statements from CMS both preceding and following issuance of the CLIA regulation indicate that IVDs offered as LDTs are devices. *See* 57 FR 7002 at 7010 (''CLIA and those implementing regulations are not intended to affect FDA's existing jurisdiction under the [FD&C Act] to regulate as devices, products used by providers of laboratory services''); CMS, ''Laboratory Developed Tests (LDTs) Frequently Asked Questions'' (Ref. 26). (''Similar to other in vitro diagnostic tests, LDTs are considered 'devices,' as defined by the FFDCA, and are therefore subject to regulatory oversight by FDA.''). Tests might not have undergone premarket review for a number of reasons, including a test not requiring premarket review due to its classification (or exemption from 510(k)) or a test being marketed without premarket authorization as a result of an FDA exercise of enforcement discretion.

(Comment 85) A comment argued that the CLIA regulation requiring laboratory directors to ensure quality laboratory services for ''all aspects of test performance,'' 42 CFR 493.1407(e)(1), includes both analytical and clinical performance, and therefore FDA cannot regulate IVDs offered as LDTs. Another comment stated that CLIA assessments administered through CLIA-approved accrediting agencies, such as CAP, COLA, and the Joint Commission, account for clinical validity, and that laboratories whose tests are approved by NYS CLEP must show clinical validity.

(Response 85) The comments are incorrect about the scope of CLIA regulation. CMS has stated explicitly that the ''CLIA program does not address the clinical validity of any test'' (Ref. 26). The NYS CLEP requirement to demonstrate clinical validity does not limit FDA's authority over laboratory-manufactured IVDs, as State requirements cannot preempt Federal law. Further, as noted in response to comment 12, FDA and CMS enforce two different regulatory schemes, and there are many aspects of IVDs offered as LDTs that CMS does not regulate under CLIA, including, but not limited to, design control and validation and other requirements intended to ensure that the IVD has appropriate assurance of safety and effectiveness for its intended use.

(Comment 86) One comment argued that Congress's establishment of a reimbursement system for laboratory tests that lack FDA clearance or approval, including section 216 of PAMA and CMS's reliance on Palmetto GBA's MolDX Program for local coverage determinations, indicates that Congress did not intend for IVDs offered as LDTs to be regulated as devices under the FD&C Act.

(Response 86) FDA disagrees that the Medicare payment requirements established under section 216 of PAMA evidence a congressional intent to exclude IVDs offered as LDTs from FDA's device authorities, and, to the contrary, believes the requirements support an interpretation that such test systems are devices under the FD&C Act. PAMA established Medicare payment requirements for certain ''advanced diagnostic laboratory tests'' (ADLTs), which the statute defines as ''a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner)'' and meets one of the following criteria: ''(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result. (B) The test is cleared or approved by the Food and Drug Administration. (C) The test meets other similar criteria established by the Secretary'' (*see* 42 U.S.C. 1395m–1(d)(5)). As ADLTs are developed,

[62] In contrast, if a laboratory offers a test on its website for an unapproved use, FDA would likely consider that offer to be evidence of a new intended use.

[63] For products not subject to premarket approval, but instead subject to premarket notification (510(k)) requirements or exempt from premarket review, we use the term *FDA-required labeling* to include labeling that provides adequate directions for use and other information required to appear on the label or in labeling.

offered, and furnished by a single laboratory they may include IVDs offered as LDTs. If ADLTs that are IVDs offered as LDTs were not subject to the FD&C Act's device authorities, FDA would have no jurisdiction to clear or approve the tests. If FDA lacked jurisdiction to clear or approve the tests, Congress would not have enacted 42 U.S.C. 1395m–1(d)(5)(B), which includes FDA clearance or approval as a criterion for an ADLT and, thus, a basis for Medicare payment. Two allegedly conflicting statutes must be interpreted ''to give effect to each if [one] can do so while preserving their sense and purpose.'' *Watt* v. *Alaska,* 451 U.S. 259, 267 (1981). Because excluding IVDs offered as LDTs from FDA's device authorities could render part of PAMA's payment scheme a dead letter, this principle applies here.

PAMA's inclusion of criteria other than FDA clearance or approval within the definition of an ADLT does not suggest that IVDs offered as LDTs are not devices under the FD&C Act. Nor does the fact that the MolDX program—which evaluates certain tests to determine whether the test meets Medicare's reasonable and necessary criteria—may list tests that are not cleared or approved by FDA. As noted in the response to comment 84, regarding the lack of a conflict with 42 CFR 493.1253(b)(2), the marketing of a laboratory-manufactured IVD without FDA clearance or approval in certain situations is not incompatible with its regulation as a device by FDA.

(Comment 87) FDA received comments asserting that the application of registration requirements and fees under FDA's device authorities to IVDs offered as LDTs would be duplicative of such requirements under CLIA.

(Response 87) FDA disagrees that such requirements are duplicative, as they go to different regulators for different activities. As noted in response to comment 12, FDA's device authorities and CMS's CLIA authorities are complementary, not duplicative. CMS determines whether a laboratory and its personnel meet CLIA requirements, whereas FDA's statutory mandate is to review and evaluate the tests themselves, including IVDs offered as LDTs, to ensure that they have appropriate assurance of safety and effectiveness for their intended use.

(Comment 88) Some comments, citing *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120 (2000), argued that FDA jurisdiction over IVDs offered as LDTs is precluded by the supposed inconsistency of FDA regulation of LDTs as devices with the regulatory structures for reimbursement for ADLTs and the regulation of clinical laboratories set forth in CLIA.

(Response 88) FDA disagrees that *FDA* v. *Brown & Williamson* precludes FDA jurisdiction. In that case, the Supreme Court found that FDA's regulation of tobacco products as devices contravened the intent of Congress. The Court explained that Congress enacted six pieces of legislation, outside of the FD&C Act, regarding tobacco and human health, and did so against the ''backdrop of the FDA's consistent and repeated statements that it lacked authority under the [FD&C Act] to regulate tobacco absent claims of therapeutic benefit by the manufacturer.'' Id. at 144. The Court also concluded that the FD&C Act's mandate to ensure products are safe and effective for their intended use would require the removal of tobacco products from the market. *See* id. at 133–39. Because such a ''ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation,'' the ''inescapable conclusion'' was that tobacco products without therapeutic claims did not ''fit'' within the FD&C Act's regulatory scheme for medical products. Id. at 143.

That is not the case here. FDA's regulation of LDTs as devices will not result in a categorical ban on LDTs. Moreover, FDA has long understood and publicly maintained that LDTs are devices, and Congress has not manifested a contrary intent. Indeed, as noted in response to comment 86, Congress has since enacted legislation that assumes LDTs are subject to FDA approval or clearance. As explained in response to comments 82–87, FDA regulation of IVDs offered as LDTs does not conflict with either the regulation of clinical laboratories under CLIA or the provisions for reimbursement for ADLTs cited in the comments to this rulemaking. The lack of a conflict here makes this situation clearly different from that in *FDA* v. *Brown & Williamson.*

Moreover, to the extent that the supposed inconsistencies are based on CMS regulations, and not Federal statutes, *FDA* v. *Brown & Williamson* is inapposite. There, the Court turned to six pieces of Federal legislation outside of the FD&C Act in order to determine whether Congress intended tobacco products to be regulated as devices under the FD&C Act. *See* id. at 137–38. Here, comments citing to individual CMS regulations or the presence of unapproved, uncleared LDTs in the MolDX program are not compelling because, unlike statutes, those sources do not shed light on Congress's intent in enacting the FD&C Act or its amendments.

(Comment 89) One commenter argued that because the performance of a test is a ''service'' or ''examination'' regulated under CLIA, even if a laboratory engages in IVD manufacturing or development activities, those activities should be understood to be governed by CLIA and not the FD&C Act because ''the lab's primary responsibility is still to perform the service.''

(Response 89) FDA does not agree that a laboratory's ''primary responsibility'' is relevant to FDA's jurisdiction or that a laboratory engaged in both manufacturing an IVD and performing a medical service has greater or ''primary'' responsibility for performing the medical service such that it is no longer obligated to comply with requirements related to manufacturing the IVD. The mere fact that laboratories conduct a CMS-regulated activity—performing a test—does not exempt them from other relevant statutory or regulatory authorities related to test manufacturing or design.

(Comment 90) One comment stated that, generally, Congress has appropriated sufficient funds for CMS to regulate clinical laboratories under CLIA, but it has not provided FDA with adequate funds to exercise regulatory authority over LDTs. This asserted disparity in funding, the comment argued, is evidence that Congress did not intend for FDA to have authority over LDTs.

(Response 90) FDA fails to see how the amount of funds appropriated to CMS that are available to implement CLIA and the amount of funds appropriated to FDA that are available to regulate devices reflects a congressional intent that these tests are not regulated as devices under the FD&C Act. FDA's device program is funded through a combination of budget authority and user fees. As enforcement discretion is phased out, FDA will receive user fees associated with establishment registrations and premarket submissions for IVDs offered as LDTs. As with all products FDA regulates, FDA intends to prioritize its available resources to oversee LDTs in a risk-based manner. Even if FDA were not provided adequate funds, the Supreme Court recently acknowledged that funding does not always match apparent statutory mandates. *See Biden* v. *Texas,* 142 S. Ct. 2528, 2535 (2022) (''The INA states that if 'an alien seeking admission is not clearly and beyond a doubt entitled to be admitted, the alien shall be detained for a proceeding.' Due to consistent and significant funding shortfalls, however, DHS has never had

'sufficient detention capacity to maintain in custody every single person described in section 1225.' '' (cleaned up)). Moreover, FDA's jurisdiction over devices and other products is established in the FD&C Act, and is not based on annual funding decisions and the relative amount of funding appropriated.

(Comment 91) One comment suggested that, rather than regulate IVDs offered as LDTs under the FD&C Act, FDA should consult with CMS and CDC on an alternative approach whereby CLIA regulations are updated with additional requirements for validation of IVDs offered as LDTs, including modifications to authorized IVDs and novel LDTs.

(Response 91) While FDA has consulted with CMS and CDC on the topic of IVDs offered as LDTs, including as part of this rulemaking, FDA disagrees that an alternative approach through updating CLIA regulations would suffice. As discussed in more detail in response to comment 10, CMS determines whether a laboratory and its personnel meet CLIA requirements, whereas FDA's statutory mandate is to review and evaluate the tests themselves, including IVDs offered as LDTs, to ensure that they have appropriate assurance of safety and effectiveness for their intended use. FDA has the resources and expertise to assess whether tests work for their intended clinical purpose; CMS does not.

9. Major Questions Doctrine

(Comment 92) Various comments argued that this rulemaking implicates the ''major questions doctrine'' under *West Virginia* v. *EPA,* 142 S. Ct. 2587 (2022). These comments asserted that: (1) the rulemaking presents the type of ''extraordinary case'' in which courts should hesitate before concluding that Congress granted the relevant authority to an agency and (2) the FD&C Act lacks the ''clear congressional authorization'' necessary to conclude that Congress granted this authority to FDA. To support their position, these comments generally focused on the facts that: (1) Congress previously has considered but declined to enact bills related to LDTs; (2) LDTs are a topic of congressional debate and therefore, in the commenters' view, a matter for Congress; (3) the claimed authority would affect a significant number of parties, ''would have a major impact on the delivery of healthcare,'' and would ''alter the market''; and (4) the Agency's approach would require billions of dollars in spending each year. Some comments also pointed to ''the overall FDCA regulatory scheme'' and ''subsequent legislation specific to clinical laboratories'' (*i.e.,* CLIA). Several comments analogized to other cases such as *FDA* v. *Brown and Williamson Tobacco Corp.,* 529 U.S. 120, *Utility Air Regulatory Group* v. *EPA,* 573 U.S. 302 (2014), and *United States* v. *Franck's Lab, Inc.,* 816 F. Supp. 2d 1209 (M.D. Fla. 2011).

(Response 92) FDA does not agree that it lacks authority for this rulemaking under the major questions doctrine. First, we do not agree that the major questions doctrine applies, because this is not the type of ''extraordinary case'' in which there is ''reason to hesitate'' before concluding that Congress intended to confer on FDA authority over laboratory-manufactured IVDs. Second, even if a court were to hold that the major questions doctrine applies, the FD&C Act supplies clear congressional authorization.

a. This rulemaking is not ''extraordinary'' for purposes of the major questions doctrine. As explained by the Supreme Court, the major questions doctrine does not apply to every agency action, or even every agency action that involves significant costs and benefits and congressional interest. Rather, it applies only in those ''extraordinary cases'' in which ''the history and the breadth of the authority that the agency has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority.'' *West Virginia* v. *EPA,* 142 S. Ct. 2587 at 2608 (cleaned up). The Court has indicated that whether there is a ''reason to hesitate'' depends on specific ''circumstances'' and ''common sense as to the manner in which Congress would have been likely to delegate.'' Id. at 2609 (cleaned up). It has identified specific factors that can signal such an extraordinary case, such as whether:

- The Agency appears to be assuming ''extravagant'' or ''broad and unusual'' power—as measured in terms of cost, politics, or policy, for example—that Congress would have been ''highly unlikely'' to leave to Agency discretion. Id. at 2608–09, 2612 (internal quotations omitted).
- The asserted authority relies on an ''ancillary,'' ''rarely . . . used'' or otherwise ''modest'' statutory provision. Id. at 2609–10 (internal quotations omitted).
- The Agency, through statements or practice, previously appeared to view the relevant language more narrowly, such that the Agency's new view seems ''unheralded'' or ''newly discovered.'' Id. at 2610, 2612 (internal quotations omitted).
- Implementation of the Agency's decision will require ''technical and policy expertise'' not traditionally within the Agency's wheelhouse. Id. at 2612 (internal quotations omitted).
- There is inconsistency between the asserted authority and the larger statutory scheme—for example, Congress has not ''conferred a like authority'' on the Agency elsewhere in the statute. Id. at 2613.

Under the major questions doctrine, the Court has described these factors as indicating that Congress may not have meant to confer the power claimed by the Agency.

Application of the factors here shows that courts should not hesitate before concluding that Congress granted FDA authority over laboratory-manufactured IVDs, consistent with the statute's plain language. In this rulemaking, FDA is not asserting any ''new'' authority at all. Over 30 years ago, FDA unambiguously stated that it has authority over laboratory-made IVDs, (Ref. 111), and in the last decade, it has applied that authority to hundreds of laboratory-made IVDs, including LDTs, without legal challenge (see, *e.g.,* Refs. 144 to 155). This Rule clarifies the statutory definition of a ''device,'' which is not an ''ancillary'' provision of the FD&C Act but rather the bedrock definition that governs the application of each device provision that FDA administers. As explained elsewhere in this preamble, the device definition encompasses diagnostic test systems, so there is nothing ''unusual'' or ''extravagant'' about concluding that it reaches test systems made by laboratories. In fact, that understanding is in lockstep with FDA's statutory mandate and the other authorities it implements, is consistent with FDA's longstanding approach, and makes the most of FDA's expertise. What would be ''unusual'' is to read an atextual laboratory exemption into the FD&C Act—thus elevating laboratories above any other type of manufacturer—of entirely amorphous breadth and scope. *See Bostock* v. *Clayton Cty.,* 140 S. Ct. 1731 at 1749 (inferring from ''broad language'' ''Congress's 'presumed point [to] produce general coverage—not to leave room for courts to recognize ad hoc exceptions.' '') (quoting A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 101 (2012)). In the following paragraphs, FDA addresses each of the major questions factors to show why this is not an ''extraordinary case'' under that doctrine.

First, FDA is not asserting ''extravagant'' or ''broad and unusual''

power that Congress would have been ''highly unlikely'' to leave to Agency discretion. Congress enacted the MDA ''to provide for the safety and effectiveness of medical devices intended for human use'' without qualification. Medical Device Amendments of 1976, Public Law 94–295 (May 28, 1976) (purpose clause). In that legislation, it tasked FDA with overseeing the safety and effectiveness of all devices used in the United States—a substantial delegation that, according to FDA's estimates, encompasses a $374.5 billion industry today. Although FDA has estimated that this rule will have important public health impacts, the costs of the rule are not ''extravagant'' or ''unusual,'' particularly when viewed in the context of FDA's regulatory responsibility for devices overall. And device regulation is just one small part of FDA's overall remit: as of January 2024, FDA-regulated products accounted for about 21 cents of every dollar spent by U.S. consumers, and FDA had responsibility for ''more than $3.6 trillion in consumption of food, medical products, and tobacco.'' [64] Given the breadth and scope of FDA's overall mandate, and its mandate with respect to devices, there is no reason to doubt that the mandate includes the subset of IVDs that are manufactured by laboratories, and the economic impact of this rule alone does not provide a reason to hesitate under the major questions doctrine.[65]

FDA also does not agree that ''political significance'' is a compelling factor here. Many comments pointed to recent legislative proposals related to IVDs, such as the Verifying Accurate, Leading-Edge IVCT Development Act of 2023 (VALID Act), H.R. 2369, 118th Cong. (2023). Some comments portrayed the VALID Act as a proposal to grant FDA new authority over LDTs, or interpreted Congress's decision not to enact the VALID Act as evidence that FDA lacks authority to issue the rule. These characterizations do not accurately describe the VALID Act. Congressional deliberations over the VALID Act involved the question whether a whole new statutory scheme, instead of the device framework in the FD&C Act, should apply to IVDs. Under the VALID Act, all IVDs, including LDTs, would have been carved out from the definition of a ''device''—a step that would not have been necessary were they not covered by the existing definition—and would have been subject to a novel statutory framework including, for example, a new statutory approval standard, new types of premarket review (such as ''technology certification''), and different QS requirements. Thus, contrary to commenters' suggestions, the fact that Congress has not passed that bill does not represent a decision that FDA lacks authority over LDTs, but rather that Congress has not chosen to create a statutory scheme for IVDs that is different than for all other devices. Around the same time, Congress also considered, but did not pass, a bill that, as summarized by Congressional Research Service, would have ''shift[ed] the regulation of laboratory-developed testing procedures from the Food and Drug Administration (FDA) to the Centers for Medicare & Medicaid Services (CMS).'' [66] In not passing that bill, Congress opted to maintain the longstanding, well-understood status quo: that IVDs, including LDTs, are devices subject to device requirements under the FD&C Act. Congress's consideration of these bills does not show that there is an open question whether Congress conferred this authority on FDA under the FD&C Act; instead, it provides additional evidence affirming that LDTs fall within FDA's existing authority.

In any event, even if a court were to find the foregoing economic and political facts relevant under the major questions doctrine, FDA does not agree that they are sufficient to implicate that doctrine. The Court's major-questions cases examine a variety of factors to determine whether there is a ''reason to hesitate'' before concluding that Congress meant to confer the power claimed by the Agency. For example, in West Virginia, the Court cited a range of factors to conclude that the rulemaking there presented a ''major question.'' The Court did not rest the decision solely on the ''billions of dollars in compliance costs,'' *EPA* v. *West Virginia,* 142 S. Ct. 2587 at 2604, and the fact that Congress had ''consistently rejected proposals'' to create a cap-and-trade scheme for carbon, id. at 2614. Instead, it devoted much attention to other factors, such as those described in the remaining paragraphs of this comment response. This fact suggests that economic and political factors, even where applicable, are not enough. And the other hallmarks of an ''extraordinary case'' are absent here.

For example, FDA's asserted authority does not rely on an ''ancillary,'' ''rarely . . . used'' or otherwise ''modest'' statutory provision, but on the meaning of ''device,'' which defines the scope of articles subject to device requirements under the FD&C Act. Congress knew this definition would play a central role in the application of FDA's authorities, so it gave the provision special attention in 1976, adding new terms and carefully distinguishing ''devices'' from ''drugs.'' *See, e.g.,* H.R. Rep. 94–853 at 13–15. Given the detailed nature of the definition and Congress's care in drafting it, this provision is very different from the ''vague statutory grant'' at issue in West Virginia, which, in the Court's view, was susceptible of interpretation in a manner that went ''beyond what Congress could reasonably be understood to have granted.'' *EPA* v. *West Virginia,* 142 S. Ct. 2587 at 2609, 2614. Here, the definition's text is reasonably understood to reflect the true scope of FDA's authority as intended by Congress. *See* id. at 13 (''[T]he Committee has attempted to design device authority such that the law and the intent of the Congress is clear.''); *see also United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (''Congress fully intended that the [FD&C] Act's coverage be as broad as its literal language indicates.'').

FDA is not exercising ''newly uncovered'' or ''unheralded'' authority. *West Virginia* v. *EPA,* 142 S. Ct. 2587 at 2610, 2614. FDA publicly communicated its view that test systems are subject to the Agency's authority over 50 years ago, see 38 FR 7096; that laboratories are subject to the Agency's authority almost 50 years ago, see 42 FR 42521; and that laboratory ''in house'' tests are devices nearly 30 years ago, see 62 FR 62249. And in the years since, FDA has consistently reiterated these assertions (see NPRM section III.D.1., ''FDA's Longstanding Recognition That IVDs Manufactured by Laboratories Are Devices'' 88 FR 68006 at 68015–16). Over the last 10 years, FDA has applied its device authorities to hundreds of laboratory-manufactured tests. For example, dating back to at least 2014, it has granted premarket approval to IVDs offered as LDTs,[67] and during the

[64] Ref. 156.

[65] One commenter's discussion of the major questions doctrine emphasized the Agency workload under the NPRM. Even assuming that were a relevant factor, the Agency's workload for purposes of this rule is not so great that it raises a question about whether Congress intended to confer authority on FDA to regulate laboratory-manufactured IVDs. As stated, FDA's regulation of devices is just one small part of FDA's overall remit; and the regulation of the subset of IVDs that are manufactured by laboratories is just one part of that broader regulatory authority over devices.

[66] *See* Congressional Research Service summary, Verified Innovative Testing in American Laboratories (VITAL) Act, S. 1666, 117th Cong. (introduced May 18, 2021), available at *https://www.congress.gov/bill/117th-congress/senate-bill/1666.*

[67] Ref. 157.

COVID–19 public health emergency, the Agency issued EUAs for scores of IVDs offered as LDTs (see Ref. 18). All of these activities were predicated on the legal conclusion that test systems manufactured by laboratories are devices. *See* 21 U.S.C. 360e (premarket approval authority applicable to devices); 21 U.S.C. 360bbb–3 (EUA authorities applicable to drugs, devices, or biological products). Thus, this is not a situation in which ''the want of assertion of power by those who presumably would be alert to exercise it'' raises a question about ''whether such power was actually conferred.'' Id. at 2608. FDA has repeatedly expressed its view of its authority, including in public statements and through public actions, and its consistent position over decades—without congressional intervention—suggests that there is no ''reason to hesitate'' here. *See, e.g., United States* v. *Tuente Livestock,* 888 F. Supp. 1416, 1423 (S.D. Ohio 1995) (upholding FDA interpretation based on, among other things, the fact that ''Congress has been aware of the FDA's understanding and practice concerning live animals for almost twenty-five years, yet has in no way acted to limit the agency's jurisdiction'').[68]

Implementation of this Rule involves technical and policy expertise traditionally within FDA's wheelhouse. FDA has amassed significant experience and expertise regulating IVDs (including test systems) over the course of five decades. This work is squarely within the expertise of FDA's OHT7. OHT7 employs staff across a wide range of disciplines to evaluate test systems and other IVDs, including the principles of their operation and the analytical validity, clinical validity, and safety data behind them. As explained in the NPRM, FDA's work in this area does not meaningfully differ whether an IVD comes from a laboratory or another manufacturer (88 FR 68006 at 68014) (see also responses to comments 67 and 71). Applying this sort of technical and scientific knowledge to devices is a quintessential function performed by FDA, and undoubtedly an area where FDA has ''comparative expertise.'' Id. at 2613. Indeed, no other Federal Agency is similarly equipped to do it. These facts underscore the conclusion that FDA has a legitimate role to play—and value to add—in overseeing laboratory-made IVDs. They also reinforce the commonsense point that laboratory-manufactured IVDs fall within the basic mandate of the FD&C Act. Here, FDA is exercising authority, applying expertise, and serving its public-health mission in exactly the ways that are contemplated under the FD&C Act.

Finally, the FD&C Act as a whole supports the conclusion that the Agency has authority for this rulemaking. Congress enacted both the FD&C Act and the MDA with public-health protection in mind. See *United States* v. *Sullivan,* 332 U.S. 689, 696 (1948) (''[T]he Act as a whole was designed primarily to protect consumers from dangerous products.''); *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470, 476 (''In response to the mounting consumer and regulatory concern, Congress enacted the statute at issue here: the Medical Device Amendments of 1976.''). Congress tasked FDA with protecting the public with respect to certain defined categories of articles—as relevant here, ''devices''—and sought to avoid ''language which afforded loopholes for the escape of the unscrupulous.'' S. Rep. 74–361 at 2 (March 13, 1935). Given that risky products could originate from all corners of the country by all manner of ''persons,'' see 21 U.S.C. 321(e), Congress did not key the ''device'' definition to any particular type of entity and did not limit FDA's enforcement authorities to particular actors, see 21 U.S.C. 331 (listing ''prohibited acts'' generally without reference to the identity of an actor). Instead, it delegated broad authority and crafted exemptions from certain requirements as appropriate. *See, e.g.,* 21 U.S.C. 360(g)(2), 360i(c)(1), 374(a)(2)(B) (even licensed practitioners are subject to the FD&C Act, though their activities may be exempt). Consequently, the best reading of the FD&C Act is that it contains no carveout for laboratories, and Congress has enacted legislation supporting that interpretation. *See* 42 U.S.C. 1395m–1(d)(5)(B) (certain tests developed by laboratories subject to FD&C Act). With respect to commenters' assertions regarding specific provisions of the FD&C Act and the enactment of CLIA, FDA has addressed those elsewhere in this preamble (see response to comment 54 and sections VI.D.3, VI.D.4, and VI.D.8 of this preamble).

Some commenters also analogized FDA's proposed action to those in *FDA* v. *Brown and Williamson Tobacco Corp.,* 529 U.S. 120 and *Utility Air Regulatory Group* v. *EPA,* 573 U.S. 302. But important factors influencing the Court's opinions in those cases are not present here. For instance, here, there is no inconsistency between the FD&C Act and FDA's regulation of laboratories as ''device'' manufacturers. *See Brown and Williamson,* 529 U.S. 120 at 125 (FDA ''may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law.'') (internal quotations omitted); *Utility Air Regulatory Group,* 573 U.S. 302 at 321 (Agency interpretation ''would be inconsistent with—in fact, would overthrow—the Act's structure and design.''). Indeed, FDA has regulated in this way for years, and FDA has never disclaimed authority over laboratory-manufactured IVDs. In addition, this final rule will not have the type of ''calamitous consequences'' that have caused the Court to consider other regulatory actions to be ''incompatible with the substance of Congress' regulatory scheme.'' [69] 573 U.S. 302 at 322. Quite the opposite: FDA believes that a continuation of the status quo—or a construction of the FD&C Act that incorporates an atextual exemption for laboratories—would have serious consequences for the public, which is why FDA is issuing this rule.[70]

[68] One commenter attempted to discredit FDA's statement of authority in one preamble (62 FR 62243) on the basis that FDA lacked ''any supporting analysis,'' among other things. But FDA is aware of no basis for the position that the major-questions doctrine requires an Agency to produce a detailed legal analysis in order to show its historical view. As the Supreme Court has described it, the question is whether the Agency's asserted authority is ''unheralded,'' ''newly uncovered,'' or ''not previously exercised,'' *West Virginia* v. *EPA,* 142 S. Ct. 2587 at 2610, 2614, and that is not the case here. FDA also notes that the statement identified by the commenter was just one in a long line of public statements (*see* NPRM section III.D.1., ''FDA's Longstanding Recognition That IVDs Manufactured by Laboratories Are Devices'' 88 FR 68006 at 68015–16), and it was not the first statement of FDA's authority over laboratory-manufactured IVDs. *See, e.g.,* (Ref. 111). Draft CPG: Commercialization of Unapproved In Vitro Diagnostic Devices Labeled for Research and Investigation (Aug 3, 1992) (stating that laboratory ''home brew'' products ''are subject to the same regulatory requirements as any unapproved medical device'').

[69] One comment argued that this rulemaking will have practical consequences analogous to those in *Utility Air*—a significant increase in the number of applications, administrative costs, and the review period for applications—which shows that it presents a ''major question.'' FDA disagrees. As already discussed, FDA does not agree that the current effects of this rule are a reliable indicator of Congress's intent in 1976. In addition, we do not agree that the practical effects here have the same weight as they did in *Utility Air. See Utility Air Regulatory Group* v. *EPA,* 573 U.S. 302, 321–22 (2014) (''EPA described the calamitous consequences of interpreting the Act in that way.''). And in this rulemaking, unlike *Utility Air,* FDA has discretion to develop enforcement policies to address practical concerns about implementation, underscoring the point that practical concerns should not be understood to reflect a lack of jurisdiction. *Id.* at 326 (rule was not ''an exercise of EPA's enforcement discretion'' given the possibility of citizen suits).

[70] One comment also compared this rulemaking to the facts in *United States* v. *Franck's Lab, Inc.,* 816 F. Supp. 2d 1209 (M.D. Fla. 2011), which concerned FDA's authority over pharmacy compounding. However, that case was not a ''major questions'' case, and in any event, it was vacated

b. Even if the major-questions doctrine applies, the FD&C Act supplies ''clear congressional authorization'' for this rulemaking. In response to comment 52, FDA explained that the device definition, by its plain terms, encompasses IVDs manufactured by laboratories. This conclusion has more than ''a merely plausible textual basis.'' Id. at 2609. It is the most reasonable reading of the text, and the one that matches congressional intent as expressed through the statutory scheme overall, the legislative history, and subsequent statements from Congress.

Congress drafted the FD&C Act with broad reach, consistent with the remedial purpose of the legislation, and then exempted specific actors and activities as appropriate, but never exempted laboratories. In 1938, Congress included the term ''diagnosis'' in the FD&C Act specifically to empower FDA to address articles producing false diagnostic results, without any carveout for laboratories. FD&C Act (June 25, 1938), Public Law 75–717, 52 Stat. 1040 (defining ''drug'' and ''device'' with reference to an intended use in ''diagnosis,'' among other things). In 1976, Congress reiterated that diagnostic articles should be regulated by FDA, now under the new, more robust device framework, and again made no distinction in the device definition between entities manufacturing those articles. See, *e.g.,* H.R. Rep. 94–853 at 11 (February 29, 1976). As described in response to comment 53, the authorizing committees discussed concerns about diagnostic systems at length—and particularly the potential harms of faulty test results—but never mentioned that entities such as laboratories should fall outside the reach of the FD&C Act, even though laboratories were manufacturing tests at the time and FDA had recently announced, by regulation, that IVDs were devices regardless of their manufacturer. And in the over 30 years since FDA first stated its authority over LDTs specifically, Congress has not acted to limit the Agency's jurisdiction. Instead, in 2014, Congress passed legislation expressly recognizing that ''a clinical diagnostic laboratory test . . . offered and furnished only by a single laboratory'' can be ''cleared or approved by the Food and Drug Administration,'' 42 U.S.C. 1395m–1(d)(5) & (d)(5)(B), and thus is within the definition of a device. Therefore, examining the text in context, the definition provides ''clear congressional authorization'' for this rulemaking.

E. Other Legal Comments

(Comment 93) Two comments raised First Amendment concerns. One comment asserted that LDTs are different from other devices in that the design and execution of LDTs, as well as the communication of test results, involve speech. In particular, the comment pointed to two CLIA regulations, 42 CFR 493.1445 and 493.1457, which provide that laboratory directors and clinical consultants must ''[e]nsure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.'' The comment asserted that these communications will be restricted if FDA has not authorized them through premarket review. The comment then argued that the premarket review requirement for LDTs cannot survive First Amendment analysis. Although the comment conceded that there is a government interest in ensuring that test results do not include misleading information, the comment asserted that premarket review of LDTs would be too burdensome because such review would restrict laboratory directors and clinical consultants from sharing information about the meaning of test results. That outcome, the comment continued, would undermine the goal of providing healthcare practitioners with information relevant to treatment.

The other comment focused on the right of physicians to receive information as part of their professional speech. The comment suggested that professional speech is subject to special protections under *National Inst. of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361 (2018) (NIFLA) and this special protection extends to physicians' right to receive information. Similar to the first comment, this comment asserted that an LDT is different from many other medical devices in that it is ''an informational service'' incorporating expert professional judgments. While the comment admitted that the FD&C Act properly places the burden on product sponsors to produce evidence that their products are safe and effective before they can be used, the comment asserted that ''the Constitution flips the burden of proof'' when regulating flows of medical information, so that FDA would bear the burden of establishing that an LDT is unsafe in order to regulate the LDT.

(Response 93) We disagree with these comments, both in terms of the premises and the analyses. As an initial matter, it is important to clarify the limited impact that the application of the device authorities to LDTs will have on professional communications. As the phaseout of the general enforcement discretion approach is implemented, laboratories that manufacture IVDs offered as LDTs will be generally expected to comply with several pre- and post-market submission and reporting requirements applicable to devices for humans. As most relevant to this discussion, the premarket review requirements are intended to ensure that a device has a reasonable assurance of safety and effectiveness (or other assurances as required under the FD&C Act) for its intended uses prior to being offered for use. For IVDs, appropriate assurances of safety and effectiveness mean, among other things, that a test is not providing false results, which can stem from an analytical error or from a lack of clinical validity where a measured result is incorrectly associated with a particular clinical state. Accordingly, premarket review involves a scientific evaluation of the functioning of the device for accuracy and reliability. Where premarket requirements apply, a test may not be offered for use if those requirements have not been satisfied. But FDA does not generally consider professional advice regarding a patient's results as evidence of a new intended use, and nothing in this rule is intended to change this practice or otherwise limit the speech clinical professionals may employ in describing and interpreting the outputs of the devices that are lawful to employ. As discussed in more detail below, courts have upheld these premarket review requirements against First Amendment challenges.

Both comments suggested that LDTs are different from other devices because they convey individuals' health information—that is, test results. The comments asserted that this information constitutes speech. But LDTs are not unique in conveying individuals' health information. So too do many non-laboratory IVDs have informational outputs, as well as numerous other types of diagnostic devices, such as radiological imaging devices (such as mammography, x-ray, CT, ultrasound machines), electrocardiograms, blood pressure cuffs, pulse oximeters, cardiac monitors including fetal heart rate monitors, and thermometers. These devices all communicate information—in the form of words, numbers, images, and/or sounds. Yet FDA's statutory authority to regulate diagnostic devices is well established. *See* 21 U.S.C. 321(h)

by the Eleventh Circuit. *United States* v. *Franck's Lab, Inc.,* 2012 U.S. App. LEXIS 27100 (11th Cir. 2012).

(defining ''device'' in part as an article ''intended for use in the diagnosis of disease or other conditions''). And the constitutionality of Congress's grant of authority to regulate these devices, and to prohibit their sale or use where applicable premarket requirements are not satisfied, has not been questioned. There is nothing about LDTs, as compared with these other devices (or with non-LDT IVDs that produce diagnostic results), that suggests they uniquely implicate the First Amendment. They do not.

We are not aware of any instance in which a litigant has raised a First Amendment challenge to the application of the premarket review provisions of the FD&C Act for diagnostic devices based on the informational nature of their outputs. Any such challenge should fail on legal grounds. Even where LDTs or other diagnostic devices convey information about the health of patients, they do not convey ideas, creative expression, or editorial judgments—that is, they do not convey speech that implicates the First Amendment. Rather, they simply convey scientifically-generated test results purely as a function of the device. In this regard, they cannot be distinguished from a vast array of products whose regulation does not implicate the First Amendment: radar detectors, gas gauges, expiration lights for water filters, and so forth. Even though the very point of these products is to convey information, the Government may seek to ensure that they do so accurately and reliably—and may bar the sale of those that are not accurate and reliable—without triggering First Amendment scrutiny. Indeed, requirements of prior certification before commercial use of weighing and measuring devices—devices whose purpose is to convey information in ways analogous to diagnostic tests—are ubiquitous. *See, e.g.,* Nat'l Inst. of Standards & Technology, *Weights and Measures Program Requirements: A Handbook for the Weights and Measures Administrator* 13–14 (2017) (''Before measuring instruments may be installed in stores or at business locations, most states require that the many types of measuring instruments have type evaluation certificates reporting that the models comply with the requirements of NIST Handbook 44,'' which provides ''the technical and performance requirements for commercial measuring instruments used in the United States''). But we are unaware of a single court that has even applied First Amendment scrutiny to these requirements. The application of the FD&C Act's medical device regulation to LDTs is the same in all relevant respects.[71]

The comments also erred in their assessment of how the rule would affect professional speech. More specifically, the first comment was incorrect in suggesting that premarket review will preclude the laboratory directors and clinical consultants from consulting on the quality of the test results and their interpretation concerning specific patient conditions pursuant to the CLIA regulations. Premarket review for LDTs is intended to help assure that LDTs generate accurate and reliable test results. As noted, FDA does not generally consider professional advice regarding a patient's results as evidence of a new intended use, and nothing in this rule is intended to change this practice.[72] FDA recognizes that laboratory directors and clinical consultants help with interpretation and consulting to the healthcare provider, and they can and do give recommendations that are not limited to the content of FDA-required labeling. This clinical consultation is unaffected by FDA's oversight of LDTs. Indeed, the CLIA provisions are not specific to LDTs and have coexisted with FDA regulation of other IVDs for some time. The commenter therefore was incorrect in construing the premarket review and related requirements discussed in this preamble as restricting laboratory directors and clinical consultants from sharing truthful and nonmisleading information about the meaning of a test result.

In addition, with respect to speech by laboratories more generally, contrary to the first comment's suggestion, FDA does not take the position that communications by medical product manufacturers are strictly limited to the content of FDA-required labeling. For example, FDA has issued final guidance regarding medical product manufacturers sharing data and information about the authorized uses of their products that are not contained in their products' FDA-required labeling; the final guidance provides recommendations on how to share the information in a truthful and non-misleading way (see Ref. 62). FDA has also issued draft guidance with recommendations on how medical product manufacturers can share truthful and non-misleading information about unapproved uses of medical products (see, *e.g.,* Refs. 158 and 159).

Essentially, then, the only content restriction is the requirement of premarket review itself—that laboratories cannot offer test results without first subjecting its device to premarket review to help assure that the device produces accurate and reliable results. A First Amendment challenge to the rule is therefore fundamentally a challenge to the FD&C Act's existing premarket requirements themselves, which prohibit the conduct of marketing devices absent satisfaction of those requirements. Even to the extent that the premarket requirements relate to speech in the form of labeling and marketing, they have long been upheld.

Courts have upheld these premarket review requirements in the context of First Amendment challenges on a variety of grounds. The premarket review requirements do not burden free expression because they are directed to conduct and not to speech. *United States* v. *Facteau,* 89 F.4th 1, 29 (1st Cir. 2023), *petition for cert. filed,* ____ U.S.L.W. ____ (U.S. March 13, 2024) (No. 23–1016). A device is adulterated or misbranded ''if, among other things, it is intended for a use [subject to premarket review] that has not been approved or cleared by FDA.'' January 2017 Memorandum at 40; *see generally* id. at 40–47 (Ref. 17). In this case, the relevant conduct includes making LDTs available for use and sale without premarket review when such review is required, which constitutes adulterating or misbranding the device while it is held for sale in violation of section 301(k) of the FD&C Act. ''[I]t has never been deemed an abridgment of freedom of speech'' to regulate conduct that involves language where the ''effect on speech would be only incidental to its primary effect on conduct.'' *Expressions Hair Design* v. *Schneiderman,* 581 U.S. 37, 47 (2017) (cleaned up). Accordingly, regulation of the conduct of making a device available without premarket review has only ''incidental effects'' on speech and ''do[es] not implicate the First Amendment.'' Facteau, 89 F.4th 1 at 29 *petition for cert. filed,* ____ U.S.L.W. ____ (U.S. March 13, 2024) (No. 23–1016) (cleaned up). *See also Flytenow, Inc.* v. *FAA,* 808 F.3d 882, 894 (D.C. Cir. 2015) (any ''incidental burden'' that regulatory requirements impose on speech ''does not violate the

[71] *See also Winter* v. *G.P. Putnam's Sons,* 938 F.2d 1033, 1035–36 (9th Cir. 1991) (citing numerous courts that have applied products liability law, without First Amendment scrutiny, to aeronautical charts that contain erroneous information, noting that: ''Aeronautical charts are highly technical tools. They are graphic depictions of technical, mechanical data. . . . The chart itself is like a physical 'product.'. . . . [not] pure thought and expression.'').

[72] In contrast, if a laboratory offers a test on its website for an unauthorized use, FDA would likely consider that offer to be evidence of a new intended use.

First Amendment'' where the requirements ''further an important government interest unrelated to the suppression of free expression,'' such as promoting safety). As explained above, premarket review helps assure medical products are safe and effective—which is a substantial government interest unrelated to the suppression of free expression.

And it is ''constitutionally permissible'' to rely on speech to ''infer intent,'' including where that intent establishes that the product is within a category that is subject to and violative of FDA premarket review requirements. *Whitaker* v. *Thompson,* 353 F.3d 947, 953 (D.C. Cir. 2004). For example, charcoal products intended for emergency treatment of poisoning by ingestion are drugs regulated by FDA, but charcoal sold as fuel is not within FDA's jurisdiction. The product's intended use, which may be determined from the product's labeling, establishes whether the product is within FDA's jurisdiction (see Ref. 17). The First Circuit recently observed that ''courts to consider the issue have uniformly concluded that using speech merely as evidence of a misbranding offense under the [FD&C Act] does not raise First Amendment concerns.'' *United States* v. *Facteau,* 89 F.4th 1 at 25, *petition for cert. filed,* ____ U.S.L.W. ____ (U.S. March 13, 2024) (No. 23–1016). *See, e.g.,* Nicopure Labs, 944 F.3d 267 at 282 (''FDA's reliance on a seller's claims about a product as evidence of that product's intended use, in order that the FDA may correctly classify the product and restrict it if misclassified, does not burden the seller's speech''); *United States* v. *LeBeau,* 2016 U.S. Dist. LEXIS 13612, *27 (E.D. Wisc. February 3, 2016) (''A product's labeling can be used to infer the seller's intended use and whether the product is an unapproved drug under the FDCA.''), aff'd, 2016 U.S. App. LEXIS 12375 (7th Cir. 2016); *United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166 (D. Or. 2015); *United States* v. *Livdahl,* 459 F. Supp. 2d 1255 (S.D. Fla. 2005); *United States* v. *Lane Labs-USA, Inc.,* 324 F. Supp. 2d 547 (D.N.J. 2004); *U.S.* v. *Undetermined Quantities of Articles of Drug,* 145 F. Supp. 2d 692 at 703 (D. Md. 2001). *See also Flytenow, Inc.* v. *FAA,* 808 F.3d at 894 (the ''evidentiary use of speech'' is ''well settled'').[73]

Nor does FDA's determination to exercise enforcement discretion with respect to premarket review in certain specific contexts (see discussion in section V.B) restrict or burden speech. As the First Circuit recently explained in rejecting a First Amendment challenge to an FDA final guidance describing an enforcement discretion policy, the enforcement policy does not ''burden[ ] what [medical product] manufacturers may say,'' but instead ''expands, rather than contracts, the domain of speech that the government shields from being used as evidence'' of intended use. Facteau, 89 F.4th at 28, *petition for cert. filed,* ____ U.S.L.W. ____ (U.S. March 13, 2024) (No. 23–1016). The court held that ''a policy that limits the consideration of [certain] speech as evidence of intended use does not raise First Amendment concerns.'' Id. at 25. The D.C. Circuit similarly held, regarding an earlier iteration of the enforcement policy, that a policy that provides a ''safe harbor'' from the use of certain speech as evidence of intended use did not establish ''independent authority to regulate manufacturer speech'' and therefore was not subject to First Amendment scrutiny. *Washington Legal Found.* v. *Henney,* 202 F.3d 331, 336 (D.C. Cir. 2000).

Moreover, to be protected under the First Amendment, commercial speech must ''concern lawful activity.'' *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557, 566 (1980). Where Congress requires FDA premarket review of a product, making the LDTs available for use or sale without such review ''renders the sale-as-labeled unlawful.'' *Nicopure Labs.* v. *FDA,* 944 F.3d 267, 284 (D.C. Cir. 2019). The speech proposing an illegal sale of such a product is ''related to illegal activity'' and therefore is ''not subject to constitutional protection.'' Id.; *accord United States* v. *LeBeau,* 654 Fed. App'x 826, 831 (7th Cir. 2016) (''Because [defendant]'s statements promoted the unlawful sale of an unapproved drug, they were not entitled to protection.''); *United States* v. *Caputo,* 517 F.3d 935, 940–41 (7th Cir. 2008) (the unapproved device ''could not lawfully be sold at all'' and therefore ''[t]here was no lawful activity for speech to promote''); *United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166–67 (D. Or. 2015) (''[d]efendants' speech concerns an illegal activity—the introduction into interstate commerce of unapproved new drugs[,] . . . the First Amendment is not violated.'').

And commercial speech is protected under the First Amendment only to the extent that it is ''not . . . misleading.'' *Central Hudson,* 447 U.S. 557 at 566. The labeling and advertising for unapproved medical products may be considered misleading where the labeling or advertising ''claim [the product] to be safe and effective without any scientific support.'' *United States* v. *Undetermined Quantities of Articles of Drug,* 145 F. Supp. 2d 692, 703. In such instances, the labeling and advertising is ''entitled to no First Amendment protections.'' Id.

Even if the premarket review and related requirements for devices were subject to First Amendment scrutiny, they would easily pass muster under *Central Hudson* and even more exacting levels of scrutiny. Under the *Central Hudson* framework, if the speech is truthful, not inherently or actually misleading, and relates to lawful activity, the government may impose restrictions that advance a ''substantial'' government interest and are no ''more extensive than is necessary to serve that interest.'' *Central Hudson,* 447 U.S. 557 at 566. As FDA has explained elsewhere, premarket review and related requirements for medical products advance several substantial government interests including motivating the development of robust scientific data on safety and efficacy; maintaining the premarket review process for safety and efficacy to prevent harm, protect against fraud, misrepresentation, and bias, and to prevent the diversion of healthcare resources toward ineffective treatments; and ensuring required labeling is accurate and informative. *See* January 2017 Memorandum at 3; *see also* id. at 4–11 (Ref. 17); Nicopure Labs, 944 F.3d 267 at 285 (premarket and labeling requirements ''directly advance[ ] the government's interest in accuracy and public health''). These interests apply to LDTs: as explained above, premarket review and related requirements help assure the safety and effectiveness of IVDs offered as LDTs.

These premarket review and related requirements are appropriately tailored to achieve these goals. To the extent that premarket review requirements relate to speech at all, they implicate speech only by firms responsible for the product's development and/or distribution—the parties best able to conduct the research and gather information necessary for premarket review and otherwise take steps necessary to assure that the

[73] Although the Second Circuit stated in *United States* v. *Caronia,* 703 F.3d 149, 169 (2d Cir. 2012) that ''the government cannot prosecute pharmaceutical manufacturers and their representatives under the [FD&C Act] for speech promoting the lawful, off-label use of an FDA-approved drug,'' the Second Circuit later confirmed that ''*Caronia* left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA approved label.'' *United States ex rel. Polansky* v. *Pfizer, Inc.,* 822 F.3d 613 n.2 (2d Cir. 2016). The First Circuit likewise found that *Caronia* provides ''no basis to depart from the rule . . . that the evidentiary use of speech does not violate the First Amendment.'' *Facteau,* 89 F.4th at 24, *petition for cert. filed,* ____ U.S.L.W. ____ (U.S. March 13, 2024) (No. 23–1016).

medical product is safe and effective (see Ref. 17 at 24–25). In this way, these requirements are similar to other Federal regulatory programs that are directed to particular regulated industry and the products those companies produce. Moreover, these requirements do not operate to ban speech but rather to establish a process for evaluating medical products that fosters truthful, non-misleading, and appropriately substantiated speech. *See* Nicopure Labs, 944 F.3d 267 at 289 (products subject to premarket review are ''not excluded from the marketplace of information, only evaluated first to prevent them from misleading consumers''); Ref. 160 (''Commercial speech serves an 'informational function' and can be regulated to ensure that the public has access to accurate information. The FDA serves exactly this end. The agency aims not to censor company speech, but to foster the development of accurate and reliable information, and channel that information into settings where it can be rigorously evaluated.'').

The Agency has also considered a variety of alternative approaches and has determined that they would not optimally advance the government interests described above. One alternative would be to continue to exercise enforcement discretion in perpetuity regarding premarket review requirements for IVDs offered as LDTs and instead rely on postmarket remedies, such as enforcement actions for LDTs shown to be unsafe. However, FDA has carefully tailored this final rule to balance competing interests important to the protection of the public health and determined to exercise enforcement discretion with respect to premarket review in certain specific contexts (see discussion in section V.B); FDA has determined that, in other contexts, exclusive reliance on post-market remedies would not be in the best interest of public health because it does not provide a reasonable assurance of safety and effectiveness prior to the introduction of an IVD to the market.

One comment suggested, as an alternative approach to premarket review, that LDT regulation should ''replicate CLIA's reliance on private ordering solutions (*e.g.,* private accreditation) and rely on postmarketing assessment (rather than premarket review) of LDT safety and effectiveness.'' Another alternative would be to enforce premarket review requirements only for the highest risk LDTs. Yet another alternative would be for FDA to continue to exercise enforcement discretion for IVDs offered as LDTs but have unauthorized LDTs disclose that they are not FDA-reviewed. All of these potential alternatives, like FDA's continuing to exercise enforcement discretion in perpetuity, would fall short in achieving FDA's public health objectives: by forgoing most or all premarket review except in the limited circumstances covered by the enforcement discretion policies described in section V.B of this preamble (or other enforcement discretion policies that FDA may adopt), these approaches would not sufficiently address the safety and effectiveness concerns that have led to the issuance of this rule.

More specifically, the steps suggested by the comment—replicating CLIA's reliance on private ordering solutions and relying on postmarketing assessments—would be inadequate substitutes for premarket review. Among other things, CLIA inspections are conducted biennially, so that, if a laboratory has not developed a safe and effective test, it could be giving false or invalid results to healthcare providers or patients for up to 2 years before the laboratory's CLIA inspection. Also, CLIA inspectors typically pick a sample of tests for detailed review. Therefore, an LDT from a laboratory test manufacturer that has added multiple new tests since its last inspection may not have any review of the underlying documentation for that test. For additional discussion of why CLIA does not provide sufficient assurances of safety and effectiveness for IVDs offered as LDTs, see our responses to comments in section VI.C.2 of this preamble.

Now we turn to the remaining arguments made in the comments. As noted, one comment suggested that the rule would impermissibly interfere with physicians' right to receive information as part of their professional speech. As discussed above, however, this comment failed to acknowledge that premarket review relates to a scientific evaluation of the accuracy and reliability of the test results, which is the function of the device; FDA does not intend to consider professional advice regarding a patient's results as evidence of a new intended use. In addition, framing the issue from the perspective of the healthcare practitioner receiving information, as opposed to the perspective of the speaker, does not change the First Amendment analysis. For example, the origin of the commercial speech doctrine was based largely on the interests of consumers in receiving information. *See Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council,* 425 U.S. 748, 757 (1976). Accordingly, focusing on the interests of the listener, as opposed to the interests of the speaker, does not render the *Central Hudson* analysis inapplicable in evaluating the constitutionality of premarket review.

It also makes no difference whether the recipient of the information is a healthcare practitioner or a patient. Congress enacted the FD&C Act to cover medical products directed to both healthcare practitioners and patients. For example, FDA regulates the labeling of medical products to help assure that they are used safely and effectively, whether the labeling is directed to healthcare practitioners or patients. And the government interest in providing a reasonable assurance of safety and effectiveness of devices applies no matter who is the audience for the information.

Contrary to one comment's suggestion, the Supreme Court's opinion in *NIFLA* is inapposite. On the topic of professional speech, that decision merely held that ''neither California nor the Ninth Circuit has identified a persuasive reason for treating professional speech as a unique category that is exempt from ordinary First Amendment principles'' but the Court did not ''foreclose the possibility that some such reason exists.'' *NIFLA,* 138 S. Ct. 2361 at 2375. In any event, our analysis does not rely on treating professional speech as a unique category that is exempt from ordinary First Amendment principles.

We also disagree with the comments' assertions that strict scrutiny should apply because the speech regarding test results is not itself commercial. As discussed above, these devices produce scientifically-generated informational outputs as their function; they do not convey the type of speech that might justify heightened scrutiny. Moreover, courts do not apply the concept of commercial speech so narrowly: information disclosed ''in connection with a proposed commercial transaction'' constitutes commercial speech, even where the relevant speech itself does not propose a commercial transaction. *See N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 131 (2d Cir. 2009) (a requirement to post calorie content information on menus ''is clearly commercial speech''). More specifically, courts have held that FDA's premarket review requirements are subject to review under the commercial speech doctrine rather than strict scrutiny, even where the manufacturer's speech involves matters of science. *See Discount Tobacco* v. *United States,* 674 F.3d 509, 532–33 (6th Cir. 2012) (*Central Hudson* was the appropriate test for premarket review of tobacco harm reduction claims where the claims

were ''consumer-directed'' and ''regarding a manufacturer's specific products''); *Washington Legal Foundation* v. *Friedman,* 13 F. Supp. 2d 51, 62–65 (D.D.C. 1998) (finding manufacturers' dissemination of scientific information about their products to health practitioners to be commercial speech), vacated in part on other grounds, 202 F.3d 331 (D.C. Cir. 2000). Nevertheless, even if this rule were subject to First Amendment scrutiny (which, as explained above, it is not) and even if strict scrutiny were then applied, that test would be satisfied here because the government has a compelling interest in protecting the public health, and premarket review is narrowly tailored to achieve that result, for the reasons explained above.

Finally, we are not aware of any authority to support the flipped-burden-of-proof theory regarding premarket review. Congress established the premarket review requirements under the FD&C Act, which places the burden on the manufacturer to establish the safety and effectiveness of medical products. To the extent a stakeholder challenges those requirements under the First Amendment, it is the government's burden to establish that the requirements are constitutionally permissible. That is, the government bears the burden on the *Central Hudson* analysis or other applicable First Amendment doctrine of making the required showing, *e.g.,* that the premarket review requirement directly advances a substantial government interest. But there is no First Amendment principle that would result in a court or an agency rewriting the premarket review provisions of the FD&C Act to require FDA to prove that an individual LDT is unsafe.

In sum, FDA's premarket review and related requirements for medical devices do not violate the First Amendment, and the action FDA is taking today to clarify their application to LDTs does not raise any constitutional concerns.

(Comment 94) One comment suggested that the rule might raise concerns under Equal Protection principles on the ground that the rule unduly favors large entities over smaller ones without a rational basis for the distinction. The comment similarly suggested the rule may have antitrust implications by disproportionately affecting smaller laboratories to the benefit of larger entities because the costs of entry or operation will be too high for the small laboratories to compete.

(Response 94) The rule does not raise either Equal Protection or antitrust concerns. Under Equal Protection jurisprudence, the government has ''considerable leeway'' to issue rules that ''may appear to affect similarly situated people differently.'' *Clements* v. *Fashing,* 457 U.S. 957, 962–963 (1982). The case law refers to such an effect as a ''classification.'' Where the classification involves a suspect class, such as race or nationality, or infringes on a fundamental right, the law will be subject to heightened scrutiny. *Massachusetts Bd. of Retirement* v. *Murgia,* 427 U.S. 307, 312 (1976). In the absence of those circumstances, a law containing a classification is ''accorded a strong presumption of validity,'' *Heller* v. *Doe,* 509 U.S. 312, 319 (1993), and will be upheld if it ''bears some fair relationship to a legitimate public purpose.'' *Plyler* v. *Doe,* 457 U.S. 202, 216 (1982).

We disagree with the comment's suggestion that this rule involves a classification. Neither the underlying provisions of the FD&C Act, nor the gradual phaseout of FDA's general enforcement discretion approach, treats smaller entities differently from larger ones. Thus, Equal Protection principles have no application here.

But even assuming that the rule involved a classification in the form of a different effect on smaller entities, the rule would be subject to rational basis review. The comment did not claim that this rule involves any suspect classification or fundamental right. Although the comment stated that certain diseases are more prevalent in certain ''ethnic groups,'' and the rule must be implemented in a non-discriminatory manner to the extent it may affect IVDs offered as LDTs that are intended for those diseases, the comment does not explain how these facts would support a suspect classification theory. Even if the rule were to have a disproportionate impact, a disproportionate impact, by itself, does not trigger strict scrutiny under Equal Protection principles. *Washington* v. *Davis,* 426 U.S. 229, 242 (1976).

Accordingly, even if the rule involved a classification (which it does not), the rule would be subject to rational basis review, which the rule would easily satisfy. FDA rationally concluded that the phaseout policy will help to ensure the safety and effectiveness of IVDs offered as LDTs and more accurate diagnoses, which will lead to better care and advance public health overall. The rule therefore is rationally related to a legitimate purpose.

FDA also disagrees that the rule raises antitrust concerns. Antitrust law is directed toward preserving free and unfettered competition by curtailing anti-competitive conduct by private entities, such as precluding private arrangements among companies that unreasonably restrain competition. *See, e.g., Northern Pac. Ry. Co.* v. *United States,* 356 U.S. 1, 4–5 (1958). Antitrust law does not concern and does not curtail the Federal government's oversight in the interest of protecting and promoting the public health.

(Comment 95) One comment asserted that the LDT rule would constitute a ''taking'' under the Fifth Amendment to the U.S. Constitution because it would disadvantage smaller, more specialized laboratories to the benefit of larger laboratories and AMCs. The comment contended that this would be a regulatory taking in that it would significantly diminish the value of property without a valid public purpose.

(Response 95) We disagree that the rule would constitute a taking. The Fifth Amendment to the U.S. Constitution prohibits the Government from taking private property for public use without just compensation. The Supreme Court has held that the Government effects a ''per se'' taking when it physically appropriates property, which is the ''clearest sort of taking.'' *Cedar Point Nursery* v. *Hassid,* 141 S. Ct. 2063, 2071 (2021). The Court has also recognized that there may be a regulatory taking where regulations that ''restrict an owner's ability to use his own property'' go ''too far.'' Id. at 2071–72. In such cases, a taking may be found based ''on a complex of factors, including: (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action.'' *Murr* v. *Wisconsin,* 582 U.S. 383, 393 (2017) (cleaned up) (referred to as the ''Penn Central factors'' after *Penn Central Transp. Co.* v. *New York City,* 438 U.S. 104, 124 (1978)). The force of any one of these three Penn Central factors may be ''so overwhelming . . . that it disposes of the taking question.'' *Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1005.

As the phaseout of the general enforcement discretion approach is implemented, laboratories that manufacture IVDs offered as LDTs generally will be expected to comply with several pre- and post-market submission and reporting requirements applicable to devices for humans, including premarket notification/PMA requirements (as applicable), registration and listing, labeling requirements, reporting requirements regarding adverse events and corrections and removals, QS

requirements, and certain IDE regulations. To our knowledge, the FD&C Act's premarket review and related requirements have never been held to effectuate a taking of property. It has long been established that the government may regulate products in the interests of public health and safety and such regulation ''cannot, in any just sense, be deemed a taking.'' *Mugler* v. *Kansas,* 123 U.S. 623, 668 (1887). The takings doctrine is based on the concept that, when the government seizes property for the public benefit, such as land for a road or a dam, the public should compensate the owner. But that is a different scenario from where the government limits the use of property to protect public health and safety. *See* id. at 669. As the Supreme Court has elaborated, ''[l]ong ago it was recognized that all property in this country is held under the implied obligation that the owner's use of it shall not be injurious to the community, and the Takings Clause did not transform that principle to one that requires compensation whenever the State asserts its power to enforce it.'' *Keystone Bituminous Coal Ass'n* v. *DeBenedictis,* 480 U.S. 470, 491–92 (1987) (cleaned up). As a result, restrictions on ''uses of personal property'' that are ''directed at the protection of public health and safety'' are ''the type of regulation in which the private interest has traditionally been most confined and governments are given the greatest leeway to act without the need to compensate those affected by their actions.'' *Rose Acre Farms, Inc.* v. *United States,* 559 F.3d 1260, 1281 (Fed. Cir. 2009).

The phaseout of the general enforcement discretion approach for LDTs is intended to protect public health and safety and to prevent injuries to the community. FDA is taking this action to help ensure the safety and effectiveness of IVDs offered as LDTs and to achieve more accurate diagnoses, which will lead to better care and advance the public health overall. Accordingly, the character of the government's action here—to advance the public health—weighs heavily, if not conclusively, against finding that the phaseout effects a taking.

The other Penn Central factors also weigh in favor of finding no taking here. With regard to economic impact, the comment asserted that the value of the property of small laboratory manufacturers will be diminished. However, many changes in government laws, regulations, and policies have economic consequences, and the Supreme Court has long recognized that ''[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'' *Pennsylvania Coal Co.* v. *Mahon,* 260 U.S. 393, 413 (1922). The Supreme Court has explained that ''mere diminution in the value of property, however serious, is insufficient to demonstrate a taking.'' *Concrete Pipe & Prods.* v. *Constr. Laborers Pension Trust,* 508 U.S. 602, 645 (1993). Similarly, a ''loss of profit'' does not establish a taking. *74 Pinehurst LLC* v. *New York,* 59 F.4th 557, 566 (2d Cir. 2023). And courts have rejected regulatory takings claims even where the government's action ''impose considerable costs on private actors in the regulated industry.'' *Mobile Relay Assocs.* v. *FCC,* 457 F.3d 1, 12 (D.C. Cir. 2006). Instead, in evaluating the economic impact of a regulation, courts have explained that the ''touchstone'' is ''proportionality'': ''the size of a liability only weighs in favor of finding a taking insofar as it is out of proportion to the legitimate obligations society may impose on individual entities.'' *B&G Constr. Co.* v. *Dir., OWCP,* 662 F.3d 233, 260 (3d Cir. 2011) (cleaned up).

In enacting the FD&C Act, Congress determined that manufacturers of medical products should bear the costs of ensuring that their products are appropriately safe and effective, and these costs are proportional to the resulting benefits of FDA oversight to the public health. Furthermore, as discussed elsewhere in this preamble, FDA has taken several steps to address the economic impact of the final phaseout policy—for example, by including certain enforcement discretion policies in the final phaseout policy (see section V.B of this preamble). Accordingly, the phaseout policy does not place disproportionate costs on laboratory manufacturers.

With respect to the last Penn Central factor, a ''reasonable investment-backed expectation must be more than a unilateral expectation or an abstract need.'' *Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986 at 1005 (cleaned up). Courts have held that those who do business in highly regulated fields are on notice that changes are possible. *Connolly* v. *Pension Ben. Guar. Corp.,* 475 U.S. 211, 226–27 (1986) (''Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end'') (cleaned up).

Laboratory manufacturers have been on notice for some time that their tests could be subject to increased oversight. As a legal matter, FDA has long taken the position that LDTs are devices subject to regulation under the FD&C Act, over which it was exercising enforcement discretion. Moreover, laboratory manufacturers have been on notice that their tests could be subject to increased oversight at various times—*e.g.,* after issuance of the preamble to the ASR rule nearly 30 years ago, stating that ''FDA believes that clinical laboratories that develop [in-house] tests are acting as manufacturers of medical devices and are subject to FDA jurisdiction under the act'' (62 FR at 62249), and after two draft guidance documents were issued by FDA on October 3, 2014, entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' (79 FR 59776) and ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)'' (79 FR 59779) (Refs. 38 and 112). Accordingly, laboratory manufacturers did not have reasonable investment-backed expectations that they would not ever be subject to FDA oversight.

Accordingly, application of the Penn Central factors confirms that FDA's phaseout of the general enforcement discretion approach for LDTs will not effect a taking.

(Comment 96) Various comments requested, or stated that FDA should have granted,[74] an extension of the 60-day comment period. Most of these comments requested a 60-day or longer extension. The comments argued for an extension given the following: (1) the complex and multifaceted nature of the proposed rule, which required review by experts in various fields; (2) the significant implications that the final rule will have on stakeholders; (3) the numerous legal issues raised by the rule; (4) differences in FDA's proposal compared to its previous proposals (*e.g.,* with respect to tests currently on the market and the timeline for premarket review expectations); (5) a longer comment period would be in line with Agency precedent (*e.g.,* the comment period for the 2014 draft LDT guidance documents was 120 days, and other FDA rulemakings ''with more modest impact'' had longer than 60-day comment periods); (6) the length of time that FDA has been working on the proposed rule (at least 7 months, according to one comment); and/or (7)

[74] FDA received 14 requests for extensions soon after publication of the NPRM. For those requests, FDA responded directly to the requesters (and submitted a sample of such a response to the docket, see *e.g.* Ref. 161) and posted an update to its website stating that ''[a]fter considering the [request/requests] and other factors, including the extensive background of public comment on this topic and the public health benefits of proceeding expeditiously, the FDA has determined to proceed with the standard 60-day comment period'' (Ref. 113).

the comment period spanned the Thanksgiving holiday season. Various comments described what they would do with additional time, which included surveying small businesses and investors to better understand the implications of the costs of the rule; estimating added costs to the U.S. healthcare system from the loss of competition resulting from the rule; and assessing the harm to patients resulting from small entities exiting the market and/or reducing operations. Several comments stated that FDA's denial of requests for extensions raised concerns about the thoroughness of stakeholder engagement and noted that the denials were based on FDA's ''manufactured sense of urgency.''

(Response 96) After reviewing the public comments and the requests for additional time for comment, FDA does not believe that extending or reopening the comment period is necessary for the public to receive a meaningful opportunity to comment on the NPRM. Consequently, and in light of the public health benefits of proceeding expeditiously, FDA is again declining to extend the comment period.

Under the APA, agencies are required to provide interested persons an opportunity to participate in the rulemaking through submission of comments. 5 U.S.C. 553(c). Although the APA does not delineate a minimum number of days that a comment period must run, courts have said that the length of a comment period must provide a meaningful opportunity to comment. See *Rural Cellular Ass'n* v. *FCC,* 588 F.3d 1095, 1101 (D.C. Cir. 2009). And while some courts have found comment periods of less than 30 days to be appropriate, various courts have observed that 30 days is generally the shortest time period for interested persons to meaningfully review a proposed rule and provide informed comment. *See, e.g., Nat'l Lifeline Ass'n* v. *FCC,* 921 F.3d 1102, 1117 (D.C. Cir. 2019). FDA's own regulations require that the Agency generally provide 60 days for comment on proposed regulations, see 21 CFR 10.40(b)(2), and E.O. 12866 generally recommends a comment period of at least 60 days for most rulemaking, see E.O. 12866, sec. 6(a), 58 FR 51735, October 4, 1993.

The Supreme Court has stated that the APA ''sets forth the full extent of judicial authority to review executive agency action for procedural correctness.'' *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 513 (2009). Moreover, the Court has emphasized that beyond the APA's minimum requirements, courts lack authority ''to impose upon [an] agency its own notion of which procedures are 'best' or most likely to further some vague, undefined public good.'' *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 549 (1973). Under this rubric, many courts have refused to find an APA violation where an agency provides a 60-day (or even shorter) comment period and otherwise provides a meaningful opportunity to comment. *See Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania,* 140 S. Ct. 2367, 2386 (2020) (''The Departments complied with each of these statutory procedures. They 'request[ed] and encourag[ed] public comments on all matters addressed' in the rules. . . . They also gave interested parties 60 days to submit comments.'') (internal citations omitted); see also *Chamber of Com. of United States* v. *United States Sec. & Exch. Comm'n,* 85 F.4th 760, 779–80 (5th Cir. 2023) (''We cannot conclude that the initial [45-day] comment period was so short as to deprive petitioners of a meaningful opportunity to comment on the proposed rulemaking. Petitioners may have hoped for more time, but it is not for us to decide whether an agency has chosen a maximally net beneficial comment period.'').

FDA has determined that the 60-day comment period for the NPRM allowed sufficient time for a meaningful opportunity to comment. There was ample time for the submission of more than 6,500 comments. A variety of entities submitted comments, including medical device associations, industry, medical and healthcare professional associations, other advocacy organizations, government agencies, and individuals, and they offered a broad array of perspectives on FDA's proposal. In addition, FDA has determined that an extension would not be appropriate in light of the public health benefits of proceeding expeditiously in finalizing this rulemaking.

We note that many of the complex policy and legal issues have been discussed by FDA and stakeholders for over a decade.[75] In addition, after publication of the NPRM, FDA worked to ensure that stakeholders fully understood the proposal, including by hosting a webinar (see Ref. 162). The webinar addressed, among other things, the various differences in FDA's proposal compared to its previous proposals.

We are not persuaded by the other arguments made in the comments. For example, we do not believe it would be appropriate to extend the comment period for this NPRM to align it with the comment period of other FDA proposed rules or the 2014 LDT draft guidance documents. The appropriate length for a comment period is not a one-size-fits-all analysis but rather depends on many relevant factors, which were all considered in choosing a 60-day comment period for this NPRM and considering extension requests. In addition, we disagree that the length of time that FDA spent developing, drafting, and publishing the NPRM suggests that a meaningful opportunity to comment was not provided to interested persons or that an extension is appropriate based on that timing. Finally, as noted above, one comment argued for an extension because the comment period was over Thanksgiving, and also because various small laboratories would be preparing during the 60-day comment period for a January conference. Although the 60-day comment period covered Thanksgiving, it ended on December 4, 2023, and a 30- or 60-day extension would have extended the comment period through the December/January holiday season. Moreover, although certain small laboratories impacted by this rulemaking may have participated in a January conference, we do not believe that an extension to accommodate such a commitment would have been appropriate in light of the public health benefits of proceeding expeditiously in finalizing this rulemaking.

[75] As discussed in the NPRM (88 FR 68006 at 68016) and elsewhere in this preamble, the Agency held a 2-day public meeting and opened a docket for public comment in 2010 regarding FDA's plans to develop a broad approach to the oversight of LDTs (75 FR 34463, June 17, 2010). Input received through those proceedings informed two draft guidance documents issued by FDA on October 3, 2014, entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' (79 FR 59776) and ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)'' (79 FR 59779). FDA solicited public feedback on the draft guidance documents and held a public workshop on January 8 and 9, 2015 (79 FR 69860, November 24, 2014). From October 2014 through 2016, FDA analyzed more than 300 sets of comments on the draft guidance documents, as well as discussion from the public workshop, and engaged extensively with stakeholders in meetings and conferences. A number of interested parties provided feedback, including laboratories, healthcare providers, patients, conventional IVD manufacturers, government agencies, and members of Congress. The feedback ranged generally from strong opposition to strong support for FDA's proposed increased oversight of LDTs and addressed a wide range of topics, including FDA's authority to regulate LDTs, the risks posed by LDTs without increased FDA enforcement, the effect of a new enforcement approach on test access and innovation, the potential interplay between FDA regulation and CLIA, and the implications of increased FDA oversight for competition in the IVD market. FDA also has received and responded to multiple citizen petitions raising some of the same policy and legal issues raised in this rulemaking. *See* Refs. 114–115.

(Comment 97) One comment stated that a 180-day extension of the comment period was appropriate (and preferred a 9 to 12-month extension), noting that such a request aligns with the **Federal Register**'s Guide to the Rulemaking Process.

(Response 97) For the reasons set forth in response to comment 96, after reviewing the public comments and the requests for additional time for comment, FDA does not believe that extending the comment period is necessary for the public to receive a meaningful opportunity to comment on the NPRM. Consequently, and in light of the public health benefits of proceeding expeditiously, FDA is again declining to extend the comment period.

Notably, in its Guide to the Rulemaking Process, the **Federal Register** acknowledges that comment periods on proposed rules typically range from 30 to 60 days: ''[i]n general, agencies will specify a comment period ranging from 30 to 60 days in the 'Dates' section of the **Federal Register** document, but the time period can vary'' (Ref. 163). Although the **Federal Register** states that for complex rulings, agencies may provide for longer periods, such as 180 days or more, see id., the **Federal Register** is clear that this is not a requirement.

(Comment 98) Several comments emphasized that a 60-day comment period was insufficient specifically for practitioners, who are directly impacted by the rule. These comments noted that practitioners are busy taking care of patients, some were uncertain regarding the details of the proposed rule, and many were not aware of the proposed rule when it issued.

(Response 98) For the reasons discussed in response to comment 96, FDA disagrees that the 60-day comment period was insufficient. Moreover, we note that to help ensure stakeholders understood the proposal, FDA held a webinar on October 31, 2023, providing information on and answering questions about the NPRM (see Ref. 162). In addition, although certain individual practitioners may not have been aware of the proposal after it was issued, FDA received numerous lengthy and substantive comments from practitioners, trade groups, and other organizations representing practitioners, and those comments have helped to shape the final phaseout policy.

(Comment 99) One comment urged FDA to hold a public meeting (not less than 60 days before the comment deadline) to educate laboratories on the specifics of the ''regulatory requirements FDA plans to impose,'' among other things.

(Response 99) To help stakeholders understand and comment on the NPRM, FDA held a webinar on October 31, 2023, to provide stakeholders with information on and answer questions about the NPRM (see Ref. 162). The presentation, printable slides, and transcript from the Webinar have been available on FDA's website since that date (see Ref. 72).

(Comment 100) One comment stated that the initial categorization of the proposed rule as not ''Section 3(f)(1) significant'' was inconsistent with E.O. 12866 and the Office of Information and Regulatory Affairs' (OIRA's) April 6, 2023 memorandum regarding implementation of that E.O. because the proposed rule impacts the three listed categories of significant regulatory actions and exceeds the threshold for economic significance. The comment noted that although the proposed rule was later re-assigned a categorization of ''Section 3(f)(1) significant,'' the original categorization demonstrates ''a lack of consideration of all relevant factors by the FDA'' and ''portrays a lack of partnership in helping to identify and establish a regulatory framework that could work for the industry being regulated.''

(Response 100) The proposed rule was originally categorized as ''Other significant'' in the Spring 2023 Unified Agenda—*i.e.,* as significant under a provision of E.O. 12866 other than section 3(f)(1)—and then categorized as ''Section 3(f)(1) significant'' in all subsequent Unified Agendas. For the Spring 2023 Unified Agenda, the exact proposal was still under development and it was not clear whether the proposed rule would be ''Section 3(f)(1) significant.'' As such, FDA categorized it as ''Other significant.'' As discussed in section VIII, OIRA has determined that the final rule is a significant regulatory action under E.O. 12866 section 3(f)(1). In any event, the comment does not explain, and it is otherwise unclear to FDA, how this initial categorization demonstrates a lack of consideration by FDA of ''relevant factors'' or a ''lack of partnership'' with industry to establish an appropriate policy.

(Comment 101) One comment stated that FDA failed to conduct the required federalism analysis under E.O. 13132 and the Agency erroneously stated in the NPRM that ''this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.'' [76] The comment stated that because the proposed rule has such effects, and would preempt state law under section 521 of the FD&C Act (21 U.S.C. 360k), FDA must comply with all of the requirements of sections 6(c) [77] and 8(a) [78] of E.O. 13132. Another comment stated that the conclusions in the proposed rule regarding federalism ''do not reflect the impact on practice of medicine'' given that the proposed rule conflicts with certain state medical practice acts as well as NYS CLEP that currently permits the review, approval, and use of LDTs.

(Response 101) Although E.O. 13132 contains principles that apply broadly to ''policies that have federalism implications,'' which means ''regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government,'' a federalism summary impact statement is required for a ''regulation'' that has federalism implications and that meets certain additional criteria. Because the requirement for a federalism summary impact statement applies specifically to ''regulation'' and not to policy, the requirement for a federalism summary impact statement applies to the proposed amendment to § 809.3 and not to the proposed phaseout policy. And because the proposed amendment to § 809.3 would not establish any new requirements, it would not have any federalism implications under E.O. 13132 (see section XI).

Even if the requirement for a federalism summary impact statement were to apply to the phaseout policy, the policy does not have federalism implications because it is not establishing any new requirements. Rather, the phaseout policy is about increasing oversight of existing requirements under the FD&C Act and

[76] Another comment agreed with this comment to the extent FDA was asserting authority to regulate States and State-owned entities (*see* comment 106).

[77] Section 6(a) of E.O. 13132 states that ''[t]o the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation'' meets certain prescribed requirements.

[78] Section 8(a) of E.O. 13132 states that ''[i]n transmitting any draft final regulation that has federalism implications to the Office of Management and Budget pursuant to Executive Order 12866 of September 30, 1993, each agency shall include a certification from the official designated to ensure compliance with this order stating that the requirements of this order have been met in a meaningful and timely manner.''

FDA regulations. All laboratory manufacturers, including State-owned laboratories, have been legally subject to these requirements even though the Agency generally has not enforced them. As such, the enforcement policy is not changing their legal obligations.

Moreover, we note that E.O. 12866, section 11 makes clear that the order ''is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.''

For additional discussion regarding NYS CLEP, see sections V.B.2 and VI.F.5 of this preamble.

(Comment 102) Several comments stated that FDA has violated the MDA General Rule because the proposed rule is unduly burdensome and lacks flexibility.

(Response 102) The ''general rule'' provision for records and reports in the MDA states that: ''Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness,'' and that ''Regulations prescribed under the preceding sentence—(1) shall not impose requirements unduly burdensome to a device manufacturer, importer, or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act. . . .'' Section 2 of the MDA, Public Law 94–295 (1976), codified at section 519 of the FD&C Act. Section 519 has since been amended and this provision now appears at section 519(a) and (a)(4).

As an initial matter, the ''general rule'' provision referenced in the comment is not applicable to this rulemaking. FDA is not prescribing new regulations under section 519 of the FD&C Act regarding records and reports, but rather is amending § 809.3 and phasing out the general enforcement discretion approach for IVDs offered as LDTs.

In any event, FDA disagrees with the assertion that the proposed rule is overly burdensome and lacks flexibility such as might violate this provision. For additional discussion of FDA's adherence to least burdensome principles, see the response to comment 12.

(Comment 103) Several comments stated that FDA violated the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA) because it did not assess all regulatory options and select the least burdensome avenue in its proposal. Some of these comments asserted that the proposal shows no evidence of consideration of viable alternatives.

(Response 103) Under the UMRA, before issuing any rule for which a written statement is required under section 202 of the UMRA, agencies must ''identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule.'' *See* 2 U.S.C. 1535. Under section 202 of the UMRA, unless otherwise prohibited by law, a written statement containing certain prescribed information must be prepared before an agency issues any general notice of proposed rulemaking that ''is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.''

As an initial matter, the UMRA requirement referenced in the comment is not applicable to this rulemaking. This rulemaking is not likely to result in a final rule that includes any Federal mandate, as that term is defined in the UMRA (see 2 U.S.C. 658(6)), and so a written statement is not required under section 202 and the requirements at 2 U.S.C. 1535 do not apply.

Even if the requirements applied, however, FDA disagrees with the assertion that it did not assess all regulatory options and select the least burdensome avenue in its proposal such as might violate the UMRA. FDA identified and considered a reasonable number of regulatory alternatives and selected the most cost-effective or least burdensome alternative that achieves the objective of this rule, as required by the UMRA. Specifically, FDA considered five different regulatory alternatives, comparing the total costs, benefits, and transfers with one option that would be more stringent and three options that would be less stringent than the proposal. *See* section II.J of the PRIA (Ref. 60). FDA also sought comments on various additional policies and has considered those comments and made changes to the proposal based on some of the comments submitted.

(Comment 104) One comment stated that the NPRM fails to comply with a new provision of the APA, codified at 5 U.S.C. 553(b)(4), which requires that an NPRM include a website with a 100-word or less, plain language summary of the NPRM that is posted on *regulations.gov*.[79] The comment asserted that this failure undermines the ability of stakeholders—particularly smaller laboratories and their employees—to understand FDA's proposal and participate meaningfully in the public comment process. As such, the comment stated that FDA must publish a concise summary of its proposal, reissue the NPRM with the mandatory internet address included, and restart this proceeding with a new public comment period.

(Response 104) We disagree. FDA substantially complied with this new APA requirement by including an 89-word, plain-language summary of the NPRM on its website (see Ref. 115), which is included as Ref. 56 of the NPRM, posted on *regulations.gov*.[80] [81] That suffices, but even if it did not, any insufficiency would not have undermined the ability of stakeholders to understand FDA's proposal and participate meaningfully in the public comment process. During the comment period, a summary of the NPRM was included on FDA's LDT web page (see Ref. 134), a summary of the NPRM was included at the beginning of the NPRM, FDA's press release for the NPRM provided high-level information regarding the content of the NPRM (see Ref. 164), and FDA held a webinar after issuance of the NPRM to provide stakeholders with information on and

[79] On July 23, 2023, the ''Providing Accountability Through Transparency Act of 2023,'' Public Law 118–9, amended section 553(b) of the APA, adding the requirement that an NPRM include ''the internet address of a summary of not more than 100 words in length of the proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*).'' Section 553(b)(4) of the APA.

[80] Under the ''Increased FDA Oversight to Help Ensure Safety and Effectiveness of LDTs'' heading, which was posted the same day of publication of the NPRM, FDA included the following summary of the NPRM: ''On September 29, 2023, the FDA announced a proposed rule aimed at helping to ensure the safety and effectiveness of these tests. The proposed rule seeks to amend the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA is proposing a policy under which the FDA intends to provide greater oversight of LDTs through a phaseout of its general enforcement discretion approach for most LDTs.'' (Ref. 113).

[81] On March 11, 2024, a summary was added to the ''Docket Details'' of the LDT NPRM. See *https://www.regulations.gov*.

answer questions about the NPRM (see Ref. 162). In light of all of this, we disagree that stakeholders, particularly smaller laboratories and their employees, were deprived of a meaningful public comment process. In fact, the sheer number of comments submitted on the NPRM, including by small laboratories and their employees, contradicts such an assertion. Nor did any commenter identify any way in which the comments they submitted would have differed in any way had FDA published a 100-word summary on *https://www.regulations.gov.* For these reasons, FDA declines to reissue the comment period.

(Comment 105) Several comments stated that State-owned and academic institutions should not fall under the jurisdiction of FDA. One of these comments stated that FDA's regulation of State governmental entities is constrained by the text of the FD&C Act, which the comment stated does not treat states as ''persons'' subject to various significant medical device provisions of the FD&C Act (*e.g.,* registration requirements under section 510(c), premarket notification requirements under section 510(k), premarket approval requirements under section 515(c), and adverse event reporting requirements in part 803). The comment stated that these provisions regulate ''persons,'' not sovereign states, and that the Supreme Court's ''longstanding presumption'' against treating U.S. states as ''persons'' can be ''disregarded only upon some affirmative showing of statutory intent to the contrary.'' [82] The comment stated that the FD&C Act provides no affirmative showing of congressional intent for FDA to regulate laboratories owned by State agencies and State universities.

(Response 105) FDA disagrees. The comment does not include several key points that, when taken together, indicate that a state is properly understood as a ''person'' under the FD&C Act.

The comment relies on the Supreme Court's decision in *Vt. Agency for Nat. Res.* v. *U.S. ex rel. Stevens* to support the assertion that the term ''person'' does not encompass States. After its decision in Stevens, however, the Court made clear that ''qualification of a sovereign as a 'person' . . . depends not upon a bare analysis of the word 'person,' but on the legislative environment in which the word appears.'' *Inyo County* v. *Paiute-Shoshone Indians of the Bishop Cmty. of the Bishop Colony,* 538 U.S. 701, 711 (2003) (citations and internal quotations omitted); see also *Pfizer, Inc.* v. *Gov't of India,* 434 U.S. 308, 313 (1978) (''In light of the law's expansive remedial purpose, the Court has not taken a technical or semantic approach in determining who is a 'person' entitled to sue for treble damages. Instead, it has said that '[t]he purpose, the subject matter, the context, the legislative history, and the executive interpretation of the statute are aids to construction which may indicate' the proper scope of the law.'') (quoting *United States* v. *Cooper Corp.,* 312 U.S. 600, 605 (1941)).

There are two key features of the ''legislative environment'' of the FD&C Act that, taken together, make clear that the statute's reference to ''person'' encompasses States—a position long reflected in FDA's regulations. *See* § 814.3(h) (issued in 1986) (defining ''[p]erson'' to include, among other things, ''any . . . scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity''). First, the definition of ''person'' in the FD&C Act uses the term ''includes.'' 21 U.S.C. 321(e) (''[t]he term 'person' includes individual, partnership, corporation, and association''). It is a longstanding rule of statutory construction that, ''[i]n definitive provisions of statutes and other writings, 'include' is frequently, if not generally, used as a word of extension or enlargement rather than as one of limitation or enumeration.'' *Am. Sur. Co. of New York* v. *Marotta,* 287 U.S. 513, 517 (1933). Accordingly, in choosing to define ''person'' in the FD&C Act as ''includ[ing]'' individuals, partnerships, corporations, and associations, Congress indicated the term could be construed broadly to include entities in addition to the enumerated ones. This is particularly clear in light of the other definitions in section 201 of the FD&C Act, most of which use the term ''means'' (*i.e.,* ''The term X means. . . .''). If Congress had intended a limited meaning, it would have used the much more restrictive sentence structure that appears in all of the surrounding definitions and said: ''The term person *means* individuals, partnerships, corporations, and associations'' (emphasis added). Indeed, in *Vermont Agency of Natural Resources,* the Supreme Court acknowledged that very distinction in Stevens—definitions of person that used the term ''means,'' as in the example in that case, point to a different result from those that use the term ''includes.'' 529 U.S. 765, 786 n.17 (2000) (citing *California* v. *United States,* 320 U.S. 577, 585–86 (1944)).[83]

Second—and crucially—Congress demonstrated its understanding that the FD&C Act's reference to ''person'' includes government entities when it enacted provisions involving the payment of fees in connection with the submission of certain premarket review submissions to FDA. The FD&C Act requires that ''[e]ach person'' who submits several different types of premarket review submissions shall be subject to a fee. *See* 21 U.S.C. 379h(a)(1)(A), 379j(a)(2)(A), 379j–42(a)(1)(A), 379j–52(a)(1)(A). The FD&C Act then exempts ''State and Federal'' government entities from the payment of fees for submissions relating to products that will not be distributed commercially. *See* 21 U.S.C. 379g(1), 379j(a)(2)(B), 379j–41(1)(b)(ii), 379j–51(4)(b)(iv). These exemptions would be superfluous if the term ''person'' already excluded governmental entities. In addition, under the terms of the statute, governmental entities are subject to fees for submissions related to products to be distributed commercially. *See, e.g.,* 21 U.S.C. 379j(a)(2)(B)(iii). These provisions, too, demonstrate that Congress intended their devices to be subject to premarket review under the FD&C Act.

(Comment 106) One comment cited a June 2020 memorandum from Robert Charrow (then-HHS General Counsel) to Stephen Hahn, MD (then-Commissioner of Food and Drugs) that said that the FDA likely had limited to no authority to regulate states and state-owned entities. The comment noted that FDA omitted any discussion of this potential, significant legal limitation in the proposed rule and regulatory impact analysis and did not comment on whether the current HHS General Counsel or FDA accepted or rejected the prior legal analysis. The comment noted that this limitation would have a profound impact on State-owned AMCs and other State-owned laboratory entities and stated that the issue should be subject to more significant administrative or judicial consideration prior to advancing any proposed rule.

(Response 106) FDA referenced the memorandum from the HHS Office of the General Counsel in the proposed rule, noting that it informed HHS' August 2020 posting of a statement on its website entitled ''Rescission of Guidances and Other Informal Issuances.'' 88 FR 68006 at 68016. FDA

[82] *See Vermont Agency of Natural Resources* v. *US ex rel Stevens,* 529 U.S. 765, 766 (2000).

[83] Similarly, in *Return Mail, Inc.* v. *USPS,* the Court invoked the presumption that a person does not include governmental entities where the statute did not define ''person.'' 139 S. Ct. 1853, 1861 (2019).

stated that in November 2021, based on new advice from the HHS Office of the General Counsel, HHS leadership determined that the August 2020 statement no longer represented the Department's policy or legal views. Id. As stated in the response to comment 105, FDA does not agree that it has limited to no authority to regulate States and State-owned entities, and we do not agree that additional consideration of this issue is necessary or appropriate prior to advancing this rulemaking.

(Comment 107) One comment stated that FDA has significant conflicts of interest associated with the rulemaking because the final rule will significantly increase the Agency's acquisition of fees and likely also its Federal appropriations, as increased oversight will require additional funding. The comment noted that FDA's relationships with manufacturers are also a conflict of interest as the final rule will primarily benefit test manufacturers from who FDA currently receives significant user fees. Finally, the comment noted that a rule that increases test manufacturers' market share in laboratory testing and which may result in increased submissions to the FDA from such manufacturers provides additional financial incentives to FDA.

(Response 107) We disagree. FDA frequently issues rules, like this final rule, that have significant implications on the number of applications and submissions (many of which have associated user fees) that it receives. The fact that a rule may result in increased submissions/applications (with associated user fees) does not mean that there are conflicts of interest at issue.

To the extent the comment is suggesting that the motivation behind the rulemaking is some type of financial gain, we also disagree. As FDA has noted in the NPRM and elsewhere in this preamble, we are issuing this rule to help ensure the safety and effectiveness of IVDs offered as LDTs and to achieve more accurate diagnoses, which will lead to better care and advance public health overall (88 FR 68006 at 68012). Although the final rule is expected to increase the number of applications and submissions FDA receives, the collection of those fees is not the driver behind this rulemaking. Finally, FDA does not control the amount of funds appropriated by Congress, so it is unclear how this rulemaking could be argued to be motivated by FDA's desire for an increase in appropriated funds.

(Comment 108) One comment stated that FDA provides no legal basis or justification for excluding certain tests from its definition of an LDT (*i.e.,* an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing). The comment also stated that FDA excludes certain tests from its definition that are specifically recognized under CLIA regulations. Another comment expressed concern about the definition, and specifically the lack of clarity regarding the meaning of ''clinical use'' and the process for assessing ''intent'' when applied to genomics.

(Response 108) As noted in the NPRM and in this preamble, FDA has generally considered an LDT to be an IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing (88 FR 68006 at 68009). Although FDA's general enforcement discretion approach has been focused on LDTs, FDA's phaseout policy has a broader scope. Specifically, FDA is applying the phaseout policy to IVDs that are manufactured and offered as LDTs by laboratories that are certified under CLIA and that meet the regulatory requirements under CLIA to perform high complexity testing, and used within such laboratories, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory. Whether a test falls within FDA's traditional understanding of an LDT therefore is inapposite for purposes of the phaseout policy. Moreover, for the enforcement discretion policies included in this rule that apply to certain types of ''LDTs,'' FDA has included its rationale for those policies and their scopes in section V.B.

(Comment 109) One comment stated that the final rule should explicitly state the legal authority supporting the regulation and should highlight the urgency of ''addressing LDT regulation given that it currently falls within a regulatory gap.''

(Response 109) FDA has included a discussion of the legal authority for the rule (see sections I.C and IV of this preamble) as well as a discussion of the need for the rule (section III.B of this preamble).

(Comment 110) One comment stated that this rule cannot become a binding regulation until it is subjected to the centralized regulatory review process, which consists of a benefit-cost analysis and Office of Management and Budget (OMB) review.

(Response 110) To the extent the comment is implying that this rulemaking did not include centralized regulatory review, it is incorrect. FDA has gone through that process. As part of that process, it has prepared preliminary and final regulatory impact analyses under EOs 12866, 13563, and 14094, as well as the Regulatory Flexibility Act and the Unfunded Mandates Reform Act. OIRA has reviewed those analyses and this rule.

Although this rule has been issued in accordance with the centralized regulatory review process described in E.O. 12866 and its amendments, FDA disagrees with the assertion that a rule would not be ''binding'' were it not subjected to all aspects of centralized regulatory review as specified by E.O. 12866. Legal requirements for rulemaking are set forth in the APA and related statutes, organic statutes such as the FD&C Act, and applicable regulations. Additionally, Section 10 of E.O. 12866 provides: ''This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law . . . . '' *See also Alliance for Natural Health U.S.* v. *Sebelius,* 775 F. Supp. 2d 114, 135 n.10 (D.D.C. 2011) (citing Section 10 in rejecting challenge to FDA regulation for alleged violation of E.O. 12866); E.O. 13563 section 7(f) (noting that the E.O. does not create any right or benefit enforceable at law or in equity); E.O. 14094 section 4(c) (same). E.O. 12866 thus does not establish legally enforceable requirements for rulemaking.

(Comment 111) One comment argued that, to phase out the general enforcement discretion approach for IVDs offered as LDTs, FDA would have to provide data ''to cross a predetermined threshold for action,'' and the data should be presented ''along with the minutes of meetings around it.''

(Response 111) There is no requirement—in the APA, FD&C Act, or otherwise—establishing a ''predetermined threshold'' for changing an enforcement discretion approach. As FDA explained in section III.B of this preamble as well as the NPRM, the LDT landscape has evolved significantly since the enactment of the MDA (88 FR 68006 at 68009), and several factors justify this rule, including, but not limited to, the increased complexity of IVDs offered as LDTs and their growing share of the testing market. The documents supporting FDA's findings, including sources such as peer-reviewed literature and FDA memoranda, were

published in the docket for this rulemaking.

(Comment 112) One comment expressed concern with FDA characterizing the proposed rule, if finalized, as not establishing any requirements. The comment stated that ''applying a panoply of regulations to an entirely new class that had not hitherto been regulated is, from the perspective of laboratories, imposing entirely new requirements.''

(Response 112) To the extent the commenter is suggesting that FDA is required to go through notice-and-comment rulemaking to phase out the general enforcement discretion approach for applicable requirements, we disagree. The phaseout policy does not impose any binding requirements on the Agency or LDT manufacturers, but rather describes how FDA intends to phase out the general enforcement discretion approach for existing requirements under the FD&C Act that apply to LDTs as devices. The phaseout policy described in the NPRM, and this preamble, is a general statement of policy and therefore, it is exempt from the rulemaking procedures of the APA. 5 U.S.C. 553(b)(3)(A). Moreover, the phaseout policy is an enforcement policy, and the FD&C Act's enforcement provisions commit broad discretion to FDA to decide how and when they should be exercised. *See Heckler* v. *Chaney,* 470 U.S. 821, 835 (1985). In any event, such an argument is misplaced given that FDA is in fact engaging in notice-and-comment rulemaking here.

To the extent the comment is instead suggesting that FDA's characterization means that the Agency is underestimating the costs of the phaseout, we also disagree. The economic analyses in the proposed and final rules do not assume zero costs to laboratories because FDA is not changing any legal requirements. Rather, these analyses account for all of the costs associated with changes in FDA's enforcement approach.

(Comment 113) One comment stated that two sources—an overview of Federal law related to IVDs and clinical laboratories appearing in Clinical Chemistry, and a white paper written on behalf of ACLA—provide a good alternative to FDA's position.

(Response 113) It is not clear if this comment was saying that these sources provide an alternative policy FDA should consider, or if the comment was saying that these papers undermine FDA's legal position. In any event, to the extent those sources make significant arguments that have been advanced by other comments submitted to the docket for this rulemaking, those arguments have been addressed. In particular, the express purpose of the referenced journal article is ''to provide a legislative and regulatory history of IVDs to foster a foundational basis for future LDT discussions,'' and FDA addresses comments it received regarding the history of its statements on LDTs elsewhere in this preamble. The argument that LDTs are not devices and are therefore outside FDA's jurisdiction, which is advanced in the white paper written on behalf of ACLA, has likewise been addressed elsewhere in this preamble.

F. Phaseout Policy

1. General Comments on the Phaseout Policy

(Comment 114) Some comments stated that FDA's approach to phasing out the general enforcement discretion approach for LDTs is too broad and does not appropriately account for differences in the types of IVDs offered as LDTs. Some comments stated that FDA should utilize a risk-based approach in its oversight of IVDs offered as LDTs.

(Response 114) FDA does not agree with these comments. FDA has crafted a tailored phaseout policy intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance. Notably, the phaseout policy includes several new, targeted enforcement discretion policies, based in part on comments submitted on the NPRM regarding whether and how FDA should phase out the general enforcement discretion approach for more than a dozen specific types of tests (see section VI.L). FDA's reasons for adopting these policies are discussed further in section V.B. For other categories of IVDs, for the reasons discussed throughout this preamble, including responses to comments in sections L and F, FDA is not adopting enforcement discretion policies.

(Comment 115) Some comments suggested that FDA's phaseout of the general enforcement discretion approach should only apply to ''commercial'' manufacturers and for-profit laboratories, and that FDA should establish a separate framework for oversight of LDTs that are offered in laboratories that work closely with treating physicians and are directly integrated into patient care. One comment suggested that FDA continue its enforcement discretion approach for tests that are designed and overseen by physicians and laboratories for the care of their patients in consultation with their clinical providers.

(Response 115) FDA disagrees that the Agency should phase out the general enforcement discretion approach only for conventional manufacturers and for-profit laboratories. The need for greater FDA oversight to better assure the safety and effectiveness of IVDs offered as LDTs applies to IVDs offered as LDTs by non-profit laboratories as well as other types of laboratories.

Regarding the comments about LDTs manufactured by laboratories that work closely with treating physicians or that are directly integrated into patient care, we note that FDA is adopting an enforcement discretion policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. As discussed in section V.B.3, FDA has determined that an enforcement discretion policy for premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for such LDTs is appropriate given the likelihood that laboratories would stop manufacturing unmet need LDTs under the proposed phaseout policy (given the limited market for such LDTs and perceived costs of compliance with premarket review and QS requirements), the risk mitigations present in these circumstances, and the lack of available FDA-authorized IVDs to meet the patient's need.

(Comment 116) Several comments suggested alternatives to the phaseout policy, including combining a quality framework like ISO 9001 with a risk-based self-regulation model; utilizing a targeted program focusing on areas of concern by providing tools to qualify both LDTs and other IVDs for specific indications; updating the CLIA regulations or otherwise tightening the regulation of laboratories and standardizing best practices; ''leveraging'' existing quality assurance programs and programmatic guardrails for lower risk tests; ''exempting'' tests that have been reviewed and approved by NYS CLEP and providing for other ''categorical exemptions''; exercising enforcement discretion for LDTs developed and offered locally in small volumes; creating a framework for LDT manufacturers to make their validation studies public (which FDA could then utilize for risk-based enforcement); incorporating principles from the proposed VALID Act; establishing national accuracy laboratories or partnering with existing organizations to

serve as independent entities dedicated to evaluating and verifying the performance of diagnostic tests; or establishing regional market zones for LDTs (by state or locality) to facilitate conversations between laboratories and clinicians.

(Response 116) Many of the suggestions provided in these comments are outside of FDA's authority to implement. For example, FDA does not have the statutory authority to implement specific provisions of the VALID Act bill (*e.g.,* technology certification), as the bill was never enacted. Similarly, regarding the comments about CLIA, FDA is not the agency in charge of administering that statute. Other suggestions may fall outside of FDA's authority and also lack sufficient clarity, such as suggestions that FDA establish national accuracy laboratories or regional market zones for LDTs. With respect to making validation studies public, adopting a risk-based self-regulation model, or utilizing a targeted program focusing on areas of concern by providing tools to qualify LDTs and other IVDs for specific indications, FDA disagrees that these measures reduce the public health need for additional FDA oversight of IVDs offered as LDTs. These measures would not include critical aspects of FDA's oversight (such as requirements for premarket review, QS, registration and listing or centralized adverse event reporting), would not provide for oversight by independent experts, and would not address the risks associated with IVDs for indications that do not fall within specific ''areas of concern.''

Likewise, with respect to standardizing best practices or ''leveraging'' existing quality assurance programs and programmatic guardrails for lower risk tests, FDA disagrees that such mechanisms mitigate the need to phase out the general enforcement discretion approach for LDTs, as explained in sections VI.C.1 and VI.C.3. FDA also disagrees that an enforcement discretion policy for LDTs that are developed and offered locally in small volumes would be appropriate, as FDA has concerns that there would not be sufficient risk mitigations in such circumstances.

With respect to the comment about LDTs that have been reviewed and approved by NYS CLEP, we agree that an enforcement discretion policy for LDTs approved by NYS CLEP is appropriate, as explained in section V.B.2.

(Comment 117) FDA received a comment from DoD stating that FDA should continue the general enforcement discretion approach for LDTs used within DoD. Specifically, DoD explained that its ''use of LDTs is based on unique, military-relevant scenarios not encountered within the civilian or commercial sectors, therefore, there is no commercial market or incentive for private development of such tests. For example, DoD, on behalf of the United States, is a party to international agreements that require deployed service members to test negative for certain infectious diseases prior to deployment . . . In addition, with DoD personnel and US citizens deployed worldwide, to sometimes austere environments, isolated cases of rare infectious diseases require LDT testing without the benefit of a declared emergency and access to the FDA EUA pathway.'' DoD further explained that ''Department of Defense Instruction (DoDI) 6640.02, establishes the Center for Clinical Laboratory Medicine (CCLM),'' and that ''DoD would work with FDA to establish standards within the DoD unique internal program to achieve stated objectives that provide for clinical validity of LDTs.''

(Response 117) For the reasons discussed further in section V.B.1, FDA intends to exercise enforcement discretion and generally not enforce applicable requirements for LDTs manufactured and performed within DoD.

(Comment 118) FDA received several comments stating that FDA should continue the general enforcement discretion approach for LDTs manufactured and performed within VHA. Two comments suggested that FDA should not continue the general enforcement discretion approach for LDTs manufactured and performed within VHA because VHA's program is not in alignment with FDA regulation (though one of these comments supported ''leveraging'' outside programs ''in principle''). One comment asked whether continuation of the general enforcement discretion approach for LDTs manufactured and performed within VHA would extend beyond the administrative boundaries for which VHA's program is currently limited.

(Response 118) FDA agrees with those comments that stated that FDA should have an enforcement discretion policy for LDTs manufactured and performed within VHA. For the reasons discussed in more detail in section V.B.1, FDA intends to exercise enforcement discretion and generally not enforce applicable requirements for LDTs manufactured and performed within VHA. With respect to concerns that VHA's program is not currently in alignment with FDA regulation, FDA notes that VHA is taking steps in consultation with FDA to track all LDTs in its system and to ensure both the analytical and clinical validity of its LDTs, the quality manufacturing of its LDTs, and the central reporting of adverse events. As noted in section V.B.1, this enforcement discretion policy applies only to LDTs used for patients that are being tested and treated within the VHA program.

(Comment 119) One comment requested that FDA provide more clarity ''for LDTs where the testing laboratory does [not] manufacture any parts of the tests.''

(Response 119) As discussed in the responses to comments in section VI.D.2, a test system is a device regardless of who manufactures it or its components, and is subject to applicable requirements in the FD&C Act and implementing regulations.

2. Continued Enforcement Discretion for Currently Marketed IVDs Offered as LDTs

(Comment 120) We received many comments urging FDA to maintain the general enforcement discretion approach with respect to applicable requirements (or a subset thereof) for currently marketed IVDs offered as LDTs. Many of these comments stated that continuing the general enforcement discretion approach for such IVDs is critical to prevent patients from losing access to certain valuable tests. Several of these comments also suggested that ''the for-profit sector'' would not step in to fill the gaps left by market withdrawal of IVDs for which there are ''small markets.'' Other comments stated that it is important to continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs to sustain successful patient outcomes. Some of these comments asserted that certain IVDs offered as LDTs have become the standard of care, and some stated that losing access to certain currently marketed IVDs offered as LDTs could require the use of inferior tests. Other comments argued that currently marketed IVDs offered as LDTs that are already integrated into clinical practice pose a minimal safety risk, as many have been used effectively for years without causing harm, and/or already satisfy accreditation criteria from recognized accreditation bodies. A few comments noted that some currently marketed IVDs offered as LDTs address unmet needs for which authorized tests do not exist, or for which authorized tests do not reflect the latest advances in science, suggesting that FDA ought to continue the general enforcement

discretion approach to currently marketed IVDs offered as LDTs to avoid disrupting access to these IVDs.

Some comments asserted that not continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would negatively impact specific populations, such as children, individuals with rare diseases, individuals requiring transplantation, and oncology patients. Comments stated that certain IVDs offered as LDTs for use in children are the gold standard, and that essential, time-sensitive testing conducted by pediatric laboratories is performed most effectively if done rapidly in house.

Comments also stated that laboratories have substantial reliance interests in currently marketed IVDs offered as LDTs, having made business decisions against the backdrop of FDA's decades-long general enforcement discretion approach. These comments asserted that discontinuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would not recognize these reliance interests. Other comments stated that patients have reliance interests in IVDs offered as LDTs that would be ''suddenly rendered uneconomical,'' and that these reliance interests would not be recognized if FDA did not continue the general enforcement discretion approach for these IVDs.

In addition, many comments stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs to reduce the demands on FDA resources. Some comments described concerns based on experiences with EUA requests during the COVID–19 pandemic. Other comments highlighted the estimated number of premarket submissions in FDA's PRIA. The comments generally argued that continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would help to ensure that FDA has sufficient resources to conduct timely reviews of other submissions and would avoid bottlenecks such as those that have been observed in other jurisdictions. Many comments also stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs to reduce the burden on laboratories. These comments generally emphasized the many submissions that laboratories might reasonably need to prepare within the applicable timeframe and stated that user fee payments would be too high. One comment added that although it is ''critical'' that FDA not enforce against IVDs offered as LDTs for lacking premarket authorization while a submission for that IVD is reviewed, such an approach does not mitigate the need to continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs, as it does not address the burden of preparing and reviewing submissions. Several comments argued that continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would help to reduce the need for laboratories to divert resources from innovation to support the compliance of currently marketed IVDs.

Other comments supported continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs because, according to these comments, validation studies may otherwise need to be repeated that would be impossible or unethical to repeat; financial costs to patients and legal costs to providers would otherwise increase; and because FDA previously expressed support for continuing the general enforcement discretion approach with respect to certain requirements for currently marketed LDTs (see Ref. 57).

(Response 120) As discussed in section V.B.3, FDA generally intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3 The scope of and basis for this policy are set forth in section V.B.3.

Although FDA is adopting this policy, it does not necessarily agree with all of the statements made in comments supporting an enforcement discretion policy for currently marketed IVDs offered LDTs. For example, we do not agree that currently marketed IVDs offered as LDTs that are already integrated into clinical practice pose a minimal safety risk, or that meeting accreditation criteria from recognized accreditation bodies eliminates the need for FDA oversight for the reasons discussed in response to comments under section VI.C.3. Rather, FDA is including this enforcement discretion policy in consideration of other factors, as discussed in section V.B.3.

(Comment 121) In contrast, FDA received several comments that did not support continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs, or favored significantly limiting the number of IVDs that would fall under the continued enforcement discretion approach. Comments expressed concern that continuing the general enforcement discretion approach would be inappropriate given the evidence of ''low-performing'' IVDs offered as LDTs currently on the market. Other comments expressed concern that continuing the general enforcement discretion approach for these IVDs may cause certain IVDs to appear to be FDA-authorized even when they have not been authorized, and that laboratories might extensively modify their IVDs and avoid compliance with applicable requirements for these modified IVDs. One comment opposed continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs ''particularly for commercial testing''; other comments asserted that continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would inappropriately focus on where or by whom an IVD was developed, rather than the risk of the IVD, and stated that it would be more ''effective'' to narrowly tailor any continued enforcement discretion approach to LDTs that are not associated with safety or effectiveness concerns.

Finally, a few comments did not completely oppose or support an enforcement discretion policy for currently marketed IVDs offered as LDTs. For example, some comments stated that continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs would not be sufficient to address other problems with the phaseout policy, including laboratories' inability to make ''necessary'' updates to their IVDs or respond to changing public health needs. Other comments suggested that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs only if FDA does not establish other more specific policies.

(Response 121) FDA has also carefully considered the comments recommending against the inclusion of a policy for currently marketed IVDs offered as LDTs. FDA agrees that there is evidence in the record demonstrating that there are problematic IVDs offered as LDTs that are currently marketed. However, FDA remains concerned about the potential harms from loss of access to beneficial IVDs offered as LDTs on which patients are currently relying. Therefore, FDA has determined that it best serves the public health to adopt a more targeted expectation of compliance for currently marketed IVDs offered as LDTs. As noted in section V.B.3, FDA

anticipates that adverse event reporting, information contained in labeling, and other sources of information (including public reports and any relevant information from the healthcare community) will help the Agency identify problematic currently marketed IVDs offered as LDTs for which enforcement or other action is warranted. FDA intends to take such action as appropriate. In this way, FDA's policy is consistent with one comment's recommendation to ''narrowly tailor'' the approach, taking into account ''safety or effectiveness concerns'' with currently marketed IVDs offered as LDTs.

One comment argued against an enforcement discretion policy for currently marketed IVDs offered as LDTs because such a policy may cause these IVDs to appear to be FDA-authorized even when they have not been authorized. FDA disagrees. Devices marketed under an enforcement discretion policy are not lawfully on the market, and should not be understood to share the same legal status as lawfully marketed devices. Statements in labeling that an unauthorized IVD is authorized by FDA, or suggestions along those lines, would misbrand the IVD under section 502(a) of the FD&C Act. We believe that enforcing this and other labeling requirements would help to address the concern raised in the comment.

Another comment stated that a policy for currently marketed IVDs offered as LDTs could be problematic because laboratories might extensively modify their IVDs and avoid compliance with applicable requirements for these modified IVDs. As described in section V.B.3, the enforcement discretion policy for currently marketed IVDs offered as LDTs is limited to instances in which the IVD is unmodified, or the IVD is modified only in certain limited ways. If an IVD is modified in more significant ways, FDA intends to phase out the general enforcement discretion approach with respect to all requirements for that IVD. We believe this policy addresses the concern raised in the comment.

FDA also acknowledges that under this policy, its compliance expectations for currently marketed IVDs will differ depending on whether the IVD is offered by a laboratory or a conventional manufacturer. However, in light of the reliance interests engendered by FDA's longstanding enforcement discretion approach for LDTs, as described in the comments, we have determined that this differential treatment is warranted. Over time, FDA anticipates that IVDs will evolve and eventually come into compliance with FDA requirements, such that IVDs manufactured by laboratories will generally fall under the same enforcement approach as other IVDs. In the FRIA, we estimate that 50 percent of currently marketed IVDs offered as LDTs will be submitted to FDA for premarket review (*e.g.,* due to significant modifications as described in section V.B.3) over the course of 20 years.

To the extent that some comments indicated that this policy is appropriate to address unmet needs, FDA notes that discussion regarding tests for unmet needs can be found in section VI.L.5 of this preamble. Also, discussion regarding potential impacts on specific patient populations can be found in section VI.K.

(Comment 122) Some comments stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs only with respect to premarket review requirements. Other comments stated that the enforcement discretion policy for currently marketed IVDs offered as LDTs should be for premarket review requirements and all QS requirements, though one comment recommended that the policy apply for premarket review requirements and QS requirements related only to design controls. Most comments that supported continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs were focused on premarket review and QS requirements, and not all requirements. However, a few comments suggested that the general enforcement discretion approach continue for all applicable requirements. Several comments stated that MDR requirements and registration and listing requirements should be enforced, as these requirements would provide important information about the testing landscape. One comment suggested that while registration and listing requirements should still be enforced, currently marketed IVDs offered as LDTs from hospital and health system laboratories should not be ''subject to overly burdensome requirements'' for registration and listing; for example, FDA should limit the amount of listing information expected for those IVDs. Another comment expressed concern that enforcing registration requirements for laboratories manufacturing currently marketed IVDs offered as LDTs could ''be prohibitive'' for some laboratories. One comment stated that laboratories that have a system for reporting errors, and that are integrated into a health system, generally should not be expected to comply with adverse event reporting requirements (it is not clear if this comment was intended to be specific to currently marketed IVDs offered as LDTs, but the organization of the comment suggests that it was).

(Response 122) FDA agrees that it should phase out the general enforcement discretion approach for all applicable requirements other than premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. This policy reflects a careful balancing of relevant considerations, as discussed in section V.B.3 and in response to comment 120.

We note that the costs of compliance with premarket review and QS requirements are a significant portion of the overall anticipated costs to laboratories of complying with applicable FDA requirements (see section II.F.5 of the FRIA (Ref. 10)). Of the total estimated discounted costs to industry of $1.17 billion, the average estimated costs of compliance with stages 1 and 2 are approximately $9,522 per test ($74,783 per laboratory) and the average estimated costs of compliance with premarket review and QS requirements are approximately $3.02 million per test ($1.26 million per laboratory). As a result, FDA has concluded that focusing the policy on these requirements should address the concerns about widespread market exit. As noted above, FDA expects compliance with requirements under part 820, subpart M (Records), including compliance with QS requirements regarding complaint files. This will facilitate compliance with MDR requirements, because complaints will then be reviewed to determine whether they are MDR reportable. FDA intends to review complaint files during an inspection to assess compliance with relevant QS and MDR requirements.

FDA intends to phase out the general enforcement discretion approach for requirements other than premarket review and most QS requirements in order to gather information about, and take appropriate action with respect to, currently marketed IVDs offered as LDTs. FDA has determined that the public-health value of compliance with these requirements outweighs any concerns raised in the comments. In particular, based on the information in the FRIA, we do not believe compliance with these other requirements will cause laboratories to stop offering IVDs on which patients currently rely. In addition, FDA disagrees that

laboratories that have a system for reporting errors and are integrated into a health system should not be expected to submit MDRs to FDA for currently marketed IVDs offered as LDTs (or for other IVDs). Centralized reporting of adverse events enables FDA to track trends across devices of the same type, identify when issues arise, and work with stakeholders to address those issues. For example, as discussed in section III.B, FDA was able to identify a biotin interference issue through analysis of MDRs indicating inaccurate test results. Biotin is commonly used in immunoassays as part of the test technology. Therefore, when high dose biotin supplements (advertised for hair and nail growth) became more popular, FDA began seeing inaccurate test results associated with these immunoassays. FDA's investigation revealed that this biotin interference affected dozens of tests across multiple manufacturers. This led to a multiyear interactive effort to have manufacturers address the issue through assay re-design. Notably, it is likely many RUO immunoassay kits still use biotin that would be affected in the same manner by these supplements, and it is likely that those manufacturers have not addressed this issue. These RUO kits currently may be offered as LDTs by laboratories. Enforcement of adverse event reporting and registration and listing requirements for these currently marketed IVDs offered as LDTs will help FDA identify where this problem may still be occurring, and where other problems are occurring, so that these problems can be addressed.

For additional discussion of FDA's phaseout of the general enforcement discretion approach with respect to registration and listing requirements and adverse event reporting requirements, see sections VI.F.7 and VI.F.8 of this preamble.

(Comment 123) Some comments recommended that FDA continue the general enforcement discretion approach with respect to certain requirements for currently marketed IVDs offered as LDTs that were first marketed prior to publication of the *proposed rule* whereas other comments recommended such an approach should be for currently marketed IVDs offered as LDTs that were first marketed prior to publication of the *final rule,* or prior to the effective date of the final rule. One comment suggested that FDA continue the general enforcement discretion approach with respect to certain requirements for IVDs offered as LDTs that are marketed within the next 4 years. Another comment suggested that FDA continue the general enforcement discretion approach with respect to certain requirements for IVDs offered as LDTs that have been marketed for at least 3 years prior to March 31, 2024, and that are supported by post-market data that provide evidence of device performance and safety.

(Response 123) As discussed in section V.B.3, FDA has keyed the policy for currently marketed IVDs offered as LDTs to the date of this final rule, rather than the proposed rule. FDA chose this date because patients and the healthcare community may have begun relying on these IVDs during the period between publication of the proposed and final rule. Patients and the healthcare community also may have begun relying on IVDs offered as LDTs that were marketed before March 31, 2024 (and that are currently marketed), even if such IVDs were marketed for fewer than 3 years prior to that date. By contrast, for IVDs offered as LDTs that are introduced after the date of issuance of the final rule (*e.g.,* within the next 4 years), the decisions of laboratories, patients, and the healthcare community would be made taking into account the expectation of compliance and not presuming the same reliance. Furthermore, given the timing of the phaseout policy and the enforcement discretion policy for currently marketed IVDs offered as LDTs, FDA anticipates that laboratories should be able to comply with premarket review and QS requirements by the time of stages 3–5 for IVDs offered as LDTs that are marketed after the publication date for this final rule.

(Comment 124) Some comments stated that if FDA were to continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs, the approach should apply to such IVDs even if the IVDs are modified. One comment argued that modifications are essential to the evolution of patient care. However, most comments suggested that a general enforcement discretion approach for currently marketed IVDs offered as LDTs should not apply to such IVDs after certain types of modifications are made. These comments generally proposed that an enforcement discretion approach should not apply to currently marketed IVDs offered as LDTs after any changes to intended use, indications for use, and/or performance. One comment proposed that a general enforcement discretion approach for currently marketed IVDs offered as LDTs apply to those IVDs if modified in ways that do not significantly change the indications for use, except for some changes to specimen type; that do not significantly change performance claims or significantly and adversely change performance; or that do not adversely change the safety for individuals who come in contact with the IVD. Another comment proposed that a general enforcement discretion approach for currently marketed IVDs offered as LDTs apply to those IVDs if modified in ways that do not alter methodology, intended use, or performance, arguing that this would allow laboratories to continue innovating and address emerging scientific understanding and patient needs. One comment suggested that a laboratory manufacturing a currently marketed IVD offered as an LDT should not be expected to submit a premarket submission for modifications that are properly validated by the laboratory, stating that the utility of currently marketed IVDs offered as LDTs will diminish over time if overly restrictive constraints are placed on modifications.

Some comments emphasized that FDA should provide clear guidance regarding what IVDs offered as LDTs would fall within an enforcement discretion policy for currently marketed IVDs offered as LDTs, including regarding the types of modifications that would be included within that policy.

(Response 124) FDA agrees that the policy should apply to currently marketed IVDs offered as LDTs when they are modified in certain limited ways.

As discussed in response to comment 261, FDA's regulations require premarket review when an authorized device is modified in a way that affects safety and effectiveness (for a device approved under a PMA, with certain exceptions) or in a way that could significantly affect safety and effectiveness (for a device subject to 510(k)). Following a similar approach in this context, and as discussed in more detail in section V.B.3, FDA generally intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in relatively minor ways. This policy is intended to preserve access to beneficial IVDs on which patients and the healthcare community currently rely, including versions of that IVD with minor changes. However, once the IVD is changed in certain, more significant ways that could affect its basic safety and effectiveness profile, the policy no longer applies. Thus, FDA generally expects compliance with premarket review and QS requirements for currently marketed IVDs offered as

LDTs when a laboratory's modifications (individually or in aggregate) change the indications for use of the IVD, alter the operating principle of the IVD (*e.g.,* changes in critical reaction components), include significantly different technology (*e.g.,* addition of artificial intelligence/machine learning to the test algorithm, a change from targeted sequencing to whole genome sequencing, a change from immunoassay to mass spectrometry, or a change from manual to automated procedures), or adversely change the performance or safety specifications of the IVD. These modifications are generally consistent with the types of modifications that comments suggested should not fall within an enforcement discretion policy for currently marketed IVDs offered as LDTs. Although some comments suggested that the policy should encompass all modifications to currently marketed IVDs offered as LDTs, FDA does not agree that this type of broad policy would appropriately serve the public health purpose of this rulemaking.

(Comment 125) FDA received several comments that proposed specific circumstances under which FDA might continue the general enforcement discretion approach with respect to certain requirements for currently marketed IVDs offered as LDTs. Some comments stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs that are ''standard of care'' or otherwise well established in the literature; that are widely adopted and incorporated into professional society treatment guidelines; that are developed and offered locally; that are ''already in known published medical classifications''; that have ''proven performance serving a vital part of healthcare''; for which there are long-term safety and effectiveness records, or evidence of analytical and clinical validity and clinical utility; and/or that are not high risk. One comment stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs that, among other types of IVDs, have been modified from FDA-authorized devices with respect to certain parameters (in some cases supported by further studies), or that have been developed by a government or reference laboratory in good standing under CLIA. Another comment stated that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs that have ''demonstrated concordance with FDA-approved companion diagnostics.'' Yet another comment suggested FDA continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs that are used ''without issues'' within public health laboratories.

(Response 125) As discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs as long as they are not modified following issuance of this final rule, or are modified but only as described in section V.B.3. FDA is adopting this policy based on careful consideration of the comments and the economic projections in the proposed rule, and after weighing competing interests at issue here, as described in section V.B.3.

FDA does not believe that the alternative policies suggested by stakeholders in the comments summarized above would strike the appropriate balance between these competing interests. For example, policies only for some currently marketed IVDs offered as LDTs would not adequately address concerns that patients and providers may have reasonably made choices based on an assumption of continued access to certain IVDs that may not be offered as a result of the phaseout policy, and specifically if FDA were to expect compliance with premarket review and most QS requirements. These include policies that are limited only to currently marketed IVDs offered as LDTs that are offered by certain types of laboratories; that have been modified from FDA-authorized devices with respect to certain parameters; or that have ''demonstrated concordance'' with certain FDA-authorized IVDs. For discussion of FDA's determination not to phase out the general enforcement discretion approach only for IVDs that are high-risk, see section VI.L.4.

In addition, many of the policies suggested in comments would be difficult to administer or would not set clear expectations for stakeholders. For example, a policy for currently marketed IVDs offered as LDTs that are ''standard of care,'' or otherwise well established in the literature, may not be clear for stakeholders. There may be different opinions regarding what IVDs offered as LDTs are standard of care or well established in the literature, and defining those terms in a manner that could be consistently and predictably applied may not be feasible. Similar concerns apply to policies for currently marketed IVDs offered as LDTs that are ''widely adopted'' and incorporated into professional society treatment guidelines; that are developed and offered locally; that are ''already in known published medical classifications''; that have ''proven performance serving a vital part of healthcare''; or for which there are ''long-term'' safety and effectiveness records or evidence.

(Comment 126) One comment suggested that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs upon request.

(Response 126) FDA believes that continuing the general enforcement discretion approach for currently marketed IVDs offered as LDTs only upon request would not set clear expectations for stakeholders and would be administratively difficult to implement.

(Comment 127) Some comments suggested that FDA should continue the general enforcement discretion approach only for specific types of currently marketed IVDs offered as LDTs (depending on the impact to different patient populations), or for currently marketed IVDs offered as LDTs that are intended for unmet needs or for rare diseases or indications or where there is a strong public health need for the IVD, linked to ensuring access to accurate and reliable IVDs and facilitating a smooth transition for FDA oversight. Other comments suggested that FDA should continue the general enforcement discretion approach for currently marketed IVDs offered as LDTs that have been approved by other regulatory bodies, Federal agencies, or certain other programs or entities, in some cases only when the IVD has been offered for a minimum period of time without any reported adverse consequences, or when there is no credible information establishing a lack of validity, false or misleading claims, or a probability that the IVD will cause serious adverse health consequences.

(Response 127) Regarding the comments about a policy for LDTs for unmet needs, we note that FDA is adopting a policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. Moreover, regarding the comment about a policy for currently marketed IVDs offered as LDTs that have been approved by other regulatory bodies, FDA is adopting an enforcement policy for LDTs that are approved by NYS CLEP. In addition,

FDA is adopting an enforcement policy for LDTs offered within DOD's and VHA's oversight programs. For further discussion of these aspects of the phaseout policy, see sections V.B.2 and V.B.3.

Further, similar to our response to comment 125, FDA is concerned that a policy for IVDs offered as LDTs for a certain period of time without issues or that meet a strong public health need would be difficult to administer and would not set clear expectations for stakeholders as there may be different opinions regarding what IVDs offered as LDTs meet these, or any similar, descriptions.

(Comment 128) One comment suggested that IVDs falling within the policy for currently marketed IVDs offered as LDTs be labeled with a statement disclosing they have not been authorized by FDA.

(Response 128) The Agency does not believe such a policy would be appropriate at this time. FDA expects that most IVDs offered as LDTs subject to premarket review requirements will lack required FDA authorization for several years following issuance of this final rule. Under the phaseout policy described in section V.C, the phaseout of enforcement discretion with respect to premarket review requirements will begin 3.5 years (for high-risk IVDs offered as LDTs) to 4 years (for other IVDs offered as LDTs subject to premarket review) from the date of issuance of this rule. After a complete premarket submission for an IVD offered as an LDT has been submitted within these timeframes, FDA generally does not intend to enforce against the IVD for lacking FDA authorization during the pendency of FDA review. Thus, in the context of the phaseout policy, including such a statement in the labeling for currently marketed IVDs offered as LDTs could create confusion by suggesting a distinction that does not exist between those IVDs that are in the process of coming into compliance with premarket review requirements and those that are not. If our experience with implementation of the phaseout policy indicates that a different approach to inclusion of such a statement is warranted as more IVDs offered as LDTs come into compliance with premarket review requirements, FDA would consider making appropriate policy changes in accordance with good guidance practices (§ 10.115).

To the extent anyone may seek information regarding whether a particular test has been authorized by FDA, such information can be found in FDA databases. For example, tests that have been approved, cleared, or had a De Novo request granted by FDA appear in the PMA, 510(k), and De Novo databases, respectively (Refs. 165,166, and 224). We expect that most tests, including those offered without premarket review (*e.g.,* because they are exempt from premarket notification or fall within an enforcement discretion policy), will be listed in the Registration & Listing database in Stage 2 of the phaseout policy. Where a test has been approved, cleared, or had a De Novo request granted, this database will also indicate the applicable premarket submission number.

(Comment 129) Several comments stated that if FDA continues the general enforcement discretion approach for currently marketed IVDs offered as LDTs, ''FDA should retain the authority to require additional regulatory evaluation where there is a need to do so.''

(Response 129) We agree that regardless of the policy for currently marketed IVDs offered as LDTs or any other enforcement discretion policy included in the phaseout policy, FDA retains the authority to enforce any applicable requirements and pursue enforcement action at any time against violative IVDs. Moreover, we note that as discussed above, suggestions that an unauthorized IVD is authorized by FDA would misbrand the IVD under section 502(a) of the FD&C Act.

(Comment 130) One comment stated that if FDA continues the general enforcement discretion approach with respect to premarket review requirements for currently marketed IVDs offered as LDTs, FDA should allow submission of predetermined change control plans (PCCPs) for currently marketed IVDs offered as LDTs without additional submissions, to allow for ''controlled, pre-approved test modifications.''

(Response 130) Under section 515C of the FD&C Act, FDA may approve or clear a PCCP that is submitted in a PMA, supplemental PMA, or 510(k) notification. A PMA supplement or new 510(k) is not required for a modification to a device that would otherwise be required if the change is consistent with a PCCP previously approved or cleared by FDA. As set forth in section 515C, a PCCP can only be approved under section 515 of the FD&C Act or cleared under section 510(k) of the FD&C Act. For additional discussion of PCCPs, see our response to comments in section VI.M. FDA notes, however, that the policy for currently marketed IVDs offered as LDTs does encompass modifications to such IVDs when the modification involves a minor change, as discussed in section V.B.3.

(Comment 131) One comment stated that if FDA continues the general enforcement discretion approach with respect to premarket review for currently marketed IVDs offered as LDTs, those IVDs should be able to serve as predicate devices if laboratories subsequently modify the IVDs and submit 510(k)s for those modified IVDs.

(Response 131) Under section 513(i) of the FD&C Act and part 807, subpart E of FDA's regulations, a predicate device (for purposes of FDA clearance of a 510(k) submission) is a ''legally marketed'' device. FDA's regulations establish that ''[a] legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process'' (§ 807.92(a)(3)). An IVD that does not satisfy this definition, including a currently marketed IVD offered as an LDT that requires but does not have premarket authorization, would not be eligible to serve as a predicate device.

3. Small Laboratories

(Comment 132) FDA received comments stating that FDA should structure the phaseout of the general enforcement discretion approach for LDTs differently for small laboratories, as such laboratories will be more heavily affected by the phaseout. Some comments stated that small laboratories often develop and validate innovative assays or modify existing tests to serve specific populations, which can be costly. One comment stated that compliance with FDA requirements is a large and costly undertaking which only the largest corporations would be able to do, and that providing a longer phaseout period for LDTs offered by laboratories with annual receipts below $150,000 would still not be sufficient for small laboratories to come into compliance. Another comment recommended FDA have a ten-year phaseout for IVDs offered as LDTs by small laboratories and define small laboratory using the definition proffered by the Small Business Administration.

(Response 132) FDA recognizes that some small laboratories may be disproportionately impacted by the phaseout of the general enforcement discretion approach for LDTs from a financial perspective, as discussed in section III of the FRIA (Ref. 10). However, the final phaseout policy includes several enforcement discretion

policies that we anticipate will reduce costs for laboratories compared to what was estimated in the PRIA, including for small laboratories (see section V.B). As shown in table 48 of the FRIA, annualized costs per entity under the final phaseout policy (taking into account the enforcement discretion policies described in section V.B of this preamble) are estimated to be about 6 percent of receipts for small laboratories (for further discussion see section III.B of the FRIA).

In light of the anticipated costs to small laboratories associated with the final phaseout policy, and the additional considerations discussed in comment 133, FDA does not believe it is appropriate to adopt an enforcement discretion policy for small laboratories' IVDs offered as LDTs or to extend the phaseout policy to 10 years for such laboratories.

We understand that small laboratories may manufacture innovative LDTs or modify existing IVDs to serve specific populations. For small laboratories that are integrated within a healthcare system, certain of their LDTs may fall within the unmet need policy, discussed further in section V.B.3. Small laboratories that are not integrated within a healthcare system would fall outside that policy including because there are not the same risk mitigations present in such situations (see further discussion in section V.B.3).

(Comment 133) Some comments expressed opposition to FDA having a different enforcement approach for small laboratories and advocated for uniform treatment of all laboratories. Several comments stated that the size of the laboratory should not determine how certain tests are treated, noting that this type of approach would not be acceptable if applied to non-laboratory manufacturers and would be inconsistent with a risk-based approach. Some comments also stated that the harm to patients from faulty tests does not change based on the size of the laboratory and remarked that a longer phaseout period may allow for continued patient harm due to problematic IVDs offered as LDTs. One comment stated that small laboratories with fewer LDTs may actually be better able to comply with FDA requirements than larger laboratories and AMCs with hundreds of LDTs and suggested that any extension of the implementation period be based on the number of LDTs that a laboratory performs rather than annual receipts. Another comment noted that some small laboratories are associated with large hospital systems, which may prevent them from qualifying for any exemption or special considerations afforded to small laboratories.

(Response 133) FDA agrees that the phaseout of the enforcement discretion approach for LDTs should not be determined by laboratory size, as a different enforcement approach for small laboratories would not be in the best interest of the public health where we are unaware of any evidence supporting that IVDs manufactured by small laboratories are any less likely to be problematic than IVDs manufactured by large laboratories. We note that this approach is generally consistent with FDA's device regulations and policies, which generally do not distinguish small businesses from other regulated entities (though small businesses are eligible for a waiver or reduction of certain MDUFA user fees as a matter of statute). FDA also anticipates that features of the final phaseout policy will address many of the concerns of small laboratories as discussed in response to comment 132 above. FDA's phaseout policy is described in detail in section V.

4. Academic Medical Centers

(Comment 134) We received many comments responding to the questions posed in the NPRM (88 FR 68006 at 68023–24) about whether FDA should continue the general enforcement discretion approach with respect to any requirements for tests manufactured by AMC laboratories. We received a wide variety of comments spanning all sides of the issue: comments in favor of continuing an enforcement discretion approach for tests manufactured by AMC laboratories, comments recommending that FDA also continue an enforcement discretion approach for tests manufactured by other similarly situated laboratories, comments that suggested limitations to an enforcement discretion approach for tests manufactured by AMC laboratories, and comments against the continuation of an enforcement discretion approach for tests manufactured by AMC laboratories. We also received various suggestions on possible ways to define an AMC.

(Response 134) As stated in section V.B, FDA is adopting several enforcement discretion policies that may apply to certain IVDs manufactured by AMC laboratories. First, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs as long as they are not modified following issuance of this rule, or are modified but only in certain limited ways as described in section V.B.3. This includes IVDs currently offered as LDTs by AMC laboratories. Second, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP, as described in section V.B.2. We anticipate that some LDTs manufactured by AMC laboratories may fall within this policy. Third, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. We anticipate many LDTs made in AMC laboratories will fall within this policy.

For the reasons set forth in section V.B and discussed in the response to comment 135, FDA does not think it is appropriate to have an enforcement discretion policy for: all LDTs manufactured by AMC laboratories; all requirements for LDTs manufactured by AMCs laboratories; or LDTs manufactured by AMC laboratories but not LDTs manufactured by other laboratories integrated within a healthcare system (as such, and because we are not adopting an enforcement policy for AMC laboratories, we have not included a definition of AMCs in the phaseout policy).

(Comment 135) Comments suggested that FDA should continue its general enforcement discretion approach with respect to tests manufactured by AMC laboratories for various reasons. Some argued that a continued enforcement discretion approach for AMCs is necessary because increased FDA oversight of their LDTs would negatively impact the public health, access, medical training, and innovation. Comments also claimed that AMC laboratories cannot afford the cost of compliance with FDA requirements as they perform tests on hospitalized patients, with no additional revenue stream or resources to cover the cost of compliance with FDA requirements. Other comments claimed that continuing an enforcement discretion approach is necessary because AMC laboratories already operate with tight budgets, are short staffed, and struggle to find qualified talent. Similar comments indicated that due to budgets, AMC laboratories may be prevented from performing FDA-authorized alternative tests where such tests require specialized capital equipment,

additional training, and inventory management, whereas a continued enforcement discretion approach for LDTs made by AMC laboratories would account for consolidation of testing platforms for efficiency. Comments hypothesized that increased FDA oversight would cause AMC laboratories to limit their testing offerings, detrimentally impacting the most vulnerable populations, raising costs to patients, and hurting access. Many comments stated that AMC laboratories manufacture and provide tests for unmet needs to provide care for the most complex adult and pediatric patients. This includes tests for rare diseases, which are low volume or do not have a ''commercial'' alternative. For example, a comment indicated that there are less than 20 laboratories that perform advanced immunologic testing, and all such laboratories are AMC laboratories. Comments expressed concern that patients might not otherwise have access to these and other tests. Other comments focused on the role of AMCs in training medical students, research, and innovation. Some pointed out that AMC laboratories create and develop test methods that ''commercial'' laboratories later adopt and use for their tests, and that AMC laboratories are nimble and able to explore and employ creative applications of new technology to enhance clinical testing. These comments expressed concern that increased FDA oversight would inhibit training and research to the detriment of the public health.

Comments also stated that the integration of AMC laboratories into patient care at the AMC provides a direct feedback loop between providers and patients that helps to mitigate the risks of the tests by providing context about the patient, their condition, and the particular purpose a test serves in this patient's care, and thereby allowing for conversation about the interpretation of results between the physician, patient, and test manufacturer. The commenters posit that these factors allow test manufacturers to troubleshoot as needed.

(Response 135) As described in response to comment 134, FDA is adopting several enforcement discretion policies that may apply to certain IVDs manufactured by AMC laboratories, including an enforcement discretion policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. As discussed in section V.B.3, in the circumstances described in the unmet needs policy, FDA has greater confidence that ordering physicians will communicate any questions about LDTs or concerns regarding the safety and effectiveness of the LDT (*e.g.,* when the patient's symptoms point to another diagnosis; when subsequent test results contradict the original test result) to a laboratory given the built-in communication mechanisms present. Moreover, FDA generally has greater confidence that laboratories will communicate any limitations of the LDT or other relevant information to the ordering physician given these mechanisms. We think this is particularly likely to happen in the context of LDTs for unmet needs, which are likely to be a focus of attention and communication between laboratorians and providers given the uncommon nature of the issues presented.

FDA anticipates that this and other enforcement discretion policies (described in response to comment 134) that may apply to IVDs manufactured by AMC laboratories will help to avoid the access concerns discussed in the comments. Specifically, FDA anticipates that these policies will reduce the compliance costs associated with the phaseout policy for many laboratories, including AMC laboratories, thereby addressing many of the financial concerns referenced in the comments. As described in the FRIA, the costs of compliance with premarket review and QS requirements are a significant portion of the overall anticipated costs to laboratories of complying with applicable FDA requirements (see section II.F.5 of the FRIA (Ref. 10)). Of the total estimated discounted costs to industry of $1.17 billion, the average estimated costs of compliance with stages 1 and 2 are approximately $9,522 per test ($74,783 per laboratory) and the average estimated costs of compliance with premarket review and QS requirements are approximately $3.02 million per test ($1.26 million per laboratory). Therefore, these policies may help to avoid AMC laboratories from no longer offering currently marketed IVDs or from manufacturing LDTs for unmet needs in the future due to the perceived costs of compliance with premarket review and QS requirements, as discussed further in section V.B.3. We also anticipate these policies will help to address the other concerns raised in comments, such as regarding AMC laboratories' role in training medical students to understand tests.

As discussed in the response to comment 142, we believe that for unmet need LDTs, the risk mitigations present in laboratories integrated within healthcare systems will help to address some of the concerns raised regarding problematic IVDs offered as LDTs discussed in the NPRM and this preamble. Notably, this policy is limited to exercising enforcement discretion for premarket review and most QS requirements (not all FDA requirements) and LDTs for unmet needs (not LDTs for which there are available FDA-authorized alternatives).

FDA believes it is important that an enforcement discretion policy for laboratories integrated within a healthcare system be limited to premarket review and QS requirements. Compliance with other applicable requirements will help provide assurances regarding safety and effectiveness and help FDA monitor for potentially poor performing LDTs that should be addressed. Moreover, we understand that compliance with premarket review and QS requirements are what is likely to lead laboratories integrated within a healthcare system to stop manufacturing LDTs for unmet needs in the future due to perceived compliance costs.

(Comment 136) Other comments pointed out features they assert mitigate the risk of tests manufactured by AMC laboratories. Comments noted that such laboratories are already regulated under/by CLIA, CAP, and other state and local accreditation bodies and that most hospital systems have mechanisms for reporting and tracking of events that have the potential for negative patient impact in order to comply with accreditation requirements. Some pointed to the not-for-profit nature of AMCs and the fact that AMCs are working to educate providers and enhance patient care—not generate profit or ''commercialize'' the tests they manufacture. Some claimed AMC laboratories have a demonstrated track record for developing safe and effective tests. Comments stated that AMCs were not subject to the lawsuits involving misleading information which FDA cited in the NPRM. Another posited that tests developed by AMCs do not have the problems observed in ''commercial'' tests.

(Response 136) FDA does not agree with comments that assert that an enforcement discretion policy is appropriate for all requirements for all LDTs manufactured and performed by AMC laboratories. FDA does not agree with the assertion that there are no problems with IVDs offered as LDTs by AMC laboratories nor does FDA agree that CLIA and other accreditations and the not-for-profit nature of AMCs are sufficient mitigations to justify such a policy. As described in the NPRM and

memorandums to file prepared by FDA that were included in the docket for this rulemaking, we are aware of problems with certain IVDs offered as LDTs manufactured and performed by AMC laboratories (see Refs. 16 and 18).

FDA does not believe it would be appropriate to have an enforcement discretion policy for all LDTs manufactured by AMC laboratories because such laboratories must comply with CLIA, as some comments asserted. In our response to comments in section VI.C, we explain that CLIA requirements and accreditation activities serve a complementary and distinct purpose from FDA oversight, and are therefore insufficient on their own to justify FDA continuing its general enforcement discretion approach for IVDs offered as LDTs.

Although healthcare systems may already have mechanisms addressing the reporting and tracking of adverse events, that does not negate the need for FDA oversight, including of MDR requirements. FDA uses adverse event information to monitor safety signals and identify trends, so that we can inform healthcare providers about issues the Agency has identified and work with manufacturers to correct problems with their devices. Reports to FDA about corrections and removals are also important in assuring that healthcare providers, patients, and caregivers are aware of problems and how to address them.

Finally, we note that even if an AMC is a not-for-profit entity, as raised in the comments, whether or not a test is sold for profit does not determine the quality of the test itself, which is the focus of FDA's attention.

(Comment 137) In response to FDA's question whether to continue its general enforcement discretion approach for tests made by AMC laboratories, many comments made various suggestions to FDA about continuing its general enforcement discretion for LDTs made by other types of health systems that are responsible for patients' complete clinical course of care. Some comments asserted that FDA should continue its general enforcement discretion approach for LDTs: (1) made by laboratories within hospitals that provide immediate patient care or any community healthcare delivery system, (2) manufactured by laboratories in accredited hospitals and healthcare systems where the laboratory directors meet prerequisite education and experience requirements, or (3) manufactured by CLIA-certified laboratories that are integrated as part of a healthcare organization providing direct medical care. These comments claimed that a continued enforcement discretion approach for these LDTs would be appropriate, either because an AMC is too hard to define, or because some of the aspects of AMCs described in the NPRM, *i.e.,* integration into patient care, and CLIA certification and meeting requirements to perform high-complexity testing, also apply to clinical laboratories in other health systems.

(Response 137) For the reasons discussed further in section V.B.3, FDA is adopting an enforcement discretion policy for LDTs manufactured and performed by laboratories integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA is not adopting an enforcement policy specific to AMC laboratories based on FDA's understanding that AMCs are not the only healthcare systems in which integrated laboratories make LDTs to meet the needs of patients being cared for in the same healthcare system.

FDA believes that the risk mitigations present when the patient tested is receiving care within the same healthcare system as the laboratory offering the unmet need LDT, along with the other risk mitigations discussed in section V.B.3, help to address some of the concerns raised regarding problematic IVDs offered as LDTs discussed in the NPRM and this preamble. Specifically, in such situations, FDA generally has greater confidence that ordering physicians will communicate any questions about LDTs or concerns regarding the safety and effectiveness of the LDT (*e.g.,* when the patient's symptoms point to another diagnosis; when subsequent test results contradict the original test result) to a laboratory given the built-in communication mechanisms present. Moreover, FDA generally has greater confidence that laboratories will communicate any limitations of the LDT or other relevant information to the ordering physician given these mechanisms. We think this is particularly likely to happen in the context of LDTs for unmet needs, which are likely to be a focus of attention and communication between laboratorians and providers given the uncommon nature of the issues presented. For further discussion on these risk mitigations, please refer to section V.B.3. While we recognize that these features do not mitigate all risk and there may still be some uncertainty about the performance of tests subject to this policy, we believe that these features support enforcement discretion for premarket review and quality system requirements in the specific context of LDTs for unmet needs.

Thus, and as described further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. This policy may include, but is not limited to, AMC laboratories' LDTs. We believe this policy generally encompasses the scenarios described in the comments summarized above (*e.g.,* where LDTs are made by laboratories within hospitals or that are part of a healthcare organization providing direct medical care), albeit it applies only to LDTs that are intended to meet an unmet need of patients receiving care within the same healthcare system as the laboratory. As described in section V.B.3, an enforcement discretion policy whereby FDA generally would not enforce premarket review and most QS requirements for *any* LDTs manufactured by laboratories integrated within healthcare systems would appear to be overly broad, including because it would encompass LDTs for which there are FDA-authorized alternatives that we know have appropriate assurances of safety and effectiveness.

(Comment 138) Some comments suggested that FDA should continue a general enforcement discretion approach only with respect to premarket review, but phase in other requirements, such as reporting of adverse events, for LDTs manufactured by AMC laboratories.

(Response 138) FDA is adopting an enforcement discretion policy for premarket review and most QS requirements for certain unmet need LDTs manufactured and performed by laboratories integrated within a healthcare system where the patient is receiving care. Among other things, this enforcement discretion policy is intended to avoid laboratories that manufacture unmet need LDTs from no longer manufacturing such LDTs as a result of the phaseout policy and perceived costs with premarket review and QS requirements. FDA is concerned that including premarket review requirements only in the policy would not sufficiently address this concern. As noted in section V.B.3, FDA expects compliance with all other applicable requirements as described in the phaseout policy.

For the reasons discussed in section V.B.3, FDA is not adopting an enforcement discretion policy for all LDTs manufactured and performed by

AMC laboratories (or other laboratories integrated within healthcare systems).

(Comment 139) Another comment suggested that FDA continue the general enforcement discretion approach for all regulatory requirements, but only for low-risk tests offered by AMC laboratories.

(Response 139) FDA disagrees that it would be appropriate to adopt an enforcement discretion policy for all FDA requirements for low-risk tests offered by AMC laboratories. As an initial matter, FDA does not believe that AMC laboratories would stop offering low-risk tests as a result of the phaseout policy (including because most low-risk tests are exempt from premarket notification, meaning premarket submissions are not required). Moreover, for the reasons discussed throughout this preamble, compliance with other applicable requirements, such as registration and listing and adverse event reporting, among others, will provide critical assurances regarding these tests and allow FDA to monitor and take action in the event a problematic IVD is offered.

(Comment 140) A comment urged FDA to recognize that some hospitals and integrated patient facilities, including AMCs, may need to use devices ''off label,'' and asked how certain provisions, like the custom device exemption and IDE expanded access, apply to laboratories.

(Response 140) FDA recognizes that, under the FD&C Act, healthcare practitioners may prescribe or administer a legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship (see section 1006 of the FD&C Act (21 U.S.C. 396)). As discussed further in section VI.D.6, however, section 1006 of the FD&C Act does not reach the manufacturing of a device, including by a laboratory.

Regarding the custom device exemption and IDE expanded access, FDA has issued a final guidance document on the custom device exemption (Ref. 168) and has provided information on its website about expanded access for medical devices (Ref. 169) as resources to device manufacturers, including laboratory manufacturers, among others.

(Comment 141) Some comments claimed that AMCs engage in the practice of medicine when they modify or use FDA-authorized tests off-label and so AMCs are not subject to FDA laws and requirements when they engage in these activities. Another comment stated that there are exclusions in the FD&C Act that apply to AMCs. Specifically, the comment quoted the following provision from the FD&C Act: ''practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound or process drugs or devices solely for use in the course of their professional practice,'' and cited the following provisions in the FD&C Act: 21 U.S.C. 360(g)(2), 360i(c)(2),[84] and 374(a)(2)(B).

(Response 141) We do not agree that the ''practice of medicine'' provision in the FD&C Act is so broad as to encompass all of the activities raised in the comments (see response to comment 74 for a further discussion of this provision). Section 1006 of the FD&C Act expressly states what conduct within the practice of medicine falls outside of FDA's statutory authority. *See* 21 U.S.C. 396 (''Nothing in this [Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship,'' with several explicit limitations). Notably, the provision limits FDA's oversight of certain practitioners' ''prescrib[ing] or administer[ing]'' of a ''legally marketed device,'' but it does not reach the manufacturing of a device. Thus, to the extent that an AMC or AMC laboratory is manufacturing a device, including by modifying another entity's device, its actions do not fall within the ''practice of medicine'' provision.

Regarding the comment asserting that various referenced exemptions in the FD&C Act generally apply to AMCs or AMC laboratories, we note that these exemptions apply when a ''practitioner[ ]'': (1) is ''licensed by law to prescribe or administer'' a device, such as an IVD, (2) ''manufacture[s]'' that device, and (3) does so ''solely for use in the course of their [or his] professional practice.'' As discussed in response to comment 77, these exemptions are only relevant when a particular individual meets all three criteria and, by their plain terms, do not apply to an institution or an entity. Thus, to the extent the commenter is asserting that all AMCs or all AMC laboratories generally fall within these exemptions, we disagree.

(Comment 142) Several comments suggested that AMCs should be subject to the same enforcement approach as all other IVD manufacturers because it is important that patients be able to depend on tests regardless of who develops them. One comment stated that applying the same oversight approach would help to ''standardize the development and validation of LDTs.'' Another comment thought that FDA should not continue an enforcement discretion approach for LDTs manufactured and used in an AMC laboratory because it falsely gives the impression that LDTs manufactured by AMCs are superior to LDTs manufactured by non-AMCs. Another comment highlighted that FDA's memorandum to file entitled ''Summary of 2020 Assessment of the First 125 EUA Requests from Laboratories for Molecular Diagnostic Tests for SARS–CoV–2'' concluded that the deficiencies found in design, validation, and performance of COVID–19 tests were similar across all types of laboratories, including AMCs (see Ref. 18). Other comments suggested that any continuation of enforcement discretion should be test-based, with comments highlighting that FDA should focus on continuing its enforcement discretion approach for tests developed to meet needs of those impacted by pediatric and rare diseases, regardless of where the test is manufactured.

(Response 142) FDA agrees that patients should be able to depend on IVDs regardless of who manufactures them, which is why FDA is phasing out the general enforcement discretion approach for LDTs. This phaseout policy includes several enforcement discretion policies for certain requirements for specific categories of IVDs manufactured by a laboratory. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

Regarding the enforcement discretion policies FDA is adopting, as discussed further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. We understand that AMCs generally integrate their laboratories within their

[84] Although this comment cited 21 U.S.C. 360(i)(c)(2), we believe the commenter may have intended to reference 21 U.S.C. 360(i)(c)(1), which refers to ''any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice.''

respective healthcare systems, and so this policy generally applies to their LDTs for unmet needs, as well as the unmet need LDTs manufactured and performed by other laboratories integrated within a healthcare system.

As discussed further in section V.B.3, FDA understands that laboratories integrated within a healthcare system may no longer manufacture and perform many critical LDTs for unmet needs due to a lack of financial incentive and the perceived costs of premarket review and QS requirements for such tests if expected to comply with such requirements. FDA is aware, however, of problems with certain IVDs offered as LDTs manufactured and performed by AMC laboratories (see response to comment 32). Certain evidence of problematic IVDs offered as LDTs described in the NPRM addressed tests from AMCs, including the memorandum described above entitled ''Summary of 2020 Assessment of the First 125 EUA Requests from Laboratories for Molecular Diagnostic Tests for SARS-CoV–2'' (Ref. 18). In addition, another FDA memorandum and several of the studies referenced in the NPRM referenced IVDs manufactured by AMC laboratories (see Refs. 20 and 92). We believe the risk mitigations present in laboratories integrated within healthcare systems, and various other risk mitigations, as described in section V.B.3, help to address some of the concerns raised regarding problematic IVDs offered as LDTs discussed in the NPRM and this preamble.

As discussed further in section V.B.3, while we recognize that these features do not mitigate all risk and there may still be some uncertainty about the performance of tests subject to this policy, we believe that these features support enforcement discretion for premarket review and quality system requirements in the specific context of LDTs for unmet needs. FDA considers an LDT to be for an unmet need where there is no available FDA-authorized IVD that meets the patient's needs. This may be because: (1) there is no FDA-authorized IVD for the disease or condition (for example, because it is for a rare disease or condition); (2) there is an FDA-authorized IVD for the disease or condition but it is not indicated for use on the patient, or a unique attribute needs to be added to the LDT to meet the patient's needs; or (3) there is an FDA-authorized IVD but it is not available to the patient.

We also acknowledge statements in the comments that applying the same oversight approach would help to standardize the development and validation of LDTs. In light of unique validation issues for many IVDs for unmet needs, FDA intends to consider whether issuing additional guidance regarding validation of tests, including those for rare diseases that takes into consideration the challenges in obtaining a robust number of samples for validation, would be helpful, as discussed in section V.B.3. In the event FDA were to issue any such guidance, FDA would do so in accordance with good guidance practices (see § 10.115). FDA anticipates that such guidance could result in more consistently robust validation practices across laboratories that develop tests for unmet needs and reduce the potential for introduction of poorly performing LDTs.

Finally, we do not think it is appropriate to adopt an enforcement discretion policy for all LDTs developed to meet the needs of those impacted by pediatric and rare diseases, regardless of where the LDT is manufactured and performed. As discussed further in section V.B.3, such a policy would appear to be overly broad, as there are not the same risk mitigations present for all such LDTs that would help address and avoid the use of problematic LDTs.

(Comment 143) A number of comments expressed concern that if FDA were to continue its general enforcement discretion approach for AMCs, it would distort the market and negatively impact underserved and rural regions. Comments indicated that AMCs are generally concentrated in urban areas and that many patients in rural areas are not able to access AMCs due to lack of proximity or insurance coverage. Another comment stated that community health centers provide more cancer treatment than AMCs. The comments expressed fear that continuing an enforcement discretion approach for AMCs will exacerbate the disparities in care between urban and rural regions and would be detrimental to the ability of community centers to provide tests for cancer patients. Similarly, another comment stated that non-AMCs will have trouble attracting talent if FDA continues to exercise enforcement discretion for AMCs.

(Response 143) As discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

FDA believes that this policy will help to address the concerns raised in the comments for patients in underserved and rural regions and should mitigate concerns about attracting talented laboratorians. The policy applies to all laboratories integrated within a healthcare system, not only AMCs. FDA anticipates that this policy will help to avoid laboratories integrated within healthcare systems, wherever such healthcare systems are located, from no longer manufacturing LDTs to meet the unmet needs of patients receiving care within the same healthcare system due to the costs of compliance with premarket review and QS requirements.

(Comment 144) Several comments suggested that FDA not extend its general enforcement discretion approach to AMCs if AMCs were to ''commercialize'' the tests they develop at a significant volume.

(Response 144) FDA believes that an enforcement discretion policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system should be limited only to those LDTs for which there is an unmet need, and should not apply when there is an FDA-authorized test available that meets the needs of the patient. There may be an unmet need because—(1) there is no FDA-authorized IVD for the disease/condition (for example, because it is for a rare disease/condition); (2) there is an FDA-authorized IVD for the disease/condition but it is not indicated for use on the patient, or a unique attribute needs to be added to the test to meet the patient's needs; or (3) there is an FDA-authorized IVD but it is not available to the patient. Moreover, as described in section V.B.3, this enforcement discretion policy is limited to LDTs for patients who are receiving care within the same healthcare system as the laboratory offering the test.

(Comment 145) Multiple comments indicated that it will be difficult to develop a consistently implementable definition of AMCs. Many other comments stated that AMC laboratories serve patients beyond a single physical location and that such a ''requirement'' would be too narrow. These comments indicated that it is rare for specimen collection, testing in a clinical laboratory, and treatment of the patient to all take place in the same building. Comments also pointed out that real estate availability and patient needs may force AMCs to take advantage of multiple physical spaces. Other comments indicated that while AMCs may span multiple physical locations, they may all be connected by one

electronic management record system. Some comments suggested FDA consider an enforcement discretion policy for AMCs that have closely affiliated health systems or where the laboratories work directly or in coordination or collaboration with the academic institution. Other comments questioned what it meant to have a medical residency training or fellowship program involving test development, and whether this applied to pathology. Others wanted clarity on the meaning of ''direct patient care.''

We also received many comments providing various possible definitions of an AMC. Common across many comments was that AMCs are high-complexity CLIA-accredited laboratories and that the leadership or a portion of the laboratory leadership have an academic appointment at an Accreditation Council for Graduate Medical Education (ACGME)-accredited school with a training program in pathology or laboratory medicine. Some comments suggested an AMC laboratory should provide testing for patients in their AMCs. Another comment suggested an AMC laboratory should accept at least 50 percent of its samples from patients being tested within the institution-affiliated healthcare system. Another comment suggested that FDA should not limit an enforcement discretion policy to tests where samples come from within the AMC because AMCs are often referral centers. A comment suggested that an AMC be defined as a nonprofit 501(c)(3) with a Liaison Committee on Medical Education-accredited medical school, teaching hospital, residency training program, and a mission to educate medical professionals. Other comments suggested an AMC use a single EMR where testing is performed within the system and reported into the system EMR. Another comment suggested an AMC is a unit where the physician ordering the specimen is either employed by the healthcare system or has active clinical privileges at a hospital owned by the healthcare system.

(Response 145) Based on these and other comments submitted to the docket for this rulemaking and for the reasons described in section V.B.3, FDA will not have a separate enforcement discretion policy for AMC laboratories. Instead, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. As such, FDA is not defining an AMC in this preamble and many of the concerns raised in the comments summarized above have been addressed or are no longer relevant (*e.g.,* concerns regarding limiting the policy to manufacturers at a single physical location; questions regarding what it means to have a medical residency training or fellowship program involving test development; questions regarding the meaning of ''direct patient care'').

5. New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP)

(Comment 146) FDA received several comments in support of ''leveraging'' LDT approval under established programs, specifically NYS CLEP, in lieu of ending FDA's general enforcement discretion approach for LDTs with respect to premarket review requirements, in order to prevent duplicative efforts and reduce burden for both FDA and laboratories. Some comments expressed general support for relying on established programs such as NYS CLEP, but noted that these programs would need to be aligned with FDA's regulatory review standards. Some comments noted that NYS CLEP provides a robust system of oversight and furthers the same goals as FDA's 510(k) process, but they suggested that adverse event data collection and registration and listing should be conducted at the Federal level. Other comments recommended using NYS CLEP as a model when structuring FDA's enforcement of requirements for IVDs offered as LDTs. Some comments supported the idea of continuing the general enforcement discretion approach for all FDA requirements for tests that have already been approved by NYS CLEP. One comment noted that relying on existing programs and continuing enforcement discretion for these tests would reduce concerns about bottlenecks in FDA's review capacity and constraints on innovation and alleviate concerns about increased costs.

NYS provided a comment indicating support for continued enforcement discretion with respect to premarket review requirements for LDTs they have reviewed and approved. They explained that their ''technical review is designed to determine whether the test is analytically and clinically valid. The laboratory must submit all applicable standard operating procedures, validation data demonstrating accuracy and reliability of the test results, documentation that the results are associated with a clinical or public health need, examples of reports, and other material necessary to evaluate the tes t. . . . CLEP's LDT oversight process is designed to address the risk for each LDT and considers all parts of the test, including test method, intended use, specimen type, and claims, as well as the laboratory performing the test. Each LDT application is reviewed by subject matter experts with post-graduate experience and training in the field and reviews are not conducted during onsite survey. An LDT approval is specific to the laboratory. . . . Tests that cannot meet CLEP requirements are denied. Approval may be revoked or modified if an approved test is found subsequently to be no longer analytically and/or clinically valid.'' However, NYS supported the collection of adverse event information and registration and listing information at a national level.

(Response 146) As discussed in section V.B.2, FDA intends to exercise enforcement discretion with respect to premarket review requirements for LDTs approved by NYS CLEP. FDA notes that this is an enforcement discretion policy and not a substitute for FDA premarket review. FDA believes that the term ''leveraging'' in the NPRM (88 FR 68006 at 68024) might have caused confusion. FDA recognizes that NYS CLEP's regulatory framework is not the same as FDA's (*e.g.,* NYS CLEP has a different risk classification and premarket review program). However, as explained in section V.B.2, FDA believes that NYS CLEP has a program that provides for certain mitigations that help reduce the risk of harm from inaccurate and unreliable LDTs. Specifically, NYS CLEP has a program under which high risk and moderate risk LDTs generally are evaluated for analytical and clinical validity. Based on the available information, FDA believes that generally NYS CLEP's review of analytical and clinical validity of LDTs helps to mitigate the risk of harm from inaccurate and unreliable LDTs and that, rather than enforcing premarket review requirements by FDA, it would be more efficient and effective to use our resources for other oversight activities regarding IVDs offered as LDTs. See section V.B.2. for further information. We have accounted for this enforcement discretion policy in the FRIA. Specifically, as discussed in appendix A of the FRIA (Ref. 10), we estimate that 12.1 percent of IVDs offered as LDTs would not experience new costs associated with submission preparation and review as a result of FDA's enforcement discretion policy with respect to LDTs approved by NYS CLEP.

However, as discussed in section V.B.2, FDA intends to phase out its general enforcement discretion approach with respect to other regulatory requirements, such as registration and listing and MDR requirements, for these LDTs. Enforcement of other requirements will help to protect and promote the public health, *e.g.,* by providing FDA and the public with important information about these tests. See section V.B.2 for further information.

(Comment 147) Some comments stated that an external program such as NYS CLEP should not ''replace FDA regulation,'' but noted that such programs could be used to streamline FDA review or provide additional ''flexibility'' to tests certified under such regimes. Some comments expressed concern that such external programs would be unable to handle the volume of requests from laboratories, and others noted that if FDA were to ''leverage'' such external programs and continue its general enforcement discretion approach, this may lead to an overly broad approach with FDA accepting foreign standards like the EU CE Certificate.

(Response 147) FDA's policy with regard to LDTs approved by NYS CLEP does not ''replace FDA regulation.'' As described in section V.B.2, FDA intends to exercise enforcement discretion with respect to premarket review requirements, but not other FDA requirements such as MDR reporting, for LDTs approved by NYS CLEP. See section V.B.2. for further information. Additionally, as noted above, this is an enforcement discretion policy and not a substitute for FDA premarket review. As described in section V.B.2, FDA intends to exercise enforcement discretion and generally not enforce the premarket review requirements for LDTs approved by NYS CLEP because NYS CLEP has a program under which high risk and moderate risk LDTs generally are evaluated for analytical and clinical validity. Based on the available information, FDA believes that generally NYS CLEP's review of analytical and clinical validity of LDTs helps to mitigate the risk of harm from inaccurate and unreliable LDTs and that, rather than enforcing premarket review requirements by FDA, it would be more efficient and effective to use our resources for other oversight activities regarding IVDs offered as LDTs. Further, as stated in section V.B.2, FDA retains its discretion to pursue enforcement action at any time against violative IVDs when appropriate.

This enforcement discretion policy for LDTs approved by NYS CLEP does not apply to tests with foreign approvals if those tests are not approved by NYS CLEP. With respect to concerns regarding potentially overwhelming NYS CLEP, the likelihood of this result is unclear. However, FDA anticipates collaborative communication with NYS CLEP. Should experience with this policy indicate that changes are warranted, FDA would consider appropriate policy changes through guidance in accordance with good guidance practices (see § 10.115).

(Comment 148) A few comments stated that FDA should not ''leverage'' outside programs and continue applying the general enforcement discretion approach for tests under those programs. They stated that these programs as they exist today do not have the same scope and standards as FDA's device regulations. Further, they stated that ''allowing'' external programs with different standards to ''stand in for FDA regulation'' would not further the goal of implementing a single risk-based regulatory framework.

(Response 148) As discussed in the response to comment 146, FDA believes that the term ''leveraging'' in the NPRM (88 FR 68006 at 68023) might have caused confusion. FDA recognizes that NYS CLEP's regulatory framework is not the same as FDA's (*e.g.,* NYS CLEP has a different risk classification and premarket review program). However, as discussed in section V.B.2, FDA intends to exercise enforcement discretion with respect to premarket review requirements for LDTs approved by NYS CLEP because FDA believes that NYS CLEP has a program that provides for certain mitigations that help reduce the risk of harm from inaccurate and unreliable LDTs. See section V.B.2 for further information. FDA notes that this is an enforcement discretion policy and not a substitute for FDA premarket review or a ''stand in for FDA regulation.'' Further, as described in section V.B.2, FDA generally intends to exercise enforcement discretion with respect to premarket review requirements, but not other FDA requirements such as MDR reporting, for LDTs approved by NYS CLEP. See section V.B.2 for further information.

(Comment 149) One comment asked whether an enforcement discretion policy for NYS CLEP-approved LDTs would include those used on people across all states, or whether the policy would be limited to NYS CLEP-approved tests used only in New York State.

(Response 149) FDA generally intends to exercise enforcement discretion with respect to premarket review requirements for LDTs approved by NYS CLEP. As explained in section V.B.2, these are LDTs with NYS CLEP approval, conditional approval, or within an approved exemption from full technical documentation granted by NYS CLEP. The enforcement discretion policy with respect to LDTs approved by NYS CLEP applies regardless of whether that LDT is performed on specimens from NYS or elsewhere, as the risk mitigations upon which the policy is based apply regardless of where the specimens are coming from. This enforcement discretion policy only applies to the version of the LDT approved by NYS CLEP. If the laboratory is offering and using a different version of the LDT that is not approved by NYS CLEP, this enforcement discretion policy would not apply.

(Comment 150) FDA received comments suggesting that NYS CLEP should be granted ''deemed'' status and tests subject to NYS CLEP should be exempt from the phaseout of FDA's general enforcement discretion approach for LDTs.

(Response 150) As described in section V.B.2, FDA generally intends to exercise enforcement discretion with respect to premarket review requirements for LDTs approved by NYS CLEP. FDA's policy with respect to LDTs approved by NYS CLEP is an enforcement discretion policy and not a substitute for FDA premarket review. Further, FDA intends to phase out its general enforcement discretion approach with respect to other regulatory requirements, such as registration and listing and MDR requirements, for these LDTs. Enforcement of other requirements will help to protect and promote the public health, *e.g.,* by providing FDA and the public with important information about these tests. For additional discussion of FDA's policy with respect to LDTs approved by NYS CLEP, see section V.B.2.

6. Timing and Structure of the Phaseout Policy

(Comment 151) FDA's proposed phaseout policy described a gradual phaseout of the general enforcement discretion approach for LDTs that would occur in stages over a total period of 4 years. FDA received several comments stating that this timeline is too short and should be extended. These comments generally proposed that FDA modify the phaseout period to last a total of 7–10 years, though at least one comment proposed a significantly longer phaseout period of 15 years. One

comment suggested that each stage of the phaseout period should be extended by an additional year. These comments generally characterized the length of the phaseout period as unreasonable or not workable, and emphasized laboratories' lack of experience and infrastructure for complying with FDA requirements; the number of tests that laboratories will have to address and associated resource demands; FDA's resource limitations; the time required for laboratories to become familiar with applicable requirements; and general uncertainty regarding how laboratories will navigate the phaseout process. One comment noted that in a survey of 39 laboratories, only 1 laboratory stated that it would likely be able to implement all applicable requirements within the 4-year timeframe (this survey is described in Ref. 170). In describing this survey finding, the comment characterized the proposed phaseout timeline as ''unrealistic since the requirements for FDA approval cannot be conducted in a timely fashion due to the large number of LDTs and insufficient resources,'' and further stated that ''[FDA's] review process is also lengthy once data is submitted.'' Some comments suggested that the length of the phaseout period be extended for certain types of tests, such as diagnostic flow cytometry leukemia and lymphoma immunophenotyping tests, due to the challenges associated with preparing premarket submissions for such tests.

In addition, one comment noted that the average time to bring a medical device to market has been estimated to range from 2–7 years, and several comments noted that FDA had proposed a longer phaseout period of 9 years in 2014. One comment noted that the VALID Act had proposed a transition period of up to 10 years. Another comment stated that the reliance interests of laboratories would be harmed if the length of the phaseout period were not extended, given the challenges that laboratories would face from competing demands for limited resources.

FDA also received comments stating that the overall length of the phaseout period should be reduced. One comment stated that if laboratories have been doing ''the right thing,'' they should not require 4 years to comply with applicable requirements, and patients should not have to wait 4 years to be able to rely on accurate tests. Another comment suggested that FDA consider the Agency's expectations for a startup conventional IVD manufacturer and apply the same expectations to laboratory manufacturers, stating that a conventional manufacturer could not take 4 years to come into compliance. One comment stated that FDA should shorten the phaseout period for premarket approval requirements for tests that pose a higher risk of harm from 4 years to 1–2 years.

FDA also received a comment that agreed with FDA's phaseout timeline. This comment stated that the timeline would give laboratories adequate time to come into compliance with applicable requirements while allowing FDA to gather information on the LDT market and prioritize review of high-risk tests.

(Response 151) After considering the public comments and the impact of new enforcement discretion policies included in the final phaseout policy, FDA has determined that it should retain a 4-year, gradual phaseout of the Agency's general enforcement discretion approach for LDTs.

As described in section II.F of the FRIA (Ref. 10), FDA has estimated the time and resources that will be required for laboratories to comply during each stage of the phaseout policy. We estimate total costs to be approximately $101 million for stage 1 in year 1 for 1,275 affected laboratories, $113 million for stages 1 and 2 in year 2 for 1,275 affected laboratories, $386 million for stages 1 through 4 in year 3 for 858 affected laboratories, and $1.65 billion for stages 1 through 5 for 849 affected laboratories with 7,554 premarket submissions in subsequent years (year 4 to year 20).

Based on these estimates, and in consideration of the factors discussed for each stage of the phaseout policy in section V.C, FDA has determined that the time allotted for each stage of the phaseout will give laboratories adequate time to comply with the requirements that are the focus of that stage. For example, FDA has determined that a 1-year time period is adequate to phase out the general enforcement discretion approach for LDTs with respect to MDR requirements and correction and removal reporting requirements under stage 1 of the phaseout policy, given that laboratories should already have some processes in place for detecting problems with their IVDs to comply with CLIA regulations, and in stage 1 laboratories will be reporting adverse events and malfunctions to FDA in accordance with part 803. Additional discussion of the timeframe associated with stage 1 and the timeframes associated with other stages of the phaseout policy is provided in response to comments 154–159. Additional discussion of FDA's phaseout of the general enforcement discretion approach with respect to particular requirements under each stage of the phaseout policy is provided in sections VI.F.7–13 of this preamble.

In addition, changes have been made to the phaseout policy that directly address the concerns raised in comments that laboratories' reliance interests will be harmed if the phaseout period is not extended, and that laboratories will not be able to come into compliance during the time periods set forth in the phaseout policy (*e.g.,* due to the lack of experience with FDA oversight, the cost of compliance, etc.). FDA recognizes that some laboratories may lack familiarity, experience, or existing infrastructure for complying with FDA requirements. However, we note that, as discussed elsewhere in this preamble, there are numerous existing final guidance documents and educational resources made available by FDA to help companies comply with requirements applicable to devices. FDA also intends to issue guidance documents or make other resources available to provide further clarity to stakeholders regarding implementation of certain aspects of the phaseout policy following issuance of this rule. FDA also recognizes that the time and resource demands associated with each stage of the phaseout policy may be significant for laboratories, and a laboratory's efforts to come into compliance with the requirements associated with different stages of the phaseout policy may need to take place concurrently. However, as described in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs. As discussed further in section V.B.3, this policy takes into account that laboratories may have made financial investments and other decisions based on a past assumption about the presence of the general enforcement discretion approach.

In addition, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs that are approved by NYS CLEP. As a result of these policies, the time and resources associated with stages 3, 4, and 5 of the phaseout policy are estimated to be significantly reduced as

compared to the estimates in the PRIA (see sections II.F.3, 4, and 5 of the FRIA (Ref. 10)). With fewer competing demands, laboratories may be better able to comply with the requirements that are the focus of stages 1 and 2 of the phaseout policy.

While the Agency appreciates the information provided in a comment regarding a survey in which only 1 out of 39 laboratories stated that the laboratory would likely be able to implement all applicable requirements within the proposed 4-year phaseout period, this survey did not take into account the enforcement discretion policies described in the preceding paragraph. The comment that described this survey emphasized the perceived burden of compliance with FDA's premarket review requirements, yet under many of the enforcement discretion policies included in the final phaseout policy, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements. FDA also notes that this survey was conducted with a small sample size and reflects the subjective views of entities that would be subject to increased FDA oversight under the phaseout policy.

Regarding the comments on extending the phaseout policy in light of demands on FDA resources, we note that the enforcement discretion policies included in the final phaseout policy will significantly reduce these demands. The annualized costs to FDA over 20 years are approximately $408 million less than the estimates in the PRIA (in the FRIA, the primary estimate for FDA review costs over 20 years at a 7 percent discount rate are $121 million, as compared to $530 million in the PRIA). These policies, and in particular the policy for currently marketed IVDs offered as LDTs, also address concerns that FDA should modify the length of the phaseout period for certain types of tests to account for perceived challenges associated with preparing premarket submissions for such tests.

FDA does not believe it would be in the best interest of public health to adopt a longer phaseout period or to extend the time allotted for any of the stages in the phaseout policy. Based on information currently available to the Agency regarding the risks associated with IVDs offered as LDTs (as discussed in the NPRM and sections III.B and VI.C of this preamble), an extension of the phaseout policy to a period longer than 4 years would be inconsistent with FDA's mission to protect the public health. FDA encourages manufacturers to begin working towards compliance with applicable requirements as early as possible, and to engage with FDA through a Pre-Submission or other available mechanism.

FDA recognizes that the Agency proposed a different timeline for phasing out its general enforcement discretion approach for LDTs in 2014, which, if finalized, would have involved a longer overall phaseout period. However, as noted in section III.B and described in the NPRM, FDA's concerns regarding the risks associated with IVDs offered as LDTs have grown in recent years, and more recent evidence from a variety of sources underscores the pressing need to better assure the safety and effectiveness of IVDs offered as LDTs (88 FR 68006 at 68009). Diagnostic testing is increasingly important; for example, as time goes on, more novel treatments will require use of a specialized test to identify patients likely to benefit from those treatments.[85] Furthermore, IVDs offered as LDTs are a growing sector of the diagnostic testing market (Ref. 4). FDA anticipates that IVDs will continue to become more complex and play a greater role in modern healthcare (Ref. 3). The U.S. LDT market size is anticipated to grow 6 percent from 2023 to 2030 due to varying factors including increased use in personalized medicine and rising prevalence of chronic diseases. (Id.) FDA is therefore taking steps to oversee the safety and effectiveness of IVDs regardless of where they are manufactured, so that both now and in the future, patients can have confidence about the tests used in their care.

Moreover, the longer timeline proposed in 2014 included a phaseout of enforcement discretion for LDTs already on the market, whereas the phaseout policy described in this preamble phases out enforcement discretion with respect to premarket review for IVDs offered as LDTs entering the market after publication of the final rule.

We disagree with comments that the time to bring a device to market or any timing provisions in the proposed VALID Act should dictate the timeline of the phaseout policy. For example, we note that even if the average time to bring a medical device to market ranges from 2–7 years, as one comment asserted, this does not mean that 7 years is needed to prepare and submit a premarket submission to FDA, even if new data must be collected to support the submission. FDA is aware of estimates that refer to the time required to bring a new device all the way from concept to market as 3–7 years (Ref. 171). Not only does this cover development time prior to FDA review, but it is also based on all devices including permanent implants, which generally take longer to develop and evaluate than IVDs.

FDA also does not agree that the length of the phaseout period should be reduced to less than 4 years. A reduced timeline would mean phasing out the general enforcement discretion approach with respect to premarket review requirements before the start of a new user fee cycle, which would not provide industry with a prior opportunity to participate in user fee negotiations with the knowledge that laboratory manufacturers will be expected to comply with premarket review requirements for new IVDs offered as LDTs. A shorter overall phaseout timeline would also place greater concurrent demands on laboratory resources. For the same reasons, FDA does not believe that the phaseout period for premarket review requirements for high-risk IVDs offered as LDTs should be shortened from 4 years to 1–2 years. FDA notes that the phaseout policy already prioritizes phasing out the general enforcement discretion approach for high-risk IVDs offered as LDTs by phasing out enforcement discretion with respect to premarket review requirements for high-risk tests prior to doing so for moderate-risk and low-risk tests.

Finally, some comments suggested that the length of the phaseout period be extended for certain types of tests, such as diagnostic flow cytometry leukemia and lymphoma immunophenotyping tests, due to the challenges associated with preparing premarket submissions for such tests. We believe the timelines for premarket review are reasonable and appropriate, as discussed further in section V.C and the responses to comments in section VI.F.13. Moreover, providing different timelines for the phasing out of the enforcement discretion approach for different types of IVDs would be overly complicated for laboratories to follow and for FDA to implement.

(Comment 152) FDA received comments stating that the timing of certain stages of the phaseout policy should be measured from when FDA issues final guidance documents or other educational materials regarding implementation of the phaseout policy, rather than from publication of the phaseout policy itself.

(Response 152) FDA disagrees with these comments. Although FDA intends to issue guidance documents or make

[85] *See, e.g.,* Ref. 23 (''Demand is increasing in the CDx market, due to the paradigm shift to precision medicine.'').

other resources available to provide further clarity to stakeholders regarding implementation of certain aspects of the phaseout policy, and intends to issue any such guidance documents or provide other resources expeditiously, there are numerous existing final guidance documents and educational resources on FDA's website to help companies comply with FDA requirements applicable to devices. Moreover, this preamble includes extensive information about the phaseout policy and FDA's expectations, as well as references to final guidance documents and resources available to laboratories.

(Comment 153) One comment stated that it was unclear whether FDA intended the stages of the phaseout policy to run concurrently or consecutively. The comment requested that FDA clarify this point.

(Response 153) The timing for each stage of the phaseout policy is based on the date that FDA publishes this final rule and not when the previous stage ends. For example, stage 3 will begin after 3 years, measured from the date of publication of this final rule and not relative to the timing of any other stages. However, because each stage will begin after a different length of time has passed from the date of publication of this final rule, the stages will commence in sequence. For example, as described in section V.C, stage 1 will commence 1 year after publication of this final rule. Upon the start of stage 1, FDA will generally expect compliance with applicable MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files). Stage 2 will commence 2 years after publication of this final rule. Upon the start of stage 2, FDA will generally expect compliance with applicable requirements discussed under stage 2, in addition to continued compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files) for which the general enforcement discretion approach was phased out at the beginning of stage 1.

(Comment 154) One comment stated that ending the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements 1 year after publication of the phaseout policy is appropriate, as this timeline will enable FDA to quickly identify LDTs potentially associated with safety or performance issues. This comment further stated that laboratories that are in compliance with CLIA requirements should already have systems in place for detecting problems with their tests. Another comment stated that FDA should end the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements 6 months after publication of the phaseout policy. According to this comment, 6 months is more than adequate to establish procedures for identifying events that need to be reported and for implementing a reporting mechanism (*e.g.,* through the FDA eSubmitter software). In addition, this comment recommended that all subsequent stages of the phaseout policy commence 6 months sooner than proposed by FDA, as a result of the shorter timeline for phasing out the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements under stage 1.

(Response 154) FDA agrees with the comment that stated that phasing out the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements 1 year after publication of the phaseout policy is appropriate, for the reasons discussed in section V.C. FDA also agrees that most laboratories should be able to establish and implement procedures for complying with MDR requirements and correction and removal reporting requirements within 6 months; however, we also believe it is appropriate to provide a little more time to help to ensure compliance with the requirements.[86] In recognition that phasing out the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements too quickly may lead to less effective reporting, FDA has determined to phase out the general enforcement discretion approach with respect to these requirements 1 year after publication of this final rule. As such, FDA also disagrees that all subsequent stages of the phaseout policy should commence 6 months sooner than proposed by FDA in the proposed phaseout policy.

(Comment 155) FDA received one comment which expressed concern that FDA had not proposed to phase out the general enforcement discretion approach with respect to the requirements addressed in stage 2 of the phaseout policy in a manner that would distinguish between IVDs of different risk levels. The comment stated that a decision not to pursue such an approach, which FDA had previously considered, would be arbitrary and not justified.

(Response 155) FDA does not agree that the phaseout of the general enforcement discretion approach with respect to the requirements addressed in stage 2 of the phaseout policy should be conducted in a manner that distinguishes between IVDs of different risk levels, or that the Agency's decision not to structure the phaseout policy in the manner suggested by the comment is arbitrary and unjustified. The requirements for which FDA will expect compliance in stage 2 of the phaseout policy, including registration and listing requirements under 21 U.S.C. 360, part 607, and part 807 (excluding subpart E), labeling requirements under 21 U.S.C. 352 and parts 801 and 809, subpart B, and investigational use requirements under 21 U.S.C. 360j(g) and part 812, are general controls under section 513(h)(1) of the FD&C Act, and are thus generally applicable to all devices. FDA has determined that it would best serve the public health to phase out the general enforcement discretion approach with respect to these requirements 2 years after publication of this final rule, irrespective of the risk classification of the device.

In the NPRM, FDA acknowledged that this proposal was different from FDA's prior statements in the 2017 Discussion Paper (88 FR 68006 at 68025), wherein FDA discussed a scenario in which the timing of FDA's expectations for compliance with certain requirements might depend on the type of premarket review applicable to the device (Ref. 57). FDA anticipates that 2 years is adequate time for laboratories to come into compliance with the requirements addressed in stage 2, and structuring the phaseout policy in this manner is easier for laboratories to comprehend and follow, easier for FDA to implement, and more responsive to the pressing need for additional FDA oversight of IVDs offered as LDTs.

(Comment 156) One comment requested clarification as to whether FDA intends to phase out the general enforcement discretion approach with respect to QS provisions regarding complaint files under § 820.198 during stage 1 of the phaseout policy (when FDA generally intends to phase out the general enforcement discretion approach with respect to MDR requirements), rather than during stage 3 of the phaseout policy, given that FDA's regulations regarding MDR requirements state that ''[i]f you are a manufacturer, you may maintain MDR

[86] Some comments submitted on the draft guidance documents that FDA issued in 2014, in which FDA proposed a 6-month timeframe for laboratory compliance with MDR requirements, suggested that a longer period would be appropriate.

event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter'' (§ 803.18(e)).

(Response 156) FDA has modified the phaseout policy to clarify that while FDA generally intends to phase out the general enforcement discretion approach with respect to QS requirements in stage 3 of the phaseout policy (as described in section V.C), FDA intends to phase out the general enforcement discretion approach with respect to the QS requirements under § 820.198 (complaint files) in stage 1 of the phaseout policy, given the connection between the complaint investigation and complaint file requirements and the MDR reporting regulations.

(Comment 157) FDA received one comment which stated that it could take up to a year for a sizable healthcare system to prepare a list of LDTs, before the healthcare system could list those LDTs with FDA.

(Response 157) FDA appreciates that it may take time for laboratories to identify and prepare a list of their IVDs offered as LDTs before being able to comply with device listing requirements under the FD&C Act and FDA's regulations. Under FDA's phaseout policy, FDA is phasing out the general enforcement discretion approach with respect to registration and listing requirements 2 years after publication of this final rule, which will provide sufficient time for laboratories to come into compliance even if a year is needed for some laboratories to prepare a comprehensive list of their IVDs offered as LDTs.

(Comment 158) One comment stated that 3 years could be sufficient to develop a quality management system that complies with QS requirements, but that developing a quality management system that is both QS-compliant and CLIA-compliant will be complex and require uncommon knowledge and expertise. This comment also stated that to develop a quality management system that meets FDA's expectations, laboratories will require guidance from FDA with detailed descriptions of the differences that exist between QS requirements and CLIA regulations. The comment urged FDA to phase out the general enforcement discretion approach with respect to QS requirements 4 years after publication of the phaseout policy or 1 year after FDA issues a guidance document regarding the differences that exist between the QS requirements and CLIA regulations, whichever comes later. The comment also stated that this approach should provide FDA sufficient time to amend the QSR to harmonize with international standards.

(Response 158) FDA does not agree that the Agency should phase out the general enforcement discretion approach with respect to QS requirements 4 years after publication of the phaseout policy, or 1 year after issuance of a guidance document describing differences that exist between QS requirements and CLIA regulations, rather than 3 years after publication of the phaseout policy as proposed by FDA. While FDA recognizes that laboratories will be complying with applicable CLIA requirements as well as applicable QS requirements, laboratories already comply with CLIA requirements.

Moreover, as discussed in section V.C, compliance with CLIA requirements provides certain quality assurances that may be relevant to laboratories' manufacturing practices, and laboratories may be able to apply concepts set forth under CLIA requirements to manufacturing activities regulated by FDA. As such, and as further discussed in section V.C.3, FDA intends to phase out the general enforcement discretion approach with respect to only a subset of QS requirements rather than all applicable requirements for LDTs. This subset of QS requirements is listed in section V.C.3.

FDA also notes that it has already finalized amendments to the QSR (effective in February 2026), and the amended QS requirements, which align more closely with international consensus standards for devices, will be in effect prior to the beginning of stage 3 (see 89 FR 7496). FDA anticipates providing to all its stakeholders, including laboratories, timely guidance on compliance with the regulatory requirements in that rule. In addition, several educational resources regarding the QS requirements currently applicable under part 820 are currently available on FDA's website (see Ref. 72).

(Comment 159) One comment stated that FDA should phase out the general enforcement discretion approach with respect to premarket review requirements after 4 years for PMAs and after 9 years for 510(k)s and De Novo submissions. Another comment stated that FDA should phase out the general enforcement discretion approach with respect to premarket review requirements after 5 years for PMAs, after 7 years for De Novo requests, and after 9 years for 510(k)s. In addition, one comment stated that if FDA does not continue the general enforcement discretion approach with respect to premarket review and QS requirements for ''existing LDTs,'' FDA should, in the alternative, consider ''exempting or more gradually phasing in premarket review and QSR requirements for LDTs that meet certain criteria,'' such as those ''certified by [NYS CLEP].'' Another comment stated that FDA should extend the phaseout by 5 years for premarket review and QS requirements for LDTs introduced or modified after the effective date of the rule that have approval from NYS CLEP, receive coverage from the MolDx Program, or are performed in a CLIA-certified clinical laboratory accredited by CAP, unless there is credible information establishing that the LDT is marketed with insufficient evidence of analytical or clinical validity, that the LDT is marketed with false or misleading analytical or clinical claims, or that it is probable that the LDT will cause serious adverse health consequences.

(Response 159) After considering the public comments and the impact of other policies included in the phaseout policy, for the reasons discussed in section V.C, FDA has determined that it should phase out the general enforcement discretion approach: (1) with respect to QS requirements (other than requirements under § 820.198 (complaint files)), 3 years after publication of this final rule; (2) with respect to premarket review requirements for high-risk IVDs, 3½ years after publication of this final rule; and (3) with respect to premarket review requirements for moderate-risk and low-risk IVDs (that require premarket submissions), 4 years after publication of this final rule. For further discussion of these stages and the QS and premarket review requirements, see sections V.C.3–5, VI.F.12, and VI.F.13.

FDA disagrees that the phaseout policy should be modified as suggested by these comments. As discussed in response to comment 151, FDA has determined that extending the timelines for stages of the phaseout policy is not necessary to provide an adequate opportunity for laboratories to comply with applicable requirements or to effectively implement the phaseout policy, and is not in the best interest of the public health. This is true even in the case of IVDs offered as LDTs covered by the MolDx Program or performed in a CAP-accredited CLIA-certified laboratory. As discussed in response to comments in section VI.C.3, neither the MolDx Program nor CAP accreditation

provides a substitute for FDA oversight or mitigates the need for FDA oversight. With respect to LDTs approved by NYS CLEP, as described in section V.B.2, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP. As further discussed in section V.B.2, compliance with the QS requirements that FDA intends to enforce for these LDTs will help provide for quality manufacturing of these LDTs. FDA understands that NYS CLEP's clinical laboratory standards (which exceed CLIA requirements in certain respects) and its premarket review requirements collectively could generally satisfy these QS requirements except as to certain aspects of design control documentation, and FDA therefore does not anticipate significant additional burden with respect to compliance with these QS requirements for laboratories offering LDTs approved by NYS CLEP.

We further note that the absence of ''credible information'' establishing a lack of evidence of analytical or clinical validity, false or misleading claims, or a probability that the IVD offered as an LDT will cause serious adverse health consequences does not justify delaying the phaseout of FDA's general enforcement discretion approach with respect to QS and premarket review requirements. Even in the absence of such ''credible information,'' risks may exist that will be mitigated by compliance with applicable QS and premarket review requirements.

In addition, as described above, one comment submitted to the docket suggested that FDA exempt or more gradually phase in premarket review and QS requirements for certain LDTs as an alternative option in the event that FDA determined not to continue the general enforcement discretion approach with respect to premarket review and QS requirements for existing tests. As described in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in certain limited ways.

(Comment 160) FDA received several comments which stated that the Agency should end the general enforcement discretion approach with respect to MDR requirements and/or registration and listing requirements prior to deciding whether and when to phase out the general enforcement discretion approach with respect to other applicable requirements. These comments generally asserted that FDA lacks certain information necessary to inform the feasibility of the phaseout policy. For example, one comment stated that FDA is missing information regarding how many clinical laboratories currently offer LDTs, how many LDTs are on the market, how frequently LDTs are modified, the nature of those modifications, and the intended use(s) of those LDTs. In addition to these comments, a comment suggested that FDA's 4-year phaseout policy should apply only to high-risk IVDs offered as LDTs, after which FDA should determine how best to proceed with respect to other IVDs offered as LDTs.

(Response 160) FDA does not agree that the Agency should phase out the general enforcement discretion approach only with respect to MDR requirements and/or registration and listing requirements prior to determining how to proceed with respect to other applicable requirements. Although FDA is prioritizing the phaseout of the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements (followed by registration and listing requirements) to obtain additional information about potentially harmful IVDs offered as LDTs as soon as feasible (see discussion in section V.C), FDA already possesses enough information to determine that there is no longer a sound basis to generally treat LDTs differently from other IVDs and that the general enforcement discretion approach for LDTs does not best serve the public health. As discussed in response to comment 151, recent evidence from a variety of sources underscores the pressing need to better assure the safety and effectiveness of LDTs. Adopting a phaseout policy that only addresses MDR and registration and listing requirements at this time would inevitably delay the phaseout of the general enforcement discretion approach for other requirements beyond a 4 year period, and thus would be inconsistent with FDA's mission to protect the public health.

In addition, the FRIA (Ref. 10) provides estimates of much of the information that the comments characterized as ''missing,'' such as how many laboratories currently offer IVDs as LDTs and how many IVDs offered as LDTs are on the market. Although we acknowledge that these are estimates, and we do not have exact numbers, we do not believe that should delay the phaseout of the general enforcement discretion approach, which we have determined is not in the best interest of public health. FDA also does not agree that certain information, such as the intended use(s) of all IVDs offered as LDTs, is necessary for FDA to determine whether and when to phase out the general enforcement discretion approach with respect to certain requirements.

FDA likewise does not agree that the Agency should phase out the general enforcement discretion approach for high-risk IVDs offered as LDTs prior to determining how to proceed with respect to other IVDs offered as LDTs. As FDA explained in the NPRM and in this preamble, the Agency is aware of information showing that there is a high variability in the performance of IVDs offered as LDTs even in circumstances where the test technology is relatively simple and well-understood, and where the tests are low risk (88 FR 68006 at 68010–11).

(Comment 161) Some comments suggested that FDA consider stratifying the phaseout policy by annual test volume, due to the potential impact of high-volume LDTs on larger patient populations.

(Response 161) FDA does not agree that FDA's general enforcement discretion approach for LDTs should be phased out on a different timeline, in a different sequence, or otherwise in a different manner based on annual test volume. The importance of having assurances regarding the safety and effectiveness of IVDs offered as LDTs does not depend on whether IVDs are offered in low or high volume. Moreover, we think stratifying the phaseout in this way would be overly complicated for laboratories to comprehend and follow, and for FDA to implement.

(Comment 162) Some comments stated that FDA did not provide sufficient clarity or specificity regarding how it intends to implement the phaseout policy, resulting in uncertainty among laboratories which may have a ''chilling effect.'' Another comment stated that the phaseout policy is too complicated for laboratories to follow.

(Response 162) We believe the information included in the phaseout policy, including the timeline for the various stages in the phaseout policy and information regarding enforcement discretion policies described in this preamble, provides clear expectations for laboratories that offer IVDs as LDTs. FDA appreciates that additional guidance regarding implementation of the phaseout policy may facilitate

efforts by laboratories to comply with applicable requirements. As discussed more fully in response to comment 291, FDA anticipates issuing a small entity compliance guidance, issuing guidance documents, and/or making additional resources available on specific topics over the course of the phaseout period.

(Comment 163) A comment sought clarification regarding how the phaseout policy will apply to LDTs that are developed during the phaseout period, for example, LDTs that are developed between issuance of the rule and the start of stage 1 of the phaseout policy, or that are developed between successive stages of the phaseout policy.

(Response 163) Laboratories that first introduce IVDs offered as LDTs after the publication of the final rule and during the phaseout period will be expected to comply with requirements consistent with the dates identified for each stage of the phaseout policy. For example, an IVD offered as an LDT introduced 2½ years after publication of this final rule, which would be after the start of stage 2 of the phaseout policy but before the start of stage 3, would be expected to comply with requirements for which FDA has already phased out the general enforcement discretion approach under stages 1 and 2. FDA would expect compliance with QS requirements upon the start of stage 3 (other than requirements under § 820.198 (complaint files), for which FDA would have already phased out the general enforcement discretion approach under stage 1), and so on for stages 4 and 5 as applicable. Laboratories should also be aware of the enforcement discretion policies included in the phaseout policy, including those set forth in section V.B.

7. MDR Requirements

(Comment 164) Many comments supported FDA's proposal to end its general enforcement discretion approach with respect to the MDR requirements within 1 year from publication of the final rule. A comment suggested that this approach was reasonable regardless of the risk or volume of the LDTs the laboratory distributed. However, another comment suggested that FDA would need to provide additional guidance on the types of events it is interested in to avoid being flooded with reports about events that are of the type that are within CLIA's purview. This comment stated that the vast majority of laboratory adverse events are due to human error (*e.g.,* manual mispipetting or a lost specimen) and not due to a design flaw with an LDT. Along these lines, another comment requested that FDA provide definitions of certain terms in the context of laboratories, such as: FDA reportable adverse event, causal for MDR requirements, malfunction, and recall. Another suggested that such definitions align with reporting for ''conventional'' IVDs. Yet another comment suggested that FDA continue the general enforcement discretion approach for the MDR requirements until FDA provides education on this topic.

(Response 164) FDA agrees with the comments supporting FDA's proposed phaseout of enforcement discretion regarding MDR reporting for IVDs offered as LDTs. As stated in section V.C, FDA is phasing out the general enforcement discretion approach with respect to the MDR requirements within one year from publication of the final rule for IVDs offered as LDTs. FDA acknowledges that some laboratories may not be familiar with FDA's MDR requirements in part 803. However, FDA disagrees that this justifies waiting to phase out the general enforcement discretion approach with respect to those requirements. Laboratories should already have some processes in place for detecting problems with their IVDs to comply with CLIA regulations. In addition, FDA already has a number of resources to assist manufacturers in complying with MDR requirements, including guidance, information on FDA's website, and webinars. These include, for example, FDA's final guidance document entitled ''Medical Device Reporting for Manufacturers'' (Ref. 172), and information on ''How to Report Medical Device Problems'' on the Agency's website (Ref. 173). Laboratories can better understand their responsibilities under part 803 by consulting these resources. FDA also intends to develop additional educational resources on MDR reporting to assist laboratories transitioning to compliance with these requirements.

With respect to the comment requesting that FDA provide definitions of certain terms in the context of laboratories, we note that the following terms are already defined in part 803 for purposes of MDR reporting requirements: ''MDR reportable event'' (§ 803.3(o)(2)), ''caused or contributed'' (§ 803.3(c)), and ''malfunction'' (§ 803.3(k)). These definitions apply to MDR reporting requirements regardless of whether the manufacturer of a device is a laboratory and regardless of whether the device at issue is an IVD or another kind of device. Although the term ''recall'' is not used in FDA's MDR regulations, we note that FDA regulations define the term ''recall'' at 21 CFR 7.3(g) (voluntary recalls) and 21 CFR 810.2(k) (mandatory device recalls). FDA has multiple resources for industry regarding recalls available on its website (see, *e.g.,* Ref. 174).

Further, we note that MDR reportable events can include events caused by user error and are not limited to events resulting from a flaw in device design. For example, under the regulations, a device manufacturer must submit a report to FDA when it becomes aware of information that reasonably suggests that the manufacturer's device may have caused or contributed to a death or serious injury (§ 803.50(a)(1)). Section 803.3(c) defines ''caused or contributed,'' to specifically include death or serious injury events occurring as a result of labeling or user error, among other things. However, if the manufacturer determines that an event is solely the result of user error with no other performance issue, and there has been no device-related death or serious injury, the manufacturer is not required to submit an MDR report. It would therefore generally be unlikely that a laboratorian losing a specimen (as referenced in the comment) would be considered a reportable event.

Importantly, CLIA does not require laboratories to report suspected device-associated adverse events to any Federal oversight authority. Therefore, we disagree with the comment suggesting that the phaseout of enforcement discretion for MDR requirements will result in a flood of MDRs for events ''of the type within CLIA's purview.''

(Comment 165) Several comments argued that MDR requirements should not apply to laboratories. Some of these comments indicated that the framework is not appropriate for laboratories, while others asserted that CLIA already covers the MDR activities. In particular, a comment stated that CLIA requires laboratories to identify, document, and perform corrective measures for any laboratory errors, including patient harm and that this documentation is reviewed by a CLIA inspector, its accrediting bodies, or exempt States. Further, the comment stated that CMS-approved accrediting organizations are required to notify CMS within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the patient or a hazard to the general public. Another comment suggested that FDA should not ''subject'' laboratories that have a system for reporting errors, and which are integrated within a health system, to the MDR requirements. Another comment opined that compliance with the MDR requirements was not

warranted because events were rare and for most laboratories never occur.

(Response 165) FDA disagrees with the suggestion that laboratory compliance with the MDR requirements is not warranted. MDR reporting is an important postmarket surveillance tool that FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of medical devices. FDA also disagrees that CLIA ''covers'' activities equivalent to complying with MDR reporting requirements. As explained in our responses to comments in section VI.C.2, the CLIA requirements are geared towards identifying issues and problems with the laboratory operations, not with an LDT itself. Further, unlike FDA's MDR regulations, CLIA regulations do not require centralized reporting of suspected, device-associated adverse events to inform tracking and trending by a Federal oversight authority. FDA's MDR regulations require that a manufacturer report to FDA within specified timeframes when the manufacturer receives or otherwise becomes aware of information reasonably suggesting that a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that the manufacturer markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur (§§ 803.50(a) and 803.53). It is important that FDA receive this information to enable it to identify trends and detect safety signals. For example, FDA received MDRs regarding incorrect test results due to ''carryover'' in automated test systems. ''Carryover'' is when a falsely high result is obtained due to residual analyte from a high concentration sample that was tested immediately prior. Upon review of trends across MDRs and further investigation, FDA found that ''carryover'' caused inaccurate results across multiple automated test systems. Based on this finding, FDA worked to ensure that manufacturers of affected automated test systems addressed this issue. This included FDA classification of recalls for affected tests and manufacturer notification to users. As another example, FDA received MDRs indicating that ambient temperature in laboratories was affecting test results for common tests. Upon review of trends across MDRs and further investigation, we found that temperature interference caused inaccurate results across different tests that used different instruments from different manufacturers in different laboratories. Based on this finding, manufacturers redesigned affected tests to address this issue and submitted the changes for FDA review.

For similar reasons, FDA disagrees that there generally should be continued enforcement discretion for MDR requirements for laboratories that have a system for reporting errors, and which are integrated within a health system. Being integrated within a health system does not ensure centralized reporting of suspected, device-associated adverse events to inform tracking and trending by a Federal oversight authority in accordance with the manufacturer reporting requirements in part 803. Continuing to exercise enforcement discretion for the MDR requirements for all the entities identified in the comment would undermine FDA's ability to identify trends or issues with the performance of IVDs offered as LDTs.

Moreover, FDA disagrees with the comment indicating that adverse events associated with LDTs are rare. In the absence of the type of reporting required by the MDR regulations, FDA has no assurance that adverse events associated with IVDs offered as LDTs are ''rare.'' Laboratories may not be tracking or reporting these adverse events currently, but that does not mean that they do not occur. However, if MDR reportable events are truly rare for certain laboratories, that should minimize additional burden of complying with the MDR requirements.

8. Registration and Listing Requirements

(Comment 166) FDA received many comments supporting the need for and rationale behind the proposal to phase out the enforcement discretion approach for registration and listing requirements. One comment emphasized the need to create an active and accurate account of LDTs offered. Some comments voiced the need for FDA to identify and address poorly performing tests and the importance of transparency in terms of LDTs currently in use and any related adverse events.

(Response 166) FDA agrees that registration and listing information will provide FDA with a better understanding of the exact universe of IVDs offered as LDTs and facilitate oversight. FDA is phasing out the general enforcement discretion approach with respect to registration and listing requirements under 21 U.S.C. 360 and part 807 (excluding subpart E) 2 years after publication of this final rule. Under this timeline, FDA will be able to utilize registration and listing information to obtain an understanding of the universe of IVDs offered as LDTs to facilitate premarket review of those IVDs.

FDA also agrees with comments supporting FDA addressing poorly performing IVDs offered as LDTs and noting the importance of transparency in terms of any IVD adverse events. Beginning 1 year after the publication date of this final rule, FDA no longer intends to have the general enforcement discretion approach for MDR requirements, among other requirements. Enforcement of MDR requirements will enable FDA to systematically monitor significant adverse events to identify problematic IVDs offered as LDTs, such as those with poor performance or other safety issues.

(Comment 167) One comment suggested that FDA accelerate the phaseout timeline for registration and listing requirements, emphasizing the importance of this information in implementing the rest of the phaseout policy. Some comments agreed with the need to enforce registration and listing requirements but requested that FDA enforce only the elements that are currently required for IVDs and other devices, as it is ''not appropriate to require more elements for LDTs than are currently required for IVDs and medical devices.''

(Response 167) As described in section V.C, FDA has determined that it will best serve the public health to phase out the general enforcement discretion approach with respect to registration and listing requirements 2 years after publication of this final rule. We believe laboratories will have sufficient time to come into compliance with these requirements, and that any less time may not be sufficient. Moreover, FDA is first prioritizing the phaseout of the enforcement discretion approach for MDR requirements (and related complaint file requirements) and correction and removal requirements to obtain information about potentially harmful IVDs offered as LDTs as soon as possible (stage 1).

We note that the registration and listing requirements applicable to IVDs offered as LDTs are the same as those applicable to other IVDs and other devices; FDA is not establishing any new registration and listing requirements as part of this rulemaking.

(Comment 168) Several comments supported the enforcement of registration and listing requirements but urged FDA to phase out the general enforcement discretion approach for registration and listing requirements before phasing out the general enforcement discretion approach for

other requirements. In particular, some comments suggested phasing out the general enforcement discretion approach with respect to registration and listing requirements before MDR requirements.

(Response 168) Under the final phaseout policy, FDA intends to phase out the general enforcement discretion approach for registration and listing requirements in stage 2, after first phasing out the general enforcement discretion approach for MDR requirements and correction and removal reporting requirements (as well as requirements regarding complaint files, given the connection between the complaint investigation and complaint file requirements and the MDR reporting regulations) in stage 1. FDA does not agree that the phaseout policy should address registration and listing requirements before the requirements described in stage 1. FDA has structured the phaseout policy to facilitate obtaining information about potentially harmful IVDs offered as LDTs as soon as feasible. As detailed in this preamble, FDA is concerned that some LDTs on the market may be posing risks to patients. Phasing out the general enforcement discretion approach for MDR requirements and correction and removal reporting requirements (stage 1) will help FDA to systematically monitor significant adverse events and identify problematic IVDs offered as LDTs. In addition, under this phaseout structure, laboratory manufacturers will have sufficient time to comply with registration and listing requirements (stage 2).

FDA therefore intends to phase out the general enforcement discretion approach with respect to MDR requirements and correction and removal reporting requirements before registration and listing requirements. We note that, as stated in section V.C, FDA generally does not intend to enforce requirements to include certain information (*e.g.,* registration numbers, premarket submission numbers) in reports or other submissions to the Agency until the information is addressed in a later stage of the phaseout policy.

(Comment 169) FDA received comments requesting guidance on the information required for registration and listing. One comment suggested that FDA consider creating temporary product codes in order to advance the registration and listing process while product codes are developed.

(Response 169) FDA has instructions and educational resources relating to registration and listing requirements available on FDA's website (Ref. 175). For more information on product codes, see FDA's final guidance on ''Medical Device Classification Product Codes.'' FDA intends to consider creating product codes to be used during the registration and listing process where no product code exists for a given test type. FDA also intends to consider providing additional or more targeted resources on registration and listing requirements over the course of the phaseout period, as appropriate.

(Comment 170) One comment encouraged FDA to establish a clear and publicly available mechanism that would allow patients and providers to ''ascertain the test's level of review.''

(Response 170) As detailed in section V.C, FDA intends to phase out the general enforcement discretion approach with respect to registration and listing requirements 2 years after publication of this final rule. The registration and listing database generally will provide patients and healthcare providers with information about specific IVDs as required by FDA regulation (*see, e.g.,* § 807.26(g)), including information regarding an IVD's ''level of review.'' In particular, we note that the device listing database includes information indicating the type of premarket submission (if any) for the listed device. We recognize that this information may not be included for currently marketed IVDs offered as LDTs, as well as for IVDs offered as LDTs after the publication of the final rule prior to stages 4 and 5.

(Comment 171) FDA received comments regarding the potentially prohibitive costs of registration and listing for some laboratories. One comment recommended FDA enforce ''limited'' registration and listing requirements for existing tests and allow laboratories to provide an ''electronic, internet-based test menu'' housed on the laboratory's website in lieu of individual test listings. Another comment noted that some laboratories maintain publicly available test catalogs online that include such information on tests' intended use, test method, and specimen requirements, and urged FDA to continue to exercise enforcement discretion if laboratories submit links to these test catalogs instead of providing all the information required for listing.

(Response 171) FDA disagrees with these comments. As described in section II.F.2.a of the FRIA, FDA estimates the cost of compliance with registration and listing requirements (this does not include registration fees) to range between $0.20 million and $0.82 million in initial costs and between $0.08 million and $0.34 million in recurring costs for between 590 and 2,362 affected laboratories (as well as between $0.02 million and $0.07 million in initial costs for between 47 and 189 new affected laboratories each year). This amounts to less than $500 per laboratory for compliance with initial registration and listing requirements and slightly over $100 per laboratory for compliance with annual requirements. In addition, under current user fee rates, laboratories must pay an annual establishment registration fee of $7,653. FDA believes it is unlikely for these costs of registration and listing to be prohibitively expensive for laboratories.

FDA also disagrees with the suggestions provided in these comments. FDA has determined that collecting registration and listing information for all laboratories and IVDs offered as LDTs in a uniform and systematic manner will provide the Agency with a holistic and comprehensive view of the universe of IVDs offered as LDTs and better enable FDA to help assure the safety and effectiveness of LDTs. FDA does not believe ''limited'' registration and listing information or the submission of electronic internet-based test menus/catalogs would allow the Agency to have such a comprehensive view.

(Comment 172) One comment stated that laboratories with multiple locations operating under a common quality management system should be allowed to register as a single entity with multiple sites.

(Response 172) With the phaseout of the general enforcement discretion approach, manufacturers of IVDs offered as LDTs generally will be expected to comply with registration and listing requirements under 21 U.S.C. 360, part 607, and part 807 (excluding subpart E) in the same way as other medical device manufacturers. FDA's regulations define establishment in the registration context as ''a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.'' 21 CFR 807.3(c); see also 21 CFR 607.3(c) (defining ''establishment'' in the context of registration requirements for licensed devices as ''a place of business under one management at one general physical location''). To the extent a laboratory has multiple sites in different physical locations, each of these sites would be registered separately. This information is important to inform FDA's oversight, including with respect to conducting inspections. If a laboratory with multiple sites were to register as a single entity that would impede such oversight and FDA's ability to conduct

inspections in a timely and efficient manner.

(Comment 173) One comment suggested that FDA should reduce the burden of registration and listing for clinical laboratories by continuing an enforcement discretion approach for low-risk tests with regard to registration and listing requirements if the laboratory ''documents'' all low-risk LDTs it performs as required by CAP accreditation.

(Response 173) As discussed in section VI.L.4, FDA does not think it is appropriate to continue an enforcement discretion approach for low-risk LDTs, including with respect to registration and listing requirements. Moreover, specifically regarding registration and listing requirements, comprehensive registration and listing is critical to inform FDA's understanding of the universe of IVDs offered as LDTs and to help FDA identify, monitor, and address any issues with IVDs offered as LDTs. In addition, as discussed in response to comment 171, FDA does not anticipate the costs of registration and listing to be prohibitively expensive for laboratories. We also note that under the phaseout policy, FDA expects compliance with registration and listing 2 years after publication of the final rule (stage 2), which we anticipate will be sufficient time to come into compliance with the registration and listing requirements.

9. Corrections and Removals Reporting Requirements

(Comment 174) A comment stated that it did not agree with FDA's proposal to end the general enforcement discretion approach with respect to the correction and removal reporting requirements because it perceives CLIA as adequately covering these requirements. Another comment suggested that FDA continue the general enforcement discretion approach for correction and removal reporting requirements if laboratories have documented corrective action and removal processes.

(Response 174) FDA disagrees with these comments. As described in sections V.C, VI.C.2, and VI.D.8, CLIA requirements are complementary and distinct from FDA requirements. They do not provide adequate oversight of IVDs offered as LDTs to render FDA oversight unnecessary. Under the FD&C Act, certain entities are required to report device malfunctions, adverse events, and corrections and/or removals of a device. Moreover, FDA has authority to take steps when a device presents a risk to the public health, including utilizing its mandatory recall authority. There are not the same requirements and authorities under CLIA.

Enforcement of correction and removal reporting requirements along with the MDR requirements will enable FDA to systematically monitor adverse events, identify problematic IVDs offered as LDTs, and monitor corrections and removals of IVDs offered as LDTs. Moreover, as FDA stated in response to comment 165, MDR is one of the postmarket surveillance tools that FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of medical devices. Under § 806.10, manufacturers and importers are required to submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) to reduce a risk to health posed by the device or (2) to remedy a violation of the FD&C Act caused by the device which may present a risk to health (subject to the limitation and exemption described in § 806.10(a)(2)), within 10 working days of initiating such action. This information is critical to FDA's ability to assure that patients, healthcare providers, and other stakeholders have information about safety or other issues with a device, and to monitor the effectiveness of corrective actions.

Laboratories having ''documented processes'' relating to corrections and removals does not provide the same types of critical assurances. If laboratories do have existing internal processes, however, that should ease the burden of complying with FDA's correction and removal reporting requirements.

10. Investigational Device Exemption Requirements

(Comment 175) Several comments suggested clarification around when investigational use requirements apply to IVDs offered as LDTs. One comment requested that FDA address how the phaseout would impact laboratories that validate reagents for use in a clinical trial where the reagent has been labeled by its manufacturer as being RUO, or validate kits that have been manufactured by a third party but which are validated by the laboratory for a specific purpose for use in a clinical trial, *e.g.,* for clinical trial stratification, inclusion/exclusion determinations, or safety assessments of enrolled subjects. This comment further stated that FDA should be cognizant of the time that is required to get a test ready for use in a clinical trial. Another comment sought clarification regarding potential impacts of the phaseout on clinical research organizations (CROs). This comment observed that it would be redundant for both CROs and their clients to make submissions to FDA for the same IVDs, and further stated that if ''CRO LDTs'' are ''restricted'' by the phaseout, there could be significant delays with respect to drug and IVD development. The comment recommended that FDA consider granting all accredited CRO laboratories ''an exemption'' from applicable requirements. Multiple comments requested clarification regarding clinical trial assays that have no direct impact on patient care, such as for pharmacokinetic analyses for dosing studies. Others cited the importance of IVDs offered as LDTs in drug trials and suggested continued enforcement discretion to support therapeutic product development.

(Response 175) The IDE requirements under section 520(g) of the FD&C Act and part 812 apply to clinical investigations of devices. However, certain categories of clinical investigations of devices are exempt from most IDE requirements under § 812.2(c), and certain other categories of device investigations are deemed to have an approved IDE application under § 812.2(b) if the conditions therein are met. Sponsors and investigators of investigational devices have obligations under the IDE regulations (and related regulations such as parts 50 and 56 (21 CFR parts 50 and 56), regarding protection of human subjects and institutional review boards, respectively). Thus, if a laboratory is a sponsor or investigator of an investigational IVD (including a reagent or instrument), that laboratory is responsible for ensuring compliance with all applicable requirements under the FD&C Act and FDA's regulations. Investigational IVDs may include an IVD that was previously labeled RUO by a third-party manufacturer, an IVD that was previously labeled by a third party manufacturer for a use different from the use in the clinical investigation, or an IVD manufactured by a third party but modified by the laboratory for purposes of the clinical investigation. Additional information regarding RUO-labeled products is available in FDA's final guidance document entitled ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only'' (Ref. 176).

Under the phaseout policy described in section V.C, FDA expects compliance with applicable IDE requirements and other applicable requirements, such as parts 50 and 56, for investigations that involve investigational IVDs offered as

LDTs 2 years after publication of this final rule. FDA has several resources available to help sponsors comply with IDE requirements in the context of clinical investigations of IVDs, including a final guidance document entitled ''In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions,'' which has been available to stakeholders since June 2010 (see Ref. 177).

We recognize that some sponsors of clinical investigations of investigational IVDs may choose to engage with a CRO, including a CRO laboratory, to perform certain duties, including certain obligations under the IDE regulations. It is up to the sponsor and CRO to decide which duties and obligations the CRO will undertake. The obligations that apply under the IDE regulations must be met regardless of which party performs them. If an IDE application is required, either the sponsor or the sponsor's CRO may submit the application, *i.e.,* it is not necessary for both parties to submit an IDE application for the same clinical investigation of the investigational IVD. We note that to the extent a CRO submits an IDE application to FDA, this application would be distinct from the premarket submission (such as a 510(k), De Novo, or PMA) that the CRO's client may subsequently submit to FDA if the client intends to offer the IVD.

With respect to use of IVDs offered as LDTs in clinical investigations of drugs, FDA has issued a draft guidance document entitled ''Investigational IVDs Used in Clinical Investigations of Therapeutic Products'' (this guidance has not been finalized at this time but it includes information that may be helpful, such as a discussion of certain IDE requirements) and a final guidance document entitled ''Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination Guidance for Industry,'' which provide additional information regarding investigational use requirements in such settings (see Refs. 178 and 179). As FDA has explained, sponsors should already be aware that all investigational IVDs used in therapeutic product trials are subject to IDE requirements, and may require the submission of an IDE application separate from an investigational new drug application (IND) to the extent an IDE application is required under part 812 of FDA's regulations (Ref. 178). When an IDE application is not required, a therapeutic product trial that uses an investigational IVD must still comply with other IDE requirements as applicable under part 812. An IDE and an IND may be held by the same entity or may be held by different entities (for example, a CRO and its client); however, IDE and IND applications may cross-reference each other through a letter of authorization, or in cases where either an IND or an IDE application is not required, information may be provided through the use of a master file (MAF). As explained in section V.C, FDA generally expects compliance with the device investigational use requirements 2 years after publication of the final rule. Given this time period to prepare, FDA does not anticipate that compliance with IDE requirements will meaningfully delay drug or IVD development activities. Further, FDA notes that investigations of diagnostic devices are exempt from most IDE requirements, provided that certain labeling requirements are met and the testing: is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure (§ 812.2(c)(3)). Additionally, investigations of diagnostic devices that are not significant risk are deemed to have an approved IDE (without submission of an IDE application) if the conditions in § 812.2(b) are met.

Finally, in response to comments that inquired regarding the applicability of IDE requirements to certain types of assays, FDA would generally need additional information regarding the specific assay and the investigation in which the assay is intended to be used. FDA encourages stakeholders to consult the materials that have been made available by the Agency regarding IDE requirements, including the final guidance documents referenced above. Laboratories may also contact FDA with product-specific questions, as discussed elsewhere in this preamble.

11. Labeling Requirements

(Comment 176) FDA received several comments inquiring about labeling requirements for LDTs and requesting clear guidance on the required information and where such information needs to be located. One comment asked whether labeling for LDTs should be written with the performing laboratory as the audience or the ordering physician, noting that this distinction ''is critical as it directly impacts the communication of clinical information, essential for accurate patient diagnosis and treatment.'' Another comment stated that FDA should not consider the ''test menu, educational and interpretive information, and scientific publications included on the laboratory website'' as labeling and must not treat this information in the same way as product advertisement. Another comment stated that information listed as part of test menus ''cannot be subject to rigid labeling requirements and should not be considered 'promotional.''''

(Response 176) FDA appreciates the comments requesting clarification regarding the labeling requirements for LDTs. FDA's regulations in § 809.10 set forth specific labeling requirements for IVDs, including specific information that must be included. FDA anticipates that this information might be encompassed in more than one document, such as the test protocol, test report template, and test menu.

FDA intends to provide more targeted guidance and/or additional resources regarding the applicable labeling requirements prior to stage 2 of the phaseout period.

(Comment 177) One comment expressed concern that FDA labeling requirements would be duplicative because similar information is provided in the test ordering form or as part of the electronic order entry process. The comment also expressed concern that FDA labeling requirements would be impractical because there is limited space on the label after compliance with CLIA and other requirements, and that data elements of electronic health records would need to be added and then standardized and harmonized. This comment recommended FDA continue the general enforcement discretion approach for labeling requirements if the ''LDTs' information'' is documented and made available to FDA upon request.

(Response 177) FDA disagrees with this suggestion. FDA is phasing out the general enforcement discretion approach with respect to labeling requirements under 21 U.S.C. 352 and parts 801 and 809, subpart B. FDA believes that generally enforcing the labeling requirements for IVDs offered as LDTs will provide for consistent and comprehensive information that will benefit healthcare providers and patients and help FDA to better protect and promote the public health. As noted in response to comment 176, FDA anticipates that the information required under § 809.10 might be encompassed in more than one document, such as the test protocol, test report template, and test menu. In addition, in the case of insufficient space with respect to the label, to the extent there is an immediate container onto which a label could be affixed, we note that § 809.10(a)(10) provides that some of the

required information may appear on the outer container labeling. These and other labeling requirements are additionally discussed in FDA's final guidance document entitled ''Labeling: Regulatory Requirements for Medical Devices'' (Ref. 180).

As noted in response to comment 176, FDA intends to provide more targeted guidance and/or additional resources regarding labeling requirements prior to stage 2 of the phaseout period.

(Comment 178) FDA received one comment stating that significant problems for laboratories could be expected when ''adhering to guidance for manufacturers regarding labeling practices.'' The comment also stated that LDTs cannot reasonably be expected to adhere to the label requirements under § 809.10 as there is no physical container onto which a label could be affixed. Similarly, the comment noted that creation of a package insert would not be practical in a laboratory setting.

(Response 178) It is unclear what ''guidance'' the comment is referring to as the comment did not identify any specific guidance. To the extent the comment is referring to the labeling requirements in § 809.10, as noted in response to comment 176, FDA anticipates that the information required under § 809.10 might be encompassed in more than one document, such as the test protocol, test report template, and test menu.

FDA's IVD labeling requirements in § 809.10(b) specify the information that must be included in labeling and provides a package insert as an example of labeling. However, the regulations do not require that the labeling be a package insert.

FDA recognizes that guidance and/or additional resources on the labeling requirements for LDTs would be helpful for laboratory manufacturers. Therefore, FDA intends to provide more targeted guidance and/or additional resources on labeling requirements, including label requirements, prior to phase 2 of the phaseout period.

(Comment 179) One comment requested that FDA clarify expectations regarding compliance with UDI requirements for IVDs offered as LDTs.

(Response 179) FDA recognizes that the labeling requirements under part 801 of FDA's regulations, for which FDA intends to phase out the general enforcement discretion approach under stage 2 of the phaseout policy (see section V.C), include UDI requirements. FDA intends to provide more targeted guidance and/or additional resources regarding UDI requirements prior to stage 2 of the phaseout period.

12. Quality System Requirements

(Comment 180) A number of comments agreed with FDA that laboratories should have quality systems to help ensure that there are less errors with IVDs offered as LDTs. These comments went on, however, to express concerns with FDA's proposal to exercise enforcement discretion with respect to certain QS requirements in part 820 for those IVDs for which all design and manufacturing activities occur within a single CLIA-certified laboratory that meets the regulatory requirements to perform high complexity testing and for which distribution of the IVD does not occur outside that single laboratory. In particular, comments thought that having two different systems could result in confusion about what is ''required.''

(Response 180) FDA agrees that quality systems are important to assuring that a manufacturer consistently manufactures IVDs that have appropriate assurance of safety and effectiveness, and FDA generally expects laboratories to comply with the QS requirements at the 3-year mark under stage 3 of the phaseout policy (other than requirements under § 820.198 (complaint files), for which FDA will phase out the general enforcement discretion approach under stage 1 of the phaseout policy). As stated in section V.C, FDA is also finalizing the QS policy for LDTs as proposed. For LDTs, FDA will expect compliance at the 3-year mark with some, but not all, of the QS requirements.

FDA recognizes that this policy creates a more nuanced approach in terms of expectations for QS compliance, but we believe this nuance is justified because it may be important for some laboratories while still serving FDA's public-health goals. FDA has set forth the reasoning for this policy, which is based on certain quality assurances provided through compliance with CLIA requirements, in section V.C. This policy is consistent with the Agency's least burdensome approach for devices. FDA also welcomes compliance with the full QSR, including to avoid confusion. As with any enforcement discretion policy, this policy is subject to change as circumstances warrant.

(Comment 181) Many comments sought additional clarity about the QS requirements. These comments explained that laboratories do not have experience with FDA's QS requirements and may need substantial assistance in understanding the requirements and whether they can ''leverage'' their existing quality system to meet FDA's requirements. Another comment questioned the requirements that would be included in FDA's final rule amending part 820 and whether FDA would require certification to the relevant ISO standard (*i.e.,* ISO 13485). A similar comment asked whether FDA would make guidance available to clinical laboratories on this topic and whether such guidance would be issued with enough time for laboratories to take necessary actions to come into compliance. Another comment requested that FDA provide guidance on the gaps that exist between the QSR and CLIA.

(Response 181) FDA understands that compliance with the FD&C Act and its implementing regulations, including part 820, is unfamiliar for many laboratories. We intend to engage in various educational activities, including issuing timely guidance, to assist laboratories with understanding and complying with applicable requirements. Additionally, FDA has just issued its final rule amending part 820 (see 89 FR 7496). This rule will take effect 2 years from publication on February 2, 2026. FDA anticipates providing to all its stakeholders, including laboratories, timely guidance on compliance with the regulatory requirements in that rule. Laboratories can take advantage of these efforts to obtain a better understanding of the applicable requirements.

As for the specific question about certification to ISO 13485, FDA is not requiring certification and such certification will not substitute for an FDA routine inspection under section 704 of the FD&C Act (89 FR 7496, 7518).

(Comment 182) We received several comments about the relationship between FDA's QSR and CLIA. A comment suggested that FDA should harmonize its QSR with CLIA. Another comment stated that FDA should specify whether compliance with part 820 obviates the need to maintain CLIA certification.

(Response 182) First, the requirement to comply with part 820 does not obviate the need for a laboratory to maintain CLIA certification. CMS administers CLIA and its implementing regulations, whereas FDA administers the FD&C Act and its implementing regulations, including the QSR. As FDA has explained elsewhere in this preamble, the schemes implemented by CMS and FDA are complementary and not duplicative; both are important to help assure quality testing with laboratory-manufactured tests.

Second, FDA disagrees that the QSR and CLIA regulations require harmonization because, as stated previously, the two schemes are complementary, not duplicative or conflicting. In addition, to the extent that the comments were suggesting that FDA needs to revise the QSR in light of CLIA, FDA disagrees. CLIA and its implementing regulations and FDA's QSR are two different regulatory frameworks based in different statutory authorities intended to achieve different goals. Unlike CLIA and its implementing regulations, the QSR provides a basic framework of requirements critical for a quality system for manufacturing devices. These requirements are flexible, apply to many device types, and recognize that manufacturing circumstances may vary. Under the QSR, manufacturers are responsible for complying with those parts of the regulation that are applicable to their operations, and the QSR is intended to be sufficiently flexible to be applied to the spectrum of devices as well as manufacturers of varying size and operation type. Although FDA has adopted a policy described in this preamble that takes into account certain assurances provided by CLIA for LDTs (see section V.C), that policy does not mean that the requirements are duplicative or conflicting or that amendments to the QSR are required (see comment response 82).

(Comment 183) Some comments argued that the QSR is not appropriate for laboratory testing and it does not cover all aspects of laboratory operation. A comment suggested that this is because laboratories that develop LDTs do not engage in manufacturing. Other comments stated that ISO 15189: Medical Laboratories (ISO 15189) is the more appropriate standard.

(Response 183) As stated above, the QSR provides a basic framework of requirements critical for a quality system for manufacturing devices. These requirements are flexible, applying to many device types, and recognize that manufacturing circumstances may vary. Under the QSR, manufacturers are responsible for complying with those parts of the regulation that are applicable to their operations, and the regulation is intended to be sufficiently flexible to be applied to the spectrum of devices as well as manufacturers of varying size and operation type. In this manner, the QSR is suited to the manufacture of IVDs in laboratories. Furthermore, because the QSR focuses on assuring the quality of the device itself, it need not cover ''all aspects of laboratory operation.''

FDA also disagrees with the comment that laboratories that develop LDTs do not engage in device manufacturing. Section 820.3(o) defines a manufacturer as ''any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.'' As explained in the NPRM and in section VI.D. of this preamble, LDTs are devices (88 FR 68006 at 68015–16). As such, when laboratories design, assemble, or process an LDT, they are manufacturers of a finished device and as such are subject to the QSR (for further discussion, see comment response 71).

ISO 15189, similar to CLIA, specifies requirements for quality and competence in medical laboratories, focusing on the competencies and qualifications of laboratory personnel and testing processes. The QSR is focused on a robust quality system that promotes safety and effectiveness of the device itself through controls such as adequate management oversight, procedures for validating changes, monitoring, and audits, and plans for handling non-conformances. In contrast, ISO 15189 does not address the processes involved in manufacturing an IVD, including design controls. Thus, ISO 15189 is not the appropriate standard for laboratory activities relating to device manufacturing.

(Comment 184) Several comments suggested that compliance with the QSR is not warranted because of the quality management systems laboratories already have in place. One comment went on to state that such systems comply with Federal and State facility licensure requirements, CLIA certification, medical test site requirements, CAP accreditation, and participation in CLIA-required proficiency testing surveys/challenges. Another suggested that CLIA regulation and CAP combined are sufficient. Another comment suggested that FDA did not present scientific data that having multiple quality systems produces a better test result.

(Response 184) FDA disagrees with these comments. As explained throughout this preamble, none of the requirements the comments referenced address the quality and manufacturing of the device itself. For example, the focus of CLIA is on the testing process as it is implemented in a given laboratory, focusing on the qualifications, responsibilities, and ongoing competencies of laboratory personnel, rather than the manufacture of the IVD itself. For more information about the differences between CLIA and FDA regulation, see our responses to comments in section VI.C.2.

Some commenters pointed to participation in CLIA-required proficiency testing surveys/challenges, but those surveys/challenges are only required for certain analytes; the majority of IVDs offered as LDTs test for analytes that do not have required proficiency testing (Refs. 181 and 182). Proficiency testing events are performed on a regularly scheduled basis to assess whether laboratories are performing tests appropriately. Such testing is not intended to assess a laboratory's ability to continually manufacture safe and effective IVDs, nor does it establish the performance of a particular test, as further described in response to comment 9.

With regard to CAP accreditation, as discussed in more detail in response to comment 18, CAP accreditation addresses the manner in which the laboratory performs a test and does not assess the laboratory's processes for making the test. Further, CAP accreditation is voluntary.

As for state licensure requirements, the comment did not identify specific states or their requirements for FDA to assess. When FDA considered comments about New Jersey's laboratory certification program and Washington's medical test site program, it concluded that they are focused on laboratory operations, like CLIA, and do not provide assurances regarding the analytical and clinical validity of LDTs (Ref. 84), see response to comment 22. FDA has included a policy for LDTs that are approved by NYS CLEP (see section V.B.2).

While none of the existing requirements discussed here are duplicative of the QSR, FDA is adopting an enforcement discretion policy with respect to QS requirements for LDTs in recognition that compliance with CLIA requirements provides some quality assurances that may be relevant to laboratories' manufacturing practices, as described in section V.C.

Finally, we disagree that FDA is required to produce or cite scientific data showing that ''having multiple quality systems produces a better test result.'' Regardless of the presence of other quality systems, the question is whether laboratory compliance with the quality system requirements under the FD&C Act, as applicable, will advance public health by helping assure that

IVDs are safe and effective. FDA has determined that it will, based on the evidence before it. FDA need not ''conduct or commission [its] own empirical or statistical studies'' to draw this conclusion. *FCC* v. *Prometheus Radio Project,* 141 S. Ct. 1150 at 1160.

(Comment 185) A comment concurred with the QS requirements that FDA proposed to focus on for LDTs; however, the comment indicated that FDA should also focus on § 820.70; production and process controls. The comment went on to state that CLIA does not fully address any of these regulations.

(Response 185) FDA agrees that CLIA does not duplicate QS requirements. However, CLIA does provide some relevant assurances, including with respect to § 820.70, in the context of manufacturing activities occurring within a single CLIA-certified laboratory that meets the regulatory requirements to perform high complexity testing and for which the IVD is not transferred outside that single laboratory. Section 820.70 requires manufacturers to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications and to establish and maintain process control procedures where deviations from device specifications can occur due to the manufacturing process. This provision also has requirements addressing environmental controls, personnel cleanliness, contamination control, building suitability, equipment sufficiency, manufacturing material use and removal, and validation of software used in automated processes. CLIA regulations require that the laboratory have control procedures to monitor test accuracy and precision and detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance (42 CFR 493.1256). This provision also addresses requirements for supply checks. Additionally, other CLIA requirements address facility requirements, including equipment, and personnel competency (42 CFR 493.1101 and 1235). FDA determined that these requirements, in combination with the QS requirements on which FDA is focusing oversight (such as the design controls in § 820.30), provide assurances relevant to § 820.70.

(Comment 186) Several comments raised concerns about the costs of compliance with the QSR. A comment took issue with FDA's statement, as characterized by the comment, that the final rule amending part 820 would not impose new requirements because that was a comparative statement about the differences between FDA's proposed rule and the current part 820, but that many LDT manufacturers would be complying with part 820 for the first time. Other comments asserted that the cost of QS compliance will prohibit small companies from marketing tests, hurting patients.

(Response 186) FDA acknowledges that many laboratories may not have experience with part 820. In the NPRM, FDA stated that FDA's proposed amendment of part 820 was substantially similar to the current QS requirements simply to explain that laboratories can use the current part 820 to understand FDA's requirements with respect to quality systems, and to prepare for compliance even though the final QS rule had not been issued at that time—not to diminish the effort needed to comply (see 88 FR 68006 at 68026).

FDA continues to believe that QS compliance is important to help assure the safety and effectiveness of IVDs offered as LDTs, as explained throughout this preamble (see, *e.g.,* section III.B.1). However, FDA has also considered the costs associated with QS compliance for laboratories, and has taken those costs into account in developing the policy for currently marketed IVDs offered as LDTs (see section V.B.3). Under that policy, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)), for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. This policy applies to all laboratories, including small laboratories. In light of this policy, FDA disagrees that the cost of compliance with the QSR, alone, would cause small laboratories to close. (For more information about impacts on small businesses, see section VI.G). We note that in the FRIA, we estimate $71 million less in one-time costs for compliance with QS requirements for all affected entities compared to the PRIA, and $354 million less in annual recurring costs (see Ref. 60).

Further, as discussed in the NPRM and in this preamble, FDA intends to exercise enforcement discretion with respect to certain QS requirements for LDTs as discussed in section V.C.3, which may reduce costs for such laboratories.

(Comment 187) A comment indicated that enforcing QS requirements for laboratories could have negative impacts on manufacturers of laboratory tools and instruments, and on producers of reagents and antibodies, because they may not be able to meet the supplier requirements. Another comment stated that the supplier requirements in § 820.50 (purchasing controls) expand the responsibility of the laboratory professional beyond the CLIA requirements, and inappropriately place ''liability'' on laboratory professionals, who are acting as healthcare providers, for ensuring the quality of reagents instead of placing that responsibility on suppliers.

(Response 187) The manufacturers of test components that are themselves finished devices, such as instruments, reagents, and antibodies, intended for clinical purposes should already be complying with the QSR, including requirements in § 820.50, and thus we would not expect negative impacts on suppliers as a result of this phaseout policy. FDA agrees that when a laboratory manufacturer makes a test system using components that are not intended for clinical use, such as components labeled RUO, the laboratory is subject to the purchasing controls set forth in § 820.50, which may require validation of such components for the clinical use.[87] FDA acknowledges that laboratory manufacturers may prefer to source components manufactured under a QS to help assure the quality of their test.

Section 820.50 (purchasing controls) requires that manufacturers of finished devices assess the capability of their suppliers to produce acceptable components. When the manufacturer ensures that components, such as laboratory instruments, reagents, and antibodies, are adequate for the IVD's intended use, this helps to ensure the accuracy of the IVD being manufactured. Ultimately, the laboratory manufacturer cannot be sure that the specifications for a finished IVD are met if they did not take steps to ensure that the individual components of the finished device meet specifications. As such, FDA disagrees that such a supplier requirement is inappropriate. Enforcement of supplier requirements will provide assurances that IVDs continue to be manufactured with quality components over time.

(Comment 188) A comment argued that the QSR does not translate well to laboratory activities, and that CLIA addresses many of the QS requirements on which FDA proposed to focus in the QS policy for LDTs. The comment stated that the acceptance activities in §§ 820.80 and 820.86 do not translate well to laboratories, specifically

[87] *See* Ref. 176, which states that it is important that research and investigational use only products should not be distributed for clinical diagnostic uses.

highlighting the requirements in § 820.80(d) and indicating, according to the commenter, that it is unclear how a laboratory might comply with the requirement that manufacturers establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. The comment also specified that a number of CLIA provisions in 42 CFR part 493, subparts J and K serve the same purposes as or cover the activities in § 820.30 (design controls), § 820.100 (corrective and preventive action), and part 820, subpart M (records requirements).

(Response 188) FDA disagrees that the CLIA regulations cited in the comment provide assurances relevant to the cited QS requirements in part 820. CLIA covers laboratory operations, including processes for handling and dealing with components and specimens, as well as documenting and responding to patient test result errors as a result of laboratory operations. None of the CLIA provisions include requirements for designing or monitoring issues with the IVD itself. For example, 42 CFR 493.1241 addresses the need for a test request, 42 CFR 493.1242 addresses policies for specimen handling, storage, and processing, 42 CFR 493.1252 addresses proper storage of reagents and specimens, 42 CFR 493.1253 addresses performance specification with regards to accuracy, precision, and range (without tying those specifications to the design of the test and without addressing design input and output review), and 42 CFR 493.1290 and 1291 address other issues related to laboratory operations rather than faulty device design, including the content of test reports, handling of abnormal results, error reporting requirements, and assessment and resolution of identified problems with regard to patient test result errors.

In contrast, the design controls in § 820.30, at a high level, address: design and development planning, procedures for ensuring that the design requirements are appropriate for the device intended use, including design inputs, procedures for defining and documenting design outputs, procedures for design review, verification, and validation, and procedures for documenting and validating design changes. Each of these requirements aims to ensure that devices perform as intended, which is a concept not covered by the CLIA requirements.

Similarly, the CLIA requirements on correcting errors (42 CFR 493.1291) and records requirements (42 CFR 493.1251 (procedure manual), 42 CFR 493.1101 (facilities), 42 CFR 493.1105 (retention requirements), 42 CFR 493.1291 (test report), and 42 CFR 493.1283 (test records)) are focused on addressing laboratory errors and laboratory recordkeeping. The QS requirements are focused on assuring the quality of the IVD offered as an LDT itself, and compliance with these requirements addresses issues of device quality. As detailed in comment 182, CLIA and the QSR are complementary but different in focus.

While FDA acknowledges that the terminology of the QSR may not be familiar to many laboratories, as stated in comment 181, FDA intends to engage in educational activities to assist laboratories in understanding compliance with the QSR. FDA disagrees that lack of familiarity means that the requirements are inappropriate for laboratories. The QSR is written in a flexible manner and there are many ways that a laboratory may comply with the QSR. For example, the comment cited uncertainty about how a laboratory would comply with acceptance activities in §§ 820.80 and 820.86 generally, and specifically questioned the ability for laboratories to comply with finished device acceptance requirements in § 820.80(d), which requires that manufacturers, including laboratories, establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets specified requirements; in other words, assessing whether the finished device is what you expected. For example, laboratories procure reagents from external sources for use as part of their LDT. The laboratory would need suitable methods to identify reagents in a way that distinguishes between those that have just been received and not yet evaluated, those that have been received and found unacceptable according to their purchasing controls, and those that have been received and found acceptable according to their purchasing controls and are therefore adequate for use as part of the final LDT. Manufacturers have the flexibility to choose a combination of methods to comply with these requirements, including finished device inspection and testing, acceptance criteria, and identification methods, provided such methods will accomplish the required result. For example, for final acceptance activities, laboratories may have a procedure that specifies the methods and materials and acceptance criteria (including confidence intervals) that would be used to assess whether the final LDT meets those specified acceptance criteria, prior to the LDT being used for clinical use.

(Comment 189) A comment recommended that FDA establish an ''umbrella approval'' for CGMP and software modules from each laboratory and that FDA should recognize results from third party quality efforts.

(Response 189) In general, FDA does not ''approve'' manufacturing practices, although they are reviewed within the context of a PMA. We note that, in premarket applications, manufacturers may rely on information that they previously submitted to FDA by referencing where the information was provided in a previous submission. Establishment of an ''umbrella approval'' for CGMP and software modules is outside the scope of this rulemaking.

With regards to third-party quality efforts, to the extent that the comment is referring to CAP accreditation or NYS CLEP assessments, see our response to comment 18 and section V.B.2 for more information on that topic.

13. Premarket Review Requirements

(Comment 190) Several comments expressed concern that compliance with premarket review requirements would be infeasible and cost-prohibitive for laboratories with limited resources and stated that FDA should take into account that these laboratories also pay fees to CMS associated with CLIA. One comment stated that FDA should ''[s]et reasonable pricing for LDT review and registration.'' One comment suggested that FDA should consider temporarily reducing user fees for premarket submissions during the phaseout timeline.

(Response 190) In the final phaseout policy, in recognition of patient reliance and cost considerations, among other things, FDA has included policies for enforcement discretion with respect to premarket review for several categories of IVDs, as described in section V.B. These policies should help address some of the concerns raised by the comments.

With respect to fees, FDA is unable to unilaterally change user fee amounts or adjust user fees to take into consideration other fees that laboratories may pay to CMS pursuant to CLIA. User fees associated with establishment registrations and certain premarket submissions are established by Congress in MDUFA. Under the current reauthorization of MDUFA, payment of either a standard fee or a small business fee is required for each submission type identified in 21 U.S.C.

379j(a)(2)(A) (unless the applicant qualifies for a fee waiver or for an exception under 21 U.S.C. 379j(a)(2)(B)). Payment of an establishment registration fee is required at the time of initial or annual registration (as applicable), except as provided in 21 U.S.C. 379j(a)(3)(B). More information about user fees is available on FDA's user fee website (see Ref. 183). However, FDA will have an opportunity to negotiate with industry regarding user fees at the time of the next reauthorization of MDUFA, which will occur in advance of stages 4 and 5 of the phaseout policy (when FDA intends to phase out the general enforcement discretion approach for premarket review requirements).

FDA disagrees that compliance with premarket review requirements is likely to be infeasible for laboratories with limited resources. As just noted, the existing program incorporates a different user fee amount for small businesses (see 21 U.S.C. 379j(d) and (e)), and review can occur relatively quickly when an IVD has been appropriately validated for its intended use. In addition, FDA implements premarket review consistent with several ''least burdensome'' statutory provisions and in accordance with Agency policy. This topic is discussed in detail in FDA's final guidance document entitled ''The Least Burdensome Provisions: Concept and Principles,'' which defines ''least burdensome'' to mean the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time (Ref. 72). FDA also encourages IVD manufacturers to take advantage of FDA's industry resources, including final guidance documents and resources available through the Division of Industry and Consumer Education within CDRH (see Ref. 184). These resources may facilitate efforts by laboratories to comply with premarket review requirements and other applicable requirements. Ultimately, FDA recognizes that laboratories will need to make investments to comply with premarket review requirements, but these investments are important to help ensure that IVDs are appropriately safe and effective, so that patients and providers can rely on test results for clinical decision-making.

(Comment 191) We received several comments asking specific questions about what and how different types of data should be presented in premarket submissions, and how to know when a premarket submission is required, especially for modifications. For example, comments asked what specific data are necessary to bridge a premarket authorization to new specimen types, how to handle database curation for sequencing assays, and what types of software applications are considered part of a test system. Another comment stated that the NPRM did not provide sufficient guidance on what amount or type of data may be required.

(Response 191) FDA appreciates that many laboratory manufacturers may not be familiar with FDA's regulations and the premarket submission process. FDA intends to consider providing guidance on various topics and making additional resources available over the course of the phaseout period as appropriate, including on the topic of premarket review of IVDs offered as LDTs. FDA has already made resources available on several of the specific topics identified by the comments, including FDA's final guidance documents entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' and ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process,'' regarding modifications to devices (Refs. 61 and 185); information regarding the CLSI EP35 standard (1st Edition), ''Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures,'' regarding bridging to new specimen types (Ref. 186); FDA's final guidance document entitled ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics,'' regarding database curation (Ref. 187); and FDA's final guidance documents entitled ''Clinical Decision Support Software,'' ''General Principles of Software Validation,'' and ''Content of Premarket Submissions for Device Software Functions,'' regarding software (Refs. 188 to 190). The amount and type of data needed in premarket submissions varies depending on the circumstances. For questions that are specific to a particular IVD, laboratory manufacturers may request feedback from FDA through a Pre-Submission, which is further explained in FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65).

(Comment 192) One comment questioned how premarket submissions may account for the various components of a test (*e.g.,* extraction kits, instrument platform, software, or reagent) when those components may not be manufactured by the laboratory manufacturer and the laboratory manufacturer may consider them to be interchangeable.

(Response 192) In the scenario described in the comment, the laboratory manufacturer is expected to establish specifications for such components and have purchasing and acceptance controls to ensure each component meets specifications. This is critical to help ensure the quality of the test over time. While evidence of purchasing and acceptance controls are generally not part of premarket review for 510(k) and De Novo submissions, they are required elements of a quality system. In addition, under the design control provisions of the QSR, the laboratory would be expected to validate its test system, including all components per established specifications, for its intended use. During premarket review, FDA would review analytical and clinical validation information for the test system. For PMAs, FDA would also review applicable quality system information.

(Comment 193) Some comments addressed what FDA should consider as evidence of a reasonable assurance of safety or effectiveness in premarket submissions for IVDs offered as LDTs. Some comments stated that clinical trials ''should not be required'' because they are too burdensome. One comment stated that FDA should expect less information in premarket submissions when tests are designed for use on ''commercially'' available instruments and using ''commercially'' available reagents. Another comment suggested that FDA consider peer-reviewed evidence of clinical validity and clinical utility and prior reviews by other regulatory bodies.

(Response 193) The content that must be included in a premarket submission can vary greatly based on several factors, including the type of submission and the type of device. Data relevant to the evaluation of a submission for one type of test may not be relevant to evaluating submissions for other types of tests. However, in general, FDA does not agree that the amount and type of evidence included in a particular submission should vary based on whether the IVD is manufactured by a laboratory or another manufacturer. FDA encourages IVD manufacturers to request feedback on individual submissions through FDA's Pre-Submission program, which is further explained in FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65). FDA also implements premarket review consistent with several ''least

burdensome'' statutory provisions and in accordance with Agency policy. This topic is discussed in detail in FDA's final guidance document entitled ''The Least Burdensome Provisions: Concept and Principles'' (Ref. 72).

With respect to the consideration of peer-reviewed evidence, FDA would not expect laboratories to generate additional clinical validity data when available literature is adequate to demonstrate that the IVD is clinically valid. In reviewing submissions for IVDs, FDA considers applicable information from the literature submitted by the applicant. In addition, as discussed in response to comment 203, FDA has published a final guidance document describing a recognition program for publicly accessible databases of human genetic variants as sources of valid scientific evidence for genetic and genomic tests (Ref. 188). Under this policy, test manufacturers can use information in FDA-recognized databases to support the clinical validity of their tests.

FDA disagrees that FDA should expect less information in premarket submissions when tests are designed for use on ''commercially'' available instruments and with ''commercially'' available reagents. FDA's expectations for validation apply to the test system, which includes use of all components together. Any given instrument or reagent may be a part of a test system that works well and part of another test system that does not.

With respect to the comment suggesting that FDA consider prior reviews by other regulatory bodies, as described elsewhere in this preamble, FDA anticipates expanded use of the Third Party review program and intends to exercise enforcement discretion with respect to premarket review requirements for LDTs approved by NYS CLEP. Further, FDA will continue ongoing efforts towards international harmonization with other regulatory bodies.

(Comment 194) One comment expressed concern that FDA does not have the level or depth of expertise necessary to review premarket submissions for highly complex LDTs. Another comment stated that the NPRM was focused largely on clinical pathology, and that FDA has not considered that the large quantity of premarket submissions FDA will receive will be more varied and challenging, and include digital pathology products incorporating artificial intelligence/machine learning, liquid biopsies, multiplex assays, multianalyte tests incorporating complex algorithms, and whole genome sequencing.

(Response 194) FDA disagrees with the comment's suggestion that FDA has failed to consider a wide range of IVDs in connection with this rulemaking, such as the products listed in the comment. FDA is familiar with these products, as discussed below, and has taken into account its experience with IVDs generally in issuing this rule. FDA also notes that the term ''clinical pathology'' is broad. According to the Association of Academic Medical Centers, clinical pathology includes many subspecialties, including blood banking-transfusion medicine, chemical pathology, clinical informatics, cytopathology, hematology, microbiology, and molecular genetic pathology, among others.

FDA also disagrees that it lacks the level or depth of expertise necessary to evaluate premarket submissions for a wide variety of challenging and varied highly complex IVDs offered as LDTs. FDA employs hundreds of scientists with expertise in the review of IVD safety and effectiveness, including those who have worked in clinical laboratories and developed LDTs. This expertise includes knowledge of digital pathology products, liquid biopsy-based tests, multiplex assays, multi-analyte tests incorporating complex algorithms, and whole genome sequencing, among other things. FDA also works with experts across offices, including experts in the Digital Health Center of Excellence on artificial intelligence/machine learning matters. For example, FDA has already authorized artificial intelligence/machine learning-based software (see Ref. 191), digital pathology tests incorporating artificial intelligence/machine learning (see Ref. 192), liquid biopsy assays (see, *e.g.,* Refs. 144 and 193), multiplex assays (see, *e.g.,* Refs. 194 and 195), multi-analyte tests incorporating complex algorithms (see, *e.g.,* Refs. 196 and 197), and exome sequencing based NGS tests (see, *e.g.,* Refs. 198 and 199).

(Comment 195) Several comments requested clarity around device classification and offered suggestions for how FDA should classify IVDs offered as LDTs, including what factors should be considered. One comment suggested FDA determine and continuously seek input on classification of tests through a public process. Another comment suggested FDA use a request for information process to gather information on currently available IVDs offered as LDTs and use that data to establish classification panels that IVD manufacturers could look to as a resource in the premarket submission process, which would save them time and resources. Some comments stated that, when classifying tests, FDA should consider context, including how widely a test is distributed; whether it is offered by a laboratory that is integrated into patient care; and the history of the test manufacturer, including with respect to validation generally and for specific tests.

(Response 195) As discussed more fully in section VI.P of this preamble, FDA already has processes in place and has made multiple resources available to industry to help manufacturers determine the classification of their devices. FDA notes that some IVDs offered as LDTs may already be classified under existing classification regulations. FDA recommends that stakeholders consult FDA's classification database for more information (Ref. 200). Laboratory manufacturers may also seek feedback from FDA through a Pre-Submission, or may submit a request for information regarding the class in which a device is classified or the requirements applicable to a device under section 513(g) of the FD&C Act.

We note that standards for classification of a device are set forth in statute (21 U.S.C. 360c(a)). The existing device classification processes focus on the risk of the IVD itself and availability of controls to address such risk. In classifying devices, FDA considers, among other things, the device's intended use and indications for use, which includes consideration of the intended patient population. The risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Refer to FDA's web page for more information on classification (Ref. 201).

With regard to the request for FDA to continuously seek input on classification of tests through a public process, we agree that public input can be important, and in fact required, in certain circumstances.

Among other things, there is a public process when FDA classifies a preamendments device for the first time under section 513(d) of the FD&C Act. This process involves a public meeting of the appropriate advisory committee panel and notice and comment rulemaking.

Postamendments devices are deemed to be class III by operation of law under section 513(f)(1) of the FD&C Act, but such devices can be reclassified under different processes. Under section 513(f)(3) of the FD&C Act, for example, stakeholders can petition FDA to change the classification of these devices (see § 860.134(b) (21 CFR 860.134(b))). FDA can also initiate reclassification under section 513(f)(3) of the FD&C Act, and

under that process, the public would have an opportunity to review and comment on the proposed classification and special controls, if applicable, which are published first by proposed order in the **Federal Register** (see § 860.134(c)). In addition, a manufacturer can submit a De Novo classification request under section 513(f)(2) of the FD&C Act requesting reclassification to class II or class I. FDA acts on such requests through written order, without a public comment process.

(Comment 196) Some comments stated that FDA's three-tier classification system for devices does not translate well to IVDs offered as LDTs. These comments expressed concern that FDA would inappropriately classify many IVDs offered as LDTs as high risk ''when in reality their risk is mitigated by the fact that they are part of a multi-faceted medical assessment and are rarely used in isolation for clinical decision-making.'' Some comments stated that most LDTs should be considered low- or moderate-risk because they are typically used as only one part of a more comprehensive patient evaluation and not the singular factor for clinical decisions. One comment stated that ''LDTs are comprised of not only medical products, but also analytic processes,'' and suggested that ''A regulatory review process for LDTs should consider both and achieve an appropriate balance between the two given where the risk lies in a particular test.''

(Response 196) FDA disagrees that FDA's device classification system does not translate well to IVDs offered as LDTs. FDA determines the risk class of devices, including IVDs, by applying the statutory standards set forth in the FD&C Act, including standards for class I (low-risk), class II (moderate-risk), and class III (high-risk) devices. *See* 21 U.S.C. 360c(a)(1). FDA's classification decisions take into account the risk of a device, which may depend on whether the device is the sole determinant for clinical decision-making, among other things. FDA is not aware of any unique feature of IVDs offered as LDTs that renders the statutory standards less applicable or less appropriate for these IVDs.

To the extent that the comments were suggesting that IVDs offered as LDTs are unique because they are ''part of a multi-faceted medical assessment and are rarely used in isolation for clinical decision-making,'' FDA disagrees. Many IVDs are indicated for use in conjunction with clinical assessments and not as the sole basis for clinical decisions, so IVDs offered as LDTs are not unique in that respect. For example, class III prostate specific antigen tests are intended to be used in conjunction with a digital rectal exam to aid in the detection of prostate cancer in men aged 50 years and older. Class II Duchenne muscular dystrophy newborn screening tests are intended to be used in conjunction with other clinical and diagnostic findings to aid in the screening of newborns. Class I cholesterol tests are intended to be used to aid in the diagnosis of lipid disorders. In general, any IVD, regardless of class, that is indicated to ''aid in the diagnosis'' of a clinical condition is intended to be used in conjunction with clinical assessments. Therefore, use in the context of a ''multi-faceted medical assessment'' is not unique to IVDs offered as LDTs.

FDA also disagrees that IVDs offered as LDTs should be considered low or moderate risk whenever they are part of a multifaceted medical assessment (*i.e.,* are not used in isolation for clinical decision-making). Even if such tests are used as a part of a multifaceted medical assessment and are not the sole determinant for clinical decision-making, false positive or false negative test results can still lead to unwarranted interventions or progression of disease without necessary intervention. Given the role that IVDs offered as LDTs play in modern medical care, test validity has a significant impact on the public health. However, FDA notes that most currently classified IVDs have been determined by FDA to be low or moderate risk (class I or class II).

With regard to the suggestion that FDA's regulatory review process should consider that LDTs are comprised of both ''medical products'' and ''analytic processes,'' the comment provided no additional discussion of these terms, and FDA is not clear on the distinction the commenter intended to draw. To the extent the commenter meant to distinguish between medical devices and the ''practice of medicine,'' see our responses to comments in section VI.D.6. With regard to the suggestion that FDA take a balanced approach in light of a test's risks, FDA agrees. We take a risk-based approach to the devices we regulate and determine the level of regulation warranted to provide reasonable assurance of safety and effectiveness. On January 31, 2024, FDA announced that it is undertaking an effort to initiate the process to reclassify most IVDs that are currently class III into class II because FDA believes there is sufficient information to establish special controls that, together with general controls, will provide a reasonable assurance of safety and effectiveness for these tests. The majority of these tests are infectious disease and CDx IVDs (Ref. 66). FDA aims to complete this reclassification process before stage 4 of the phaseout policy.

(Comment 197) One comment questioned how a high-risk IVD offered as an LDT that uses a class I instrument could be classified into a different class than the instrument, and whether the instrument would need to go through premarket review based on the classification of the high-risk IVD offered as an LDT.

(Response 197) The regulatory requirements applicable to a particular device can vary depending on the device's intended use. For example, the same instrument may be subject to certain requirements when it is not intended for use as part of a particular test system and subject to a different set of requirements when it is intended for use as part of a particular test system. Most instruments not intended for use as part of a particular test system are classified as class I 510(k)-exempt. However, if a manufacturer seeks to market a test system that includes such an instrument as a component, the instrument would be reviewed under the standards applicable to the overall test system. For example, in the context of a submission for a high-risk test system, FDA would review information to support use of the instrument in that test system.

(Comment 198) Several comments proposed that FDA streamline premarket submission or review for some or all IVDs offered as LDTs. Comments stated that FDA review should be expedited so that care is not delayed, and that quick turnaround times are particularly needed for infection prevention and control. Some comments suggested specific approaches FDA could take. One comment asked FDA to consider maintaining a MAF containing core data submitted by a manufacturer, which other laboratories could then draw from and use rather than repeat a data collection. Another comment suggested FDA provide standardized templates to help the manufacturers of IVDs offered as LDTs present data in a consistent and understandable format. Another comment suggested that FDA identify strategies to streamline validation of tests when there are well characterized biomarkers or numerous tests with a similar intended use.

(Response 198) Premarket pathways and certain submission requirements are

set forth in the FD&C Act,[88] and FDA cannot change those requirements. In addition, to the extent that the comments were suggesting that FDA should have a different approach to implementing premarket review for IVDs offered as LDTs compared with other IVDs, FDA disagrees.

However, in general, FDA supports tools for more efficient premarket review as consistent with applicable law. For example, FDA's device MAF system is available to device manufacturers, including laboratory sponsors of IVDs offered as LDTs. A laboratory sponsor can, with the data owner's permission, reference specific MAFs in a premarket submission for a third party's data and other information related to the subject IVD offered as an LDT. The MAFs would allow FDA's confidential review of such information to facilitate scientific evaluation of the IVD without disclosing trade secret or confidential information to the sponsor laboratory (see Ref. 202 for more details). Such use of MAFs in a manner that eliminates unnecessary burdens is consistent with the least burdensome principles directed by Congress.

FDA appreciates that standardized templates or additional guidance regarding data presentation and test validation may facilitate efforts by laboratories to comply with applicable premarket review requirements. As discussed more fully in response to comment 291, FDA anticipates issuing a small entity compliance guide, and intends to consider issuing additional guidance documents as appropriate and making additional resources available on specific topics, including test validation, over the course of the phaseout period. As described further in response to comment 293, there are multiple resources to help manufacturers, including laboratories, understand the type of data and information, including validation data and information, that is included in support of premarket submissions for IVDs. As stated elsewhere, FDA implements premarket review, including its review of analytical and clinical validation data, consistent with several ''least burdensome'' statutory provisions and in accordance with Agency policy. This topic is discussed in detail in FDA's final guidance document entitled ''The Least Burdensome Provisions: Concept and Principles,'' which defines ''least burdensome'' to mean the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time (Ref. 75). Consistent with FDA's least burdensome principles, if available literature is adequate to demonstrate that the clinical validity of the biomarker detected by the test is well-established, FDA considers such applicable information from the literature submitted by the applicant.

(Comment 199) One comment suggested that FDA collaborate with CDC and other Federal agencies so that each public health laboratory does not need to submit a separate PMA to obtain premarket approval for their shared test types. The comment noted that this suggested approach would alleviate challenges when the public health laboratory does not hold the validation dataset, which, for some test types, is validated by Homeland Security and the Laboratory Response Network.

(Response 199) When a laboratory submits an application for premarket approval of an IVD, that application can include information to support the distribution of that IVD to other laboratories; for example, CDC can obtain approval for a test that involves the distribution of that test to the Laboratory Response Network. In addition, as discussed above, data owners may choose to submit a MAF and provide a right of reference to specific laboratories, which in turn can reference the data and information in the MAF in their PMA applications.

(Comment 200) One comment suggested that FDA work with CMS, CAP, and the Joint Commission to align requirements for clinical laboratories when performing validation experiments to avoid creating redundant and misaligned regulations that will lead to costly delays.

(Response 200) FDA is responsible for implementing the requirements of the FD&C Act with respect to IVDs, including requirements for safety and effectiveness of IVDs offered as LDTs. FDA takes a least burdensome approach in its implementation of premarket review requirements, in a manner that strives to eliminate redundancy and unnecessary burdens. However, this approach does not change the applicable statutory and regulatory requirements for premarket review, including premarket submission content requirements and requirements for valid scientific evidence. As discussed more fully in sections VI.C.2 and VI.C.3, CMS and laboratory accreditation bodies, such as CAP and the Joint Commission, address clinical laboratory operations and personnel, but do not address critical aspects of laboratory development, such as clinical validity. FDA has both the authority and the expertise to oversee IVDs offered as LDTs to better assure the safety and effectiveness of these devices. In addition, FDA and CMS meet regularly to share information and coordinate our approaches, as appropriate, and will continue to do so upon implementation of this rule.

FDA appreciates that additional guidance regarding IVD validation may facilitate efforts by laboratories to comply with premarket review requirements. FDA intends to consider issuing additional guidance documents as appropriate, and making additional resources available on specific topics, which may include clinical validity, over the course of the phaseout period. See our response to comment 291.

(Comment 201) We received comments asking what standard FDA will apply for IVDs offered as LDTs that remain on the market while FDA reviews a premarket submission for that IVD. One comment urged FDA to ''allow'' these IVDs to remain on the market while the laboratory manufacturer addresses FDA's questions unless there is a likelihood of serious harm. Another comment asked FDA to confirm whether the Agency commits to take action on premarket submissions during the same stage in which sponsors are expected to submit them (*e.g.,* during stage 4 for high-risk LDTs).

(Response 201) As described in section V.C, in stage 4 of the phaseout policy (3½ years after publication of this final rule), FDA is phasing out the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs offered as LDTs. In stage 5 (4 years after publication of this final rule), FDA is phasing out the general enforcement discretion approach with respect to premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that are subject to premarket submission requirements). As described in section V.C, FDA generally does not intend to enforce against IVDs offered as LDTs for lacking premarket authorization after a complete PMA, HDE application, 510(k), BLA, or De Novo request has been submitted to FDA (by the corresponding stage of the phaseout policy) until FDA completes review of the submission. We note, however, that regardless of the phaseout timeline and enforcement discretion policies in this preamble, FDA retains discretion to pursue enforcement action at any time against violative IVDs when appropriate.

The phaseout policy does not address the timeframe within which FDA will complete review of premarket

[88] Some devices that are also biological products are licensed under the PHS Act.

submissions. FDA's timeline for phasing out the general enforcement discretion approach with respect to premarket review requirements aligns with the next reauthorization of MDUFA, which will provide an opportunity for FDA and industry to negotiate regarding user fees and performance goals with the knowledge that laboratory manufacturers will generally be expected to comply with applicable premarket review requirements.

(Comment 202) Several comments asked how premarket authorization will work when it is possible FDA will receive several De Novo requests for the same type of test. One comment stated that there would be a disincentive to being the first to submit a De Novo request for novel tests (specifically in reference to laboratories creating new intended uses for FDA-authorized tests) because such requests require payment of a higher user fee than 510(k) submissions. FDA also received comments asking about the logistics of the premarket review process when sponsors may not know whether another entity has submitted a De Novo request for the same type of test.

(Response 202) FDA has issued multiple final guidance documents outlining our policies for De Novo requests, including ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' (Ref. 203) and ''Acceptance Review for De Novo Classification Requests'' (Ref. 204), in addition to a final rule entitled ''Medical Device De Novo Classification Process'' (86 FR 54826, October 5, 2021).

With respect to the comments asking about the logistics of the premarket review process when multiple sponsors have submitted De Novo requests for the same type of IVD, FDA generally would not disclose the existence of a De Novo request under review to other submitters, but would notify them if/when a De Novo request for the same device type is granted. As further explained in our final guidance document entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation),'' when a De Novo request is granted while other devices of the same type are under review in additional De Novo requests, the additional De Novo requests will be declined. The submitters of the declined De Novo requests will be required to demonstrate substantial equivalence to the IVD that was granted a De Novo in a 510(k) submission, and comply with any applicable special controls for the device type; the sponsor may use all information in their initial De Novo request by incorporating it by reference into the new 510(k) submission.

To the extent this process and the higher user fees associated with De Novo requests compared to 510(k) submissions may disincentivize submission of De Novo requests for novel IVDs, as suggested in one comment, this concern is not specific to IVDs offered as LDTs, but rather relates to all devices. FDA is not changing the De Novo and 510k frameworks through this rulemaking.

(Comment 203) One comment requested guidance on how to handle database curation for sequencing assays, specifically regarding adding to databases without having to submit an application to FDA, and regarding regulations for curated databases pertaining to the authenticity and security of data and obtaining proper documentation for database submissions prior to inclusion in the database.

(Response 203) FDA has published a final guidance document entitled ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics,'' which describes a recognition program for publicly accessible databases as sources of valid scientific evidence for genetic and genomic tests (Ref. 187). This final guidance addresses recommendations for appropriate curation of publicly accessible databases using human expert evaluation, including recommendations around database procedures and operations, data quality and security, variant evaluation and assertions, and professional training and conflicts of interest. FDA recognition of a database indicates that FDA believes the data and assertions contained in the database can be considered valid scientific evidence. Test manufacturers can use the assertions within FDA-recognized databases to support the clinical validity of their tests.

We note that the clearance/approval of a PCCP may help manufacturers avoid the need for PMA supplements or new 510(k)s for modifications to a database that is used as part of test result generation. PCCPs provide the opportunity for a manufacturer to prospectively outline how changes to a device will be validated and implemented. This may include how a database that is used as part of the test result generation may be updated, such as to add variants. FDA can review and clear or approve the PCCP during review of a premarket submission. Manufacturers would not need to submit a PMA supplement or new 510(k) for subsequent changes when such changes are in accordance with the authorized PCCP. This approach has been successfully employed for various FDA-authorized IVDs.

(Comment 204) FDA received comments with specific questions about FDA premarket review, including the review process, FDA response timelines, associated user fees, and appeal rights, among other subjects.

(Response 204) Notably, neither the regulation amendment nor the phaseout policy changes applicable FDA requirements for IVDs or IVD manufacturers. As noted throughout this preamble, FDA has published numerous final guidance documents and resources for industry with information on how to comply with applicable requirements, including requirements for premarket review. We encourage interested parties to consult these materials, including final guidance documents and resources available through the Division of Industry and Consumer Education within CDRH (see Ref. 184). As appropriate, FDA also intends to develop guidance documents specific to the final phaseout policy, which will be forthcoming during implementation.

G. Impact on Small Businesses

(Comment 205) FDA received comments expressing concern that phasing out the general enforcement discretion approach for LDTs will put financial and administrative pressure on small laboratories, resulting in laboratory closures, consolidation of smaller entities, and monopolies in the testing space as large laboratories take more of the market share. Several comments stated that large laboratories will be advantaged as they have the resources to afford the necessary staffing and other costs related to test development and regulatory submission and emphasized the thin financial margins with which small laboratories operate. Some comments stated that the impact on small laboratories will result in a loss of expertise and infrastructure. In addition, comments noted that such centralization of LDTs at large laboratories may negatively impact medical education and training in pathology.

(Response 205) FDA appreciates the concerns regarding financial and administrative challenges for smaller laboratories. FDA anticipates that the enforcement discretion policies discussed in section V.B will sufficiently address these concerns and help to avoid undue disruption to the testing market. For example, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820,

subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. Premarket review costs and QS costs are a significant portion of the overall costs associated with compliance with applicable requirements under the FD&C Act and FDA's regulations, as described in section II.F.5 of the FRIA (see Ref. 10). Small laboratories that do not incur such costs will face significantly less of the financial and administrative pressure that the comments describe, reducing the likelihood of laboratory closures, laboratory consolidation, and monopolies predicted by the comments. For further discussion see section III.B of the FRIA. FDA also intends to issue a small entity compliance guide, which will assist small entities in complying with applicable requirements. For discussion of the potential impact of the phaseout policy on medical education and training, see our response to comment 301.

(Comment 206) Some comments enumerated specific questions for FDA regarding compliance and requested clarification as to whether FDA will make materials available to help small businesses come into compliance.

(Response 206) FDA intends to provide additional resources on specific topics that may be useful as laboratories come into compliance with applicable requirements, as discussed in response to comment 291. In addition, as noted in response to comment 205, FDA intends to issue a small entity compliance guide to provide additional guidance to small businesses.

H. Impact on Pricing

(Comment 207) Several comments stated that ending the general enforcement discretion approach for LDTs will lead to higher prices for clinical tests due to the costs of complying with applicable FDA requirements. Some comments further stated that the costs of complying with applicable requirements will result in the closure of many laboratories, the outsourcing of certain laboratory testing, or other supply chain contractions, which in turn will increase the costs of tests due to decreased test availability, decreased market competition, and increased handling costs (*e.g.,* costs associated with shipping samples to a centralized laboratory), or supply chain contractions. One comment expressed skepticism regarding FDA's statement that any losses may be offset by the market entry of IVDs from other manufacturers. FDA also received a comment which argued that increased prices for clinical tests will disincentivize people from seeking preventive care until they suffer an emergency, which will increase costs for the overall healthcare system. Collectively, these comments suggested that laboratories will pass increased costs to their customers, which some comments noted could result in higher insurance premiums. However, one comment stated that insurance companies will be more likely to cover tests (because they will have FDA authorization), which may allow for greater access to more affordable testing. Payors themselves commented in support of the rule ''given the proliferation of laboratory developed tests (LDTs) and concerns about the reliability of certain LDTs.'' One comment noted that it is inaccurate to assume that LDTs are always cheaper.

(Response 207) FDA recognizes that laboratories may pass the costs of compliance with applicable requirements, including the specific examples listed in the comments, to their customers by raising prices for IVDs offered as LDTs. We also recognize that if many laboratories reduce operations or exit the market, production may be concentrated in a few large laboratories, which may cause prices for certain IVDs offered as LDTs to increase. As we noted in section II.F.6 of the PRIA and the FRIA (Ref. 60 and 10), the exact effect of the phaseout policy on the price of IVDs offered as LDTs is unknown. A few comments received by FDA included discussion of the price differential between unauthorized LDTs and FDA-authorized tests, but comments did not otherwise provide empirical data to inform FDA's assessment of effects on test prices.

However, we note that in the final phaseout policy, after considering the public comments received on the NPRM, FDA has included certain enforcement discretion policies. As described in section V.B.3, FDA intends to exercise enforcement discretion and not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in certain limited ways as described in section V.B.3. In addition, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP. FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

As noted in response to comment 205, the costs of compliance with premarket review requirements (as well as QS requirements) are a significant portion of the overall anticipated costs to laboratories of complying with applicable FDA requirements (see section II.F.5 of the FRIA (Ref. 10)). As a result, FDA's determination to include the enforcement discretion policies described above in the final phaseout policy may significantly reduce the costs of compliance under the final phaseout policy, thus reducing the number of laboratories that scale back operations or exit the market. FDA estimates the annualized cost over 20 years to be $4.6 billion less than the estimates in the PRIA (Ref. 60).

In addition, we anticipate that FDA oversight could help to support coverage and reimbursement determinations for IVDs offered as LDTs, which we anticipate will make certain IVDs offered as LDTs for which there is a reasonable assurance of safety and effectiveness more affordable for patients. As a result, FDA does not agree that patients will necessarily be disincentivized from seeking preventive care resulting in increased costs to the healthcare system as a result of the phaseout policy.

In addition, phasing out the general enforcement discretion approach for LDTs will help to reduce other healthcare costs. Greater oversight by FDA will help to address the hidden costs associated with unsafe or ineffective IVDs (including IVDs promoted with false or misleading claims), such as costs incurred from inappropriate treatments, additional or repeat testing, unnecessary consultations with providers, or additional treatments that become necessary due to the progression or worsening of a disease or condition following misdiagnosis. While certain costs may be passed on to individuals and insurers, we expect some of these costs will be offset by the associated benefits.

A more fulsome discussion of the estimated costs and benefits is provided in FDA's FRIA (Ref. 10).

(Comment 208) FDA received one comment which stated that some laboratories may decide to utilize tests that are more expensive for patients, regardless of medical necessity, in order

to recoup the costs of complying with applicable FDA requirements.

(Response 208) FDA does not agree that phasing out the general enforcement discretion approach for LDTs will cause laboratories to utilize more expensive tests regardless of medical necessity. FDA anticipates that, to the extent some laboratories may attempt to recoup costs by utilizing more expensive tests regardless of medical necessity, such laboratories would be likely to engage in such practices irrespective of FDA's determination to phase out the general enforcement discretion approach for LDTs. In addition, the use of any particular test is a decision to be made between patients and their healthcare providers. Finally, FDA anticipates that third party payors may review the medical necessity of tests for which claims for reimbursement are submitted.

I. Impact on Access and Innovation

(Comment 209) Several comments expressed concern that ending the general enforcement discretion approach for LDTs will negatively impact patient access to clinical testing. These comments generally asserted that the cost or complexity of complying with FDA requirements, and the burdens that may fall on laboratories from the phaseout of the general enforcement discretion approach, will cause many laboratories to reduce activities and stop offering some or all IVDs offered as LDTs, particularly in the context of other challenges that laboratories face with respect to staffing, supply chains, and other challenges. Several comments stated that in a recent American Society for Microbiology survey of its members, over 80 percent of the microbiology laboratories surveyed said they would consider discontinuing LDTs if FDA finalized its proposal. Another comment stated that in an internal survey of members of the Association of Pathology Chairs, out of 39 laboratories surveyed, 37 reported that more outsourcing of tests would be necessary if FDA finalized its proposal. Some comments stated that the impact would be particularly significant for laboratories that currently lack the infrastructure to comply with applicable requirements and for emerging companies.

Based on these concerns, many comments stated that patient access to tests will be reduced, and patients will potentially be deprived of important health-related information. Some comments stated that this would result in worse patient outcomes and higher healthcare costs; comments suggested that patients would lose access to IVDs offered as LDTs that perform well, even some IVDs offered as LDTs that may perform better than FDA-authorized IVDs, while other comments stated that patients would lose access to testing that supports rapid care decisions. A few comments asserted that harm may result from losing access to certain types of tests, such as infectious disease tests or genetic tests. Other comments suggested that reduced access to tests would mean less choice, flexibility, competition, or ability to withstand disruptions to the test market. One comment stated that more tests would be offered by large laboratories that prioritize financial profits over accountability or patient care and that cannot ''keep up with the necessary fine-tuned evolution of these tests.'' Another comment suggested that by reducing access to testing, the phaseout policy would infringe on patient and physician ''rights to timely and adequate care and the freedom to exercise clinical judgment.'' Other comments reiterated the suggestion that the phaseout policy would limit access and thereby constrain a physician's ability to use his or her discretion to make treatment decisions. Some comments questioned whether the market withdrawal of some IVDs offered as LDTs would be counterbalanced by the introduction of new IVDs.

In addition, some comments stated that by reducing the availability of IVDs offered as LDTs, the phaseout policy would lead to delays in testing, including by potentially increasing reliance on reference laboratories which may increase the time for individuals to obtain test results. Other comments argued that delays will result from FDA's premarket review process, which will slow down the ability of patients to access tests that they need. Comments also stated that if FDA were to finalize its proposal, delays could result due to less competition, and that if the phaseout policy results in centralization of tests to certain locations, patients who are not in the local area could face additional hurdles.

(Response 209) As described in section V, FDA has made several changes to the phaseout policy that was described in the NPRM, including the addition of certain enforcement discretion policies. These changes significantly reduce the economic impact of the phaseout policy, and thus the likelihood that laboratories may reduce their test offerings or exit the market. Based in part on the inclusion of these enforcement discretion policies in the final phaseout policy, FDA disagrees with concerns that the phaseout of the general enforcement discretion approach for LDTs will have a significant net negative impact on patient access to IVDs that have appropriate assurance of safety and effectiveness.

Most notably, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3.

FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP, and premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system, as discussed in sections V.B.2 and V.B.3.

FDA anticipates that these aspects of the final phaseout policy will substantially reduce the overall impact of the phaseout policy on patient access to clinical tests. In addition, FDA notes that, as explained in the NPRM and discussed in the FRIA, the FD&C Act and FDA's regulations do not require premarket review for all IVDs (88 FR 68006 at 68013). FDA estimates that approximately 50 percent of IVDs offered as LDTs will not require premarket review (see section II.F.2 of the FRIA (Ref. 10)). Moreover, under FDA's phaseout policy, FDA does not intend to phase out the general enforcement discretion approach for premarket review requirements for IVDs offered as LDTs until several years after publication of this final rule. FDA also generally does not intend to enforce against IVDs offered as LDTs for lacking premarket authorization after a complete PMA, HDE application, 510(k), BLA or De Novo request has been submitted to FDA by the start of the corresponding stage of the phaseout policy, until FDA completes review of the submission, so as not to interrupt access to IVDs that are already on the market and available to patients.

To the extent that some IVDs offered as LDTs come off the market because, for example, the IVD cannot meet applicable requirements under the FD&C Act and its implementing regulations, or the laboratory does not invest resources to meet those requirements, the value of access to such IVDs is diminished in the absence

of assurances regarding the IVDs' safety and effectiveness. Neither patients nor providers are helped by access to tests that are not safe and effective for their intended use. In addition, in the event some IVDs offered as LDTs exit the market, FDA expects that other manufacturers may fill the need with IVDs that comply with applicable FDA requirements. FDA also anticipates that applying the same general oversight approach to both laboratory and non-laboratory manufacturers of IVDs will encourage genuine innovation and facilitate access to IVDs for which there is a reasonable assurance of safety and effectiveness, as discussed further in response to comment 218 (see Refs. 15, 22, 88 to 90).

Finally, it is unclear to FDA how generalizable the survey data cited in comments may be. While comments stated that the American Society for Microbiology's survey of its members found that over 80 percent of the microbiology laboratories surveyed would consider discontinuing most LDTs if FDA finalized its proposal, only 88 of the American Society for Microbiology's 36,000 members (0.2 percent) responded to the survey (Ref. 205). Similarly, the Association of Pathology Chairs' survey of its members produced only 39 responses (Ref. 170), while their comment states that the Association of Pathology Chairs ''represents the entire academic pathology leadership team of over 160 departments nationwide.'' Regardless, the policy changes to the phaseout policy, including the addition of certain enforcement discretion policies, help address the concerns identified in these surveys as described above.

(Comment 210) A few comments stated that laboratories may begin offering their tests for ''surveillance use only,'' in reference to a category of tests that FDA proposed in the NPRM would not be affected by the phaseout policy.

(Response 210) Tests for public health surveillance are limited to tests manufactured and offered for use exclusively for public health surveillance and are distinct from tests used for other purposes in that they are intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control, and tests results are not reported to patients or their healthcare providers. Tests for which results are returned to a patient or healthcare provider would not be considered public health surveillance tests. Laboratories could not simply label tests ''for surveillance use'' to avoid oversight of broader use of the tests.

(Comment 211) FDA received a comment which stated that FDA should analyze the totality of circumstances that currently exist ''in healthcare'' before phasing out the general enforcement discretion approach for LDTs. This comment suggested that such circumstances support the conclusion that the phaseout policy will contribute to a ''total disruption'' in patient access to tests. Another comment asked whether the Agency has performed, or intends to perform, an impact analysis on patient care, patient access, and patient safety, and one comment expressed concern that action by FDA in the absence of comprehensive data regarding the use of LDTs will result in severe restrictions on access.

(Response 211) As described elsewhere in this preamble, the Agency has determined that increased FDA oversight is necessary to better assure the safety and effectiveness of IVDs offered as LDTs, and that maintaining the general enforcement discretion approach for LDTs is not in the best interest of the public health. In finalizing FDA's policy for phasing out the general enforcement discretion approach for LDTs, FDA has carefully considered issues related to patient care and access, including through the Agency's review and analysis of more than 6,500 comments submitted to the docket for this rulemaking. As discussed in response to comment 209, FDA's final phaseout policy includes several policies that will substantially reduce the overall impact of the phaseout policy on patient access to IVDs offered as LDTs. FDA has also conducted a detailed regulatory impact analysis that considers costs and benefits; please see discussion in the FRIA (Ref. 10).

(Comment 212) FDA received a comment which stated that ending the general enforcement discretion approach for LDTs would impact laboratories' willingness to share new methods and rare reagents with each other. The comment stated that as a result, the phaseout policy may impede efforts that aim to address barriers to care, such as the Cancer Moonshot Initiative.

(Response 212) FDA does not agree that ending the general enforcement discretion approach for LDTs will result in less scientific exchange between laboratories, or negatively impact initiatives such as the Cancer Moonshot Initiative. FDA anticipates that the phaseout policy will help to advance the Cancer Moonshot Initiative, as cancer care is often personalized based on the genetic makeup of the tumor, and helping to ensure that IVDs offered as LDTs have appropriate assurance of safety and effectiveness will help patients with cancer get the optimal treatment. Although FDA's phaseout of the general enforcement discretion approach may lead laboratories to incur additional costs, including in connection with premarket review requirements in some cases, FDA does not anticipate that these factors will necessarily cause laboratories that currently share new methods, rare reagents, or other information or materials to cease doing so.

Moreover, better assuring the safety and effectiveness of LDTs may foster test innovation and facilitate the collective efforts of the scientific and medical communities to identify promising technologies, new therapies, or areas worthy of future research (see Refs. 15, 22, 88 to 90). The FD&C Act's premarket review requirements provide an impetus for manufacturers to conduct scientifically sound and robust research to establish the safety and effectiveness of their devices, including IVDs. Basing decisions on scientifically reliable information can help to eliminate or reduce harms to health, such as misdiagnosis or delayed diagnosis with a lost opportunity for effective treatment, as well as the diversion of limited resources to ineffective treatments. *See* January 2017 Discussion Paper at 5–6 (Ref. 57).

(Comment 213) One comment stated that during a past recall of a particular IVD, FDA recommended the use of an LDT as an alternative to the recalled device. The comment expressed concern that ending the general enforcement discretion approach for LDTs may impede FDA's ability to respond to similar recalls.

(Response 213) FDA disagrees with this comment. By phasing out the general enforcement discretion approach for LDTs, FDA seeks to better protect the public health by helping to assure the appropriate safety and effectiveness of LDTs, including IVDs offered as LDTs, which may serve as alternatives to IVDs that are the subject of a recall. Moreover, as discussed in response to comment 209, FDA's final phaseout policy includes several policies that will substantially reduce the overall impact of the phaseout policy on patient access to IVDs offered as LDTs.

(Comment 214) FDA received comments stating that the phaseout policy would have a negative impact on innovation in the testing space, as laboratories working to come into compliance would be either unable or

unwilling to engage in innovative test development. Some comments stated that the regulatory constraints associated with the phaseout policy would cause laboratory manufacturers to develop fewer tests, hindering the timely development and deployment of cutting-edge therapies and diagnostic tools and ultimately harming patients. Comments noted that LDTs are an area of rapid advancement, with some being in use only for short periods of time, and some comments expressed concern that enforcing premarket review requirements for each individual assay or slight modification would not be adequate to keep up with the progress of testing. One comment stated that the phaseout policy would force laboratories to focus efforts on developing premarket applications for current tests instead of innovating to improve patient care. Some comments stated that the phaseout policy would cause delays in the development of new diagnostics, impacting the ''competitive edge of U.S. medical research and development.''

(Response 214) FDA does not agree that the phaseout policy will hinder the timely development and deployment of innovative IVDs offered as LDTs. In fact, as discussed in response to comment 218, applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs may facilitate the development of innovative IVDs from non-laboratory manufacturers.

Even when premarket review is required for an IVD offered as an LDT, FDA does not agree that such review generally impairs innovation. The evidentiary requirements of premarket review spur innovation based on reliable scientific evidence that enables an informed determination of the safety and effectiveness of medical devices for each intended use and product labeling that provides information for using the product safely and effectively for such use. The generation of scientific evidence that is independently reviewed by FDA supports physicians in making sound clinical decisions. *See* January 2017 Discussion Paper at 3 (Ref. 57).

We note that sponsors have sought and obtained FDA authorization for innovative IVDs offered as LDTs. For example, a list of authorized CDx IVDs, which include innovative IVDs offered as LDTs, is available on FDA's website (Ref. 206). Furthermore, FDA's Breakthrough Devices program is intended to help expedite the development and review of certain devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions (21 U.S.C. 360e–3).

We agree that test innovation and development is important for patients and the public health, and we recognize the concern that expecting currently marketed IVDs offered as LDTs to come into compliance may cause laboratories to divert resources from the development of new IVDs, due to the time and resources that would be needed to comply with the regulatory requirements for their existing IVDs offered as LDTs. Based on these considerations along with concerns about reliance, and as discussed further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this final rule. This enforcement discretion policy will improve patient access by allowing laboratories to focus resources on submissions for new, innovative tests based on reliable scientific evidence, rather than expend such resources in support of tests already on the market.

In addition, FDA intends to continue exercising enforcement discretion and generally not enforce premarket review and most QS requirements for such currently marketed IVDs offered as LDTs when they are modified in certain limited ways as described in section V.B.3. This aspect of the enforcement discretion policy will help to facilitate patient access to these tests by permitting certain modifications to be made within the scope of the enforcement discretion policy.

To further facilitate access going forward, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.[89] In the context of tests for unmet needs, there may be less opportunity to recoup costs of premarket review. This policy is intended to reduce the risk that premarket review costs would dissuade development of and access to such tests, taking into account the mitigations described in section V.B.3.

Moreover, although we acknowledge that the preparation and submission of PMAs and 510(k)s impose the majority of costs estimated for laboratories under the final phaseout policy, we also note that as explained in the NPRM, under FDA's device authorities, FDA premarket review is required only for certain tests (88 FR 68006 at 68009). FDA estimates that approximately 50 percent of IVDs newly offered each year as LDTs will not require premarket review.

For these reasons, FDA does not anticipate that the phaseout policy will hinder the timely development and deployment of cutting-edge diagnostic tools, impair the competitiveness of U.S. medical research and development, or ultimately harm patients, as suggested by the comments. See also our response to comment 218 for discussion regarding how applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs may facilitate the development of innovative IVDs.

(Comment 215) Several comments noted that laboratories must be able to modify existing tests quickly to diagnose new conditions and monitor the impact of new therapies. Some comments stated that stifling modifications of currently marketed IVDs offered as LDTs would force pathologists and other healthcare providers to use older, less optimal tests, and noted that many patients do not have the time to wait for diagnostic development and rely on laboratories to be nimble and adapt to changing diagnostic criteria. One comment noted the ''redundancy and inability to update markers in flow cytometry panels based on new evidence'' as a longstanding issue and recommended FDA address the barriers that prevent laboratories from readily adapting tests in response to evolving scientific knowledge.

(Response 215) FDA appreciates the need for improvements to existing tests to better serve patients and providers, and notes that a manufacturer's modifications to its tests that have already been cleared, approved, licensed, or had a De Novo request granted by FDA require FDA review only in certain circumstances (see §§ 814.39, 807.81(a)(3), and 601.12 (21 CFR 601.12)). FDA has published several resources to help stakeholders determine whether a certain change or modification to a test may require a regulatory submission, including: (1) FDA's final guidance document entitled ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process'' (Ref. 185), (2) FDA's final guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (Ref. 61), and (3) FDA's

[89] FDA recognizes that innovation often takes place in AMCs. *See e.g.,* Refs. 207–210.

final guidance document entitled ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device'' (Ref. 211).

FDA recognizes that tests evolve in response to new scientific information, and FDA wants to avoid disincentivizing minor improvements to existing tests. As detailed in section V.B.3, for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) even if the IVD is modified in certain limited ways as described in section V.B.3. FDA intends to issue a draft guidance with additional details and examples and will seek public comment on such draft guidance.

(Comment 216) Some comments expressed concern regarding the potential impact of the phaseout policy on innovative academic research and clinical trials, suggesting that researchers will have little incentive or ability to develop new LDTs due to the costs associated with compliance with statutory and regulatory requirements. Several comments noted that non-profit AMCs are often the nexus for innovation in medicine and that LDTs developed by AMCs play a critical role in education, development, and quality monitoring for rare disease tests and other conditions that do not have a viable market for commercial test development. One comment stated that the phaseout policy may result in LDTs that are very expensive or limited to common health conditions with established demand.

(Response 216) As discussed above, FDA anticipates that the enforcement discretion policy for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in certain limited ways as described in section V.B.3, will address concerns that patient access to new tests would be reduced due to laboratories' focus on premarket submissions, as well as concerns that LDTs will become more expensive due to the cost of resources that would be needed to prepare and submit premarket submissions for currently marketed tests under the phaseout policy as proposed in the NPRM. The Agency believes that the policies described herein will help avoid undue disruption to the testing market, specifically for healthcare providers and patients that are relying on continued access to currently offered tests, and will encourage genuine innovation.

To facilitate access going forward, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. This policy carefully balances the risk of not having a test available with the risk of not having assurances of premarket review in the context of the mitigations described in section V.B.3.

For additional discussion regarding the application of the phaseout policy in the clinical trial context, see our response to comment 175.

(Comment 217) FDA received some comments disagreeing with the view that increased oversight of LDTs may lead to increased innovation in the IVD space. These comments stated that LDTs and the laboratories that develop them are the catalysts for innovation, as they are typically developed when no ''commercial'' option is available and later acquired by manufacturers after technology and market development. On the other hand, one comment stated that the investment community and some LDT manufacturers have indicated that FDA's proposal ''will not significantly impede the ability of LDTs to reach the market.''

(Response 217) FDA recognizes the concerns regarding potential impact on innovation, but for the reasons discussed in our response to comment 214, FDA disagrees with the statement that the phaseout policy will not foster innovation and access to IVDs that have appropriate assurance of safety and effectiveness. While continued patient and provider access to certain tests is important, FDA also recognizes that an uneven oversight approach for laboratory and non-laboratory manufacturers of IVDs may discourage test development and innovation, as further discussed in response to comment 218 (see also Ref. 88). By applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs, FDA will give stakeholders greater clarity regarding regulatory expectations, and may facilitate investment in the development of innovative IVDs. Additionally, as recently noted in a joint statement issued by CMS and FDA regarding the oversight of LDTs, FDA's phaseout approach will remove a disincentive for non-laboratory manufacturers to develop novel tests (Ref. 71). We anticipate that phasing out the general enforcement discretion approach for LDTs will spur genuine innovation for IVDs for which there is a reasonable assurance of safety and effectiveness.

J. Level Playing Field

(Comment 218) FDA received a few comments discussing the impact of applying the same oversight approach to laboratories and non-laboratories that manufacture IVDs. One comment expressed support for a consistent framework for LDT risk assessment and the enforcement of FDA review requirements according to a test's intended use and stated that ''[a] level playing field is critical to maintaining the integrity of FDA review, fostering innovation, and providing patients with high-quality care.'' Another comment asserted that FDA's statements that application of the same oversight approach to laboratory and non-laboratory manufacturers may remove a disincentive for non-laboratory manufacturers to innovate and thus spur innovation is speculative as FDA has not surveyed manufacturers. The comment added that ''market forces, financial considerations, and challenges with patient enrollment in clinical trials for low prevalence pathogens are more likely the disincentivizing factors.''

(Response 218) FDA agrees that it is appropriate to apply the same general oversight approach to both laboratories and non-laboratories that manufacture IVDs. The general enforcement discretion approach for LDTs has led to an oversight scheme that does not best serve the public health, and there is no longer a sound basis to have a bifurcated enforcement approach for LDTs and other IVDs. As discussed in section III.B and our responses to comments in section VI.C, most IVDs offered as LDTs are functionally the same as those made by other manufacturers of IVDs, and evidence has exposed problems associated with certain IVDs offered as LDTs.

In addition, FDA agrees that applying the same general oversight approach will result in more stability to the testing market overall, which could help to encourage the manufacture of IVDs for which there is a reasonable assurance of safety and effectiveness. FDA is also aware that some firms have claimed a superficial connection to laboratories and then offered IVDs as LDTs (see Refs. 212 to 215). Given FDA's general enforcement discretion approach for LDTs, firms that use this business model have offered tests to patients in the absence of FDA oversight, with the potential for inaccurate or incomplete results that may impact patients' healthcare decisions. In addition, FDA is aware of concerns that the use of this type of

business model unfairly disadvantages non-laboratory IVD manufacturers that manufacture and market similar tests that comply with applicable FDA requirements. The increase in firms using these business models underscores the need for more oversight.

FDA is also aware of concerns that non-laboratory IVD manufacturers may currently be discouraged from investing time and resources into developing novel tests due to the concern that once the manufacturer receives marketing authorization for its test, laboratories will develop similar tests and market them without complying with FDA requirements, thereby disincentivizing innovation (see response to comment 217).[90] We anticipate that applying the same general oversight approach to laboratories and non-laboratories that manufacture IVDs will address these business strategies that take advantage of the current bifurcated system.

However, FDA also recognizes the effect that its longstanding enforcement discretion approach has had on the market, the role that laboratory-manufactured tests play in modern healthcare, and the presence of other expert regulatory bodies. Many comments emphasized these considerations and FDA agrees with certain comments' concern, for example, that the proposed phaseout policy could lead to the widespread loss of access to safe and effective IVDs on which patients currently rely and certain LDTs for unmet needs. As such, and as further discussed in section V.B, while FDA believes it is appropriate to apply the same general oversight approach to both laboratories and non-laboratories that manufacture IVDs, the Agency has determined that targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories is appropriate and in the best interest of the public health.

(Comment 219) One comment disagreed with the statement that the phaseout of the general enforcement discretion approach would advance innovation by both laboratory and non-laboratory manufacturers, stating that under the general enforcement discretion approach, laboratory manufacturers, especially AMCs, provide innovative, personalized LDTs to fill gaps in test offerings, which then allow conventional manufacturers to assess the market impact of these LDTs and make business decisions based on the LDT experience.

(Response 219) FDA believes that the phaseout of the general enforcement discretion approach for LDTs is necessary to better assure the safety and effectiveness of IVDs offered as LDTs and that the same general oversight approach for LDTs and other IVDs will bring more stability to the market overall. FDA recognizes that laboratory manufacturers of LDTs, including AMCs, may manufacture LDTs that are in lower demand and currently fill gaps in test offerings. As discussed further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA believes that this policy will address concerns that laboratories integrated within a system and that manufacture LDTs for unmet needs will stop doing so in light of the limited market for such LDTs and the perceived costs of compliance with premarket review and QS requirements.

(Comment 220) One comment noted that FDA's proposal could lead to an unfair playing field between AMCs and for-profit laboratories. The comment indicated that IVDs offered as LDTs by AMCs are typically tests for rare diseases that are not profitable, and suggested that the phaseout policy should perhaps distinguish between for-profit and non-profit laboratories.

(Response 220) As discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA anticipates that this approach will help to reduce the possibility that laboratories in AMCs, or other healthcare systems, may stop manufacturing LDTs for unmet needs.

K. Impact to Specific Patient Populations

(Comment 221) FDA received several comments expressing concern that ending the general enforcement discretion approach for LDTs will negatively impact patient access to necessary tests and thus worsen disparities in healthcare, particularly for racial and ethnic minorities that rely on IVDs offered as LDTs for diagnosis and to inform treatment.

(Response 221) FDA disagrees with the comments stating that phasing out the general enforcement discretion approach for LDTs will exacerbate health inequities for underrepresented patient populations. As detailed in the NPRM, there are concerns that in the absence of greater FDA oversight, IVDs offered as LDTs may be exacerbating health inequities due to higher rates of inaccurate results among underrepresented patient populations, particularly racial and ethnic minorities undergoing genetic testing (88 FR 68006 at 68013; Refs. 21 and 216 to 219). Some IVDs offered as LDTs have not been validated for use across patient populations within a disease state, which may result in decreased accuracy for underrepresented patient populations and further contribute to health disparities (Ref. 220). With increased oversight, FDA will be able to help promote adequate representation of the intended use population in validation studies, and transparency regarding potential differential performance and unknown performance in certain patient populations, which will ultimately help advance health equity.

FDA also recognizes that IVDs offered as LDTs might serve communities in rural, medically underserved areas with disparities in access to diagnostic tests. However, the benefits of test access depend on the ability of tests to work as intended, and the harms of unsafe or ineffective IVDs offered as LDTs might disproportionately occur among medically underserved patient populations that such tests might aim to reach. Without appropriate oversight, IVDs offered as LDTs might exacerbate health disparities.

Nevertheless, FDA recognizes the concerns articulated in these comments regarding potential access issues resulting from the proposed phaseout policy and has adopted several targeted enforcement discretion policies to address those issues, among other things. For example, FDA acknowledges the importance of avoiding widespread loss of access to IVDs on which patients and the healthcare community currently rely, which ultimately could be more harmful than helpful to the public. As such, and for the reasons further discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M

[90] FDA also recognizes that challenges in conducting clinical trials for low prevalence pathogens may disincentivize the development of certain novel tests. As noted in section V.B.3 and in response to comment 142, FDA intends to consider whether issuing additional guidance regarding validation of tests, including those for rare diseases that takes into consideration the challenges in obtaining a robust number of samples for validation, would be helpful. In the event FDA were to issue any such guidance, FDA would do so in accordance with good guidance practices (see § 10.115).

(Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3.

FDA is also adopting a targeted enforcement discretion policy for certain unmet need LDTs to help avoid patients being deprived of critically needed LDTs where certain risk mitigations exist (see further discussion in section V.B.3).

(Comment 222) One comment stated that ending the general enforcement discretion approach for LDTs will limit access to necessary tests and make it more difficult to enroll underrepresented patients in clinical trials, which will reduce clinical trial diversity.

(Response 222) As discussed above, FDA is adopting enforcement discretion policies for currently marketed IVDs offered as LDTs and unmet needs LDTs, as described in section V.B.3. These policies will help to address concerns regarding limiting access to such IVDs and resulting difficulties in enrolling diverse populations in clinical trials.

(Comment 223) FDA received one comment that stated that FDA had ignored the special needs of the Native American population, as LDTs are used to analyze mutations with high prevalence in this population, and the population may be ''disenfranchised by the loss of LDTs diagnosing their genetic disorders'' as a result of phasing out the general enforcement discretion approach for LDTs. The comment suggested that FDA's tentative determination that ''the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes,'' as stated in section XII of the NPRM, was incorrect. The comment also suggested that other populations, specifically ''immigrant populations,'' would be similarly, negatively affected by the phaseout policy. Another comment stated that there could be legal implications if patients or groups argue that FDA's actions disproportionately affect certain populations' access to healthcare.

(Response 223) FDA appreciates the need to consider potential impacts on the Native American population and other specific patient populations. The Agency recognizes that some IVDs offered as LDTs may be currently used to diagnose genetic disorders common in the Native American population. In light of the enforcement discretion policy for currently marketed IVDs offered as LDTs that FDA is adopting, FDA does not anticipate that the Native American population will lose access to such IVDs. In addition, we believe the unmet needs policy described in this preamble, see further discussion at section V.B.3, will help to avoid laboratories integrated in healthcare systems from no longer manufacturing LDTs that meet the unique needs of the Native American population due to the limited market for such tests and perceived costs of compliance with premarket review and QS requirements. As such, FDA does not believe that the Native American population will be disenfranchised as a result of the phaseout policy. For additional discussion regarding FDA's analysis of the rule in accordance with the principles set forth in E.O. 13175, please see section XII.

The concepts described above with respect to the Native American population are also applicable to other groups, such as ''immigrant populations,'' mentioned in the comments.

(Comment 224) FDA received comments regarding the impact of the phaseout policy on medically underserved patient populations. Some comments stated that the phaseout is likely to exacerbate health inequities by further limiting access to testing in rural areas and disproportionately impacting vulnerable patient populations such as pediatric, low-income, lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+), and minority communities. A few comments stated that the phaseout will further disadvantage underserved populations from both medical and financial perspectives, as AMC laboratories and other laboratories serving these populations will not have the resources to complete FDA submissions for their tests and will need to outsource testing. One comment voiced concern that FDA has not adequately or accurately assessed the impact of the phaseout on the practice of medicine and patient care, specifically for patients in underserved geographies and those with possible rare diseases. Additionally, a few comments stated that the phaseout will have a detrimental impact on the affordability and speed of testing, which will hinder the ability of some laboratories (particularly public health laboratories) to serve marginalized groups including incarcerated, elderly, and homeless populations.

(Response 224) FDA disagrees that phasing out the general enforcement discretion approach for LDTs will negatively impact medically underserved populations' access to IVDs. FDA recognizes that IVDs offered as LDTs may serve rural communities and other patient populations with disparities in access to diagnostic tests, and recognizes the concern regarding potential disruption of access to IVDs offered as LDTs, particularly for underserved and vulnerable patient populations. However, FDA anticipates that the targeted enforcement discretion policies described in this preamble will help to address the concerns raised in the comments. For example, with respect to AMCs that serve medically underserved populations, as discussed further in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system (including an AMC) to meet an unmet need of patients receiving care within the same healthcare system. We believe this policy addresses the concerns raised in the comment regarding AMCs.

FDA disagrees with the comment that the Agency has not adequately or accurately assessed the impact of the phaseout policy on patients in underserved geographies. As indicated in the PRIA, and again in section II.K of the FRIA (Ref. 10), FDA has considered the potential effects of the phaseout on health inequities to the extent we are able to do so based on available information. FDA recognizes that IVDs offered as LDTs might serve communities in underserved geographies with disparities in access to diagnostic tests, and the harms of unsafe or ineffective IVDs offered as LDTs might therefore disproportionately occur among individuals in such geographies. As noted in response to comment 221, the benefits of test access depend on the ability of tests to work as intended, and without appropriate oversight, IVDs offered as LDTs might exacerbate health disparities.

FDA has carefully assessed information about IVDs offered as LDTs in scientific literature, news articles, submissions to FDA, and allegations and adverse event reports submitted to the Agency, among other sources, and this information supports a phaseout of FDA's general enforcement discretion approach for LDTs. By phasing out the general enforcement discretion approach, FDA seeks to better prevent and mitigate harm to patients, including those in underserved populations, that may result from inaccurate and unreliable tests, while also accounting for other important public health

considerations such as patient access and reliance.

For discussion of the impact of the phaseout policy on the affordability and speed of testing, see our responses to comments 207 and 209 in sections VI.H and VI.I of this preamble.

(Comment 225) FDA received comments expressing concern that ending the general enforcement discretion approach for LDTs will negatively impact Medicare beneficiaries. One comment stated that increased costs for tests will lead to increased Medicare and Medicaid costs, and some comments inquired whether Medicare reimbursements will be adjusted to support the increased costs resulting from the phaseout of the general enforcement discretion approach for LDTs.

(Response 225) As discussed in response to comments in section VI.H, and as noted in section II.F.6 of the PRIA and in the FRIA (Refs. 60 and 10), the exact effect of the phaseout policy on the price of IVDs offered as LDTs is unknown. However, FDA's decision to include certain enforcement discretion policies in the final phaseout policy is predicted to significantly reduce the costs of compliance under the final phaseout policy, thus reducing the number of laboratories that scale back operations or exit the market, which may in turn reduce any impact of the phaseout policy on pricing. In addition, as noted in response to comment 207, phasing out the general enforcement discretion approach for LDTs will help to reduce other healthcare costs. While certain costs may be passed on to individuals and insurers, we expect some of these costs will be offset by the associated benefits.

In terms of coverage and reimbursement, Medicare is administrated by CMS under different statutory authorities than those governing FDA regulation of IVDs, and future decisions regarding reimbursement are outside the scope of this rulemaking and phaseout policy.

(Comment 226) Other comments articulated concerns regarding the impact of the phaseout policy on laboratory testing for hospitals and providers that serve Medicare and Medicaid patients. These comments expressed concern regarding the potential for the phaseout policy to increase costs for such providers and decrease access to testing for vulnerable patients, particularly children. One comment noted that Medicaid has limited coverage policies for certain laboratory tests and large reference laboratories often do not provide services to Medicaid patients unless the services are covered.

(Response 226) As discussed above, the exact effect of the phaseout policy on the price of IVDs offered as LDTs is unknown, but the enforcement discretion policies described in this preamble are predicted to significantly reduce the costs of compliance associated with the final phaseout policy, thus reducing the number of laboratories that scale back operations or exit the market, which may in turn reduce any impact of the phaseout policy on pricing.

In terms of the comments regarding Medicaid coverage policies, as Medicaid is administrated by CMS and the States under different statutory authorities than those governing FDA's regulation of IVDs, such comments are outside the scope of this rulemaking and phaseout policy.

(Comment 227) FDA received comments stating that the phaseout policy will disproportionately impact pediatric patients. Several comments noted that tests for pediatric patients often do not have any FDA-authorized or ''commercial'' equivalents, and that tests must be modified to serve the pediatric patient population. As an example, some comments pointed to the lack of FDA-authorized tests to detect sexually transmitted infections (STIs) in children, which must be used in cases of sexual abuse and assault against children. Other comments noted that pediatric patients and their healthcare providers are highly reliant on LDTs because many conventional manufacturers do not seek FDA approval for all age groups and often choose not to develop tests for pediatric diseases, due to the challenges in studying pediatric populations and the relatively slim financial margins for such tests. These comments stated that any action that leads to LDTs not being offered for pediatric patients will result in delayed diagnosis and care for such patients.

(Response 227) FDA understands that laboratories have been using IVDs offered as LDTs to test pediatric patients, and we recognize concerns that phasing out the general enforcement discretion approach for LDTs may lead to a higher chance that laboratories stop offering these tests. FDA believes that the enforcement discretion policies discussed further in section V.B.3, specifically the policies for currently marketed IVDs offered as LDTs and for LDTs for unmet needs, will help to avoid access issues to currently marketed IVDs for pediatric patients as well as LDTs for pediatric patients that meet the unique needs of the patient (see response to comment 228).

(Comment 228) Some comments noted that specialized IVDs offered as LDTs are often vital to medical management for patients with complex medical needs. Comments asserted that the phaseout policy would leave gaps in detection and treatment for these and other vulnerable patients. One comment provided as an example the modification of FDA-authorized assays for more rapid assessment of tuberculosis.

(Response 228) FDA recognizes the need for specialized testing for patients with complex medical needs and for vulnerable populations, like children, who may not have access to FDA-authorized tests. As noted above, FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for currently marketed IVDs offered as LDTs as described in section V.B.3. FDA believes this policy will help to address concerns regarding continued access to currently marketed IVDs for patients with complex medical needs and vulnerable populations. FDA also intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA believes that as a result of this policy, laboratories integrated within healthcare systems will be less likely to not manufacture LDTs for unmet needs due to the limited market for such tests and the perceived costs of compliance with premarket review and QS requirements. Additionally, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements when a laboratory certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's lawfully marketed test that is not a PMA-approved or BLA-licensed test, in a manner that could not significantly affect the safety or effectiveness of the test or its intended use, as described in sections V.C.4 and V.C.5.

L. Specific Types of IVDs

1. Direct-to-Consumer IVDs

(Comment 229) FDA received comments stating that regulation of direct-to-consumer tests should be prioritized because, unlike in AMCs and hospitals, they are provided to

consumers outside of a regulated environment. Comments noted that the direct-to-consumer market is where much of the public concern currently lies regarding unreliable results, as they are not subject to the same controls as LDTs in clinical laboratory settings (*i.e.,* CLIA requirements). Other comments further stated that direct-to-consumer tests are often provided without accompanying healthcare counseling, which puts users at risk for misinterpretation or patient harm and therefore ''should be regulated by FDA.''

(Response 229) FDA agrees with comments that direct-to-consumer tests present risks that are unique and different from some of those posed by IVDs offered as LDTs used in clinical laboratory settings. Indeed, FDA's general enforcement discretion approach for LDTs has not applied to direct-to-consumer tests, including for this reason. FDA's general enforcement discretion approach was originally premised, in part, on the participation of medical professionals who, among other things, help determine whether a particular test is appropriate, counsel patients, assist in interpreting results, and assess how the results fit in the overall clinical picture. FDA believes there is a heightened need for oversight of tests where test results are used by consumers to make potentially significant healthcare decisions without the involvement of a learned intermediary in a legitimate healthcare practitioner-patient relationship.

(Comment 230) Some comments stated that the phaseout policy would make it harder for consumers to obtain and use at-home tests, particularly for STIs and human immunodeficiency virus (HIV). Comments noted that this would especially impact those in the LGBTQIA+ community who benefit from at-home tests that can be done discreetly and requested FDA consider ''exemptions'' for direct-to-consumer tests that further ''public health initiatives.''

(Response 230) FDA disagrees that the phaseout policy would make it more difficult for consumers to obtain necessary at-home tests, and notes that FDA has approved a home use test for HIV (Ref. 221) and has authorized an STI test with at-home sample collection for chlamydia and gonorrhea (Ref. 222). As noted in the NPRM and this preamble, FDA's general enforcement discretion approach for LDTs has not applied to direct-to-consumer tests given the greater risks to consumers presented by these tests (88 FR 68006 at 68022). In situations where consumers may be relying on direct-to-consumer tests to rule out, or otherwise diagnose, a disease or condition, there is a heightened need for FDA oversight. For these tests, FDA has generally expected compliance with applicable requirements, and the Agency is not changing that approach with the phaseout policy.

(Comment 231) One comment stated that the NPRM ''specifies [an] exemption for direct-to-consumer testing,'' the danger of which cannot be understated and noted that direct-to-consumer testing ''is the exact type of testing the FDA should be focusing on.''

(Response 231) FDA agrees that direct-to-consumer tests should be a focus of FDA oversight due to the risks they present. This comment appears to reflect a misunderstanding of FDA's proposal. The NPRM indicated that direct-to-consumer tests would not be included in the phaseout policy and, as a result, FDA would continue to expect compliance with applicable regulatory requirements for direct-to-consumer tests. As discussed above and in the NPRM, FDA's general enforcement discretion approach for LDTs has not applied to direct-to-consumer tests (88 FR 68006 at 68022). FDA has generally expected compliance with applicable requirements for direct-to-consumer tests and the phaseout policy does not change that approach.

2. Forensic Tests

(Comment 231) FDA received several comments regarding the Agency's proposal to continue its general enforcement discretion approach for tests intended solely for forensic (law enforcement) purposes. The majority of these comments supported FDA's proposed approach, including one comment which expressed that it was appropriate for FDA to focus on ''clinical uses'' and to exercise enforcement discretion for tests intended solely for forensic purposes.

(Response 232) FDA agrees with the comments supporting continued enforcement discretion for tests intended solely for forensic (law enforcement) purposes. We described an enforcement discretion approach for tests intended solely for forensic (law enforcement) purposes more than 20 years ago (see, *e.g.,* 65 FR 18230, April 7, 2000). This policy recognized that protections within the judicial process could mitigate risk related to test accuracy and sample collection. Additionally, FDA agrees that it should focus its limited resources on tests that present risks to patients, where sufficient mitigations for test accuracy and sample collection do not otherwise exist. FDA did not receive any data to justify changing its longstanding policy. FDA, therefore, intends to continue to exercise enforcement discretion for tests intended solely for forensic (law enforcement) purposes. In addition, since the policy on tests for forensic (law enforcement) purposes applies to all tests for forensic (law enforcement) purposes, including those manufactured by non-laboratory manufacturers, changing that policy would not be appropriate in the context of this rulemaking and related policies which are focused on IVDs that are manufactured by laboratories.

(Comment 233) We received a few comments that advocated against FDA's proposal to continue its enforcement discretion approach for tests intended solely for forensic (law enforcement) purposes, primarily because, according to these comments, such tests should be ''regulated'' the same as other IVDs, and FDA authorization would likely enhance fairness of the judicial system. Another comment indicated that forensic laboratories are not typically CLIA-certified and that NYS CLEP currently requires review of forensic tests. Some laboratories offering forensic tests are accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA), but this level of accreditation is currently required only if a laboratory is testing for certain Federal programs. The comment went on to argue for broader Federal oversight of this test category.

(Response 233) FDA disagrees that ceasing its longstanding enforcement discretion approach for tests intended solely for forensic (law enforcement) purposes is warranted. As FDA explained in the **Federal Register** (65 FR 18230), tests intended solely for forensic (law enforcement) purposes are subject to additional protections such as the use of rules of evidence in judicial proceedings and the representation of the accused (*i.e.,* the person being tested) through the judicial process. The fairness of the judicial process is a separate issue that is not within the scope of this rulemaking.

Further, because FDA's longstanding enforcement discretion approach for these tests is grounded in the sufficient mitigations in the judicial process, it is inapposite whether these laboratories or their tests are accredited or reviewed by/under CMS, NYS CLEP, or SAMHSA.

(Comment 234) A comment requested that FDA clarify that the general enforcement discretion approach for tests intended solely for forensic purposes includes only tests within FDA's jurisdiction and that it does not capture tests performed by forensic DNA testing laboratories that fall

outside of FDA's purview. The comment explained that tests at forensic DNA testing laboratories are not ''intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease,'' or ''intended to affect the structure or any function of the body.'' Rather, relationship testing (DNA) facilities use forensic tests exclusively for legal and immigration proceedings, criminal investigations, and identification of human remains. The comment explained that the National Institute of Justice within the Department of Justice is the lead Federal Government Agency supporting forensic laboratories, including relationship testing facilities accredited by AABB.

(Response 234) A device is defined, in relevant part, as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.'' Section 201(h)(1) of the FD&C Act. The determination of whether a product meets the definition of a device is a highly fact-dependent analysis and the context of use may not be determinative of whether a product is intended for ''diagnosis.'' [91] In any event, FDA intends to continue to exercise enforcement discretion for tests intended solely for forensic (law enforcement) purposes, meaning that it generally does not intend to enforce applicable device requirements for such tests. Moreover, FDA would not be able to enforce device requirements for any tests that do not meet the definition of a device.

3. 1976-Type LDTs

(Comment 235) A number of comments supported FDA's proposal to continue to exercise enforcement discretion for 1976-Type LDTs. However, a few comments stated that while they agreed with the spirit of this proposal, they were concerned that FDA's focus on 1976-Type LDTs ignores perceived accuracy enhancements from basic automation techniques. Other similar comments stated that FDA's proposed enforcement discretion policy for 1976-Type LDTs should be expanded to include automated techniques using components legally marketed [92] for clinical use and interpreted by a pathologist. Some comments pointed to immunohistochemistry automated staining process as an example of such automated techniques, and one comment stated that ''the technical aspect of immunohistochemistry is virtually always automated these days, while interpretation is manual.'' Another comment indicated that automation was associated with a reduction in human error rate in that particular laboratory.

(Response 235) As described in section V.B.1, FDA intends to exercise enforcement discretion and generally not enforce applicable requirements for 1976-Type LDTs given that the characteristics of these tests—*i.e.,* they involve manual techniques (without automation), are performed by laboratory personnel with specialized expertise, use components legally marketed for clinical use, and are designed, manufactured, and used within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing—mitigate the risks associated with these tests. In particular, and as explained in the NPRM, these characteristics provide the greatest risk mitigation among the characteristics that were commonly associated with LDTs offered in 1976, which resulted in the emergence of FDA's general enforcement discretion approach for LDTs (88 FR 68006 at 68022). Automation, including automated slide preparation used in immunohistochemistry, can enhance test performance, but automation also introduces new opportunities for error and other risks that, due to the nature of automation, are not easily identifiable. For these reasons, FDA does not believe that expanding the policy for 1976-Type LDTs beyond these characteristics that were commonly associated with LDTs offered in 1976 to include IVDs offered as LDTs with automation is appropriate.

(Comment 236) We received comments requesting clarity on the type of tests that FDA would consider to be 1976-Type LDTs. These comments included requests that FDA define terms such as ''automation,'' ''specialized expertise,'' or ''manual.'' Other comments asked for examples of 1976-Type LDTs.

(Response 236) Examples of tests that might be considered 1976-Type LDTs when done manually and without automation (*e.g.,* without use of software) include: various tests that use staining antibodies and general purpose reagents for cytology, hematology, and bacterial infections; cystic fibrosis sweat tests; certain colorimetric newborn screening tests; certain immunohistochemistry tests; karyotyping tests; and fluorescence in situ hybridization (FISH) tests. We reiterate that the purpose behind this category of continued enforcement discretion is to recognize the tests that have the sort of mitigations in place that resulted in the emergence of FDA's general enforcement discretion approach for LDTs, and to help focus FDA's oversight on more complex tests and tests posing higher risks.

FDA understands that commenters requested more information about the terms ''automation,'' ''specialized expertise,'' and ''manual.'' We generally intend for these terms to have their ordinary meaning. To the extent that additional information and examples would be helpful, FDA will consider issuing guidance on this topic as appropriate and in accordance with good guidance practices (§ 10.115).

(Comment 237) A few comments expressed concern that FDA's continuation of the general enforcement discretion approach for 1976-Type LDTs will encourage laboratories to avoid automation and instead perform manual tests. The comments stated that this will disincentivize efficiency and improvement, cause laboratories to close, or increase risks to patients because the comments perceived that manual tests have more room for error.

(Response 237) FDA disagrees with these comments. FDA does not anticipate that the final phaseout policy will cause laboratories to avoid automation and instead perform manual tests. Many comments from laboratories described the substantial benefits of automated approaches. These comments stated that automation improves efficiency, because, for example, fewer individuals are needed to perform a test and testing can occur more quickly. Therefore, FDA thinks it is unlikely that laboratories will stop offering automated tests and switch to manual processes so that their tests may be considered 1976-Type LDTs in the future.

FDA also does not believe that IVDs currently on the market are likely to change from an automated to manual methodology because FDA generally

[91] See, *e.g., United States* v. *An Undetermined Number of Unlabeled Cases,* 21 F.3d 1026, 1028–29 (10th Cir. 1994) (finding that containers used to collect urine and saliva specimens for HIV testing for insurance purposes were devices because ''[t]he plain meaning of 'diagnosis' disregards context and bears no connection to medical treatment''; and ''the fact insurance companies rather than health professionals considered [the results] to make business rather than medical decisions does not erase the diagnostic character of . . . the containers' use.'').

[92] As used through this rulemaking, a ''lawfully marketed'' device means a device that is in compliance with FDA requirements, which may include premarket authorization.

intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. Although this enforcement discretion policy pertains only to premarket review and most QS requirements, whereas FDA intends to exercise enforcement discretion and generally not enforce any applicable requirements for 1976-Type LDTs, the costs of compliance with applicable requirements other than premarket review and QS requirements are only a small fraction of the costs of compliance with applicable requirements under the FD&C Act and FDA's regulations (see section II.F of the FRIA (Ref. 10)). Out of the total estimated costs to industry of $1.17 billion, the estimated costs of compliance with requirements other than premarket review and QS requirements are about $95.35 million. Therefore, FDA anticipates that laboratories will not drastically change their current practices or cease to use automation for IVDs currently on the market.

Finally, FDA does not agree that 1976-Type LDTs pose more risk to patients than other tests. As previously noted, features like automation can lead to improved performance and efficiency but can also introduce new opportunities for error and other risks.

(Comment 238) A comment supported the concept of FDA continuing its general enforcement discretion approach for 1976-Type LDTs. This comment suggested, however, that FDA instead use certain other factors (instead of the 1976-Type LDT characteristics) such as the risk to the patient posed by incorrect results, availability of laboratory controls to mitigate these risks, qualification required of those performing or interpreting the test, CLIA certification level of the laboratory, the level of integration between the healthcare provider, test provider, and patient, and whether there is an IVD available, to determine if FDA's general enforcement discretion approach should continue to apply—noting that FDA should continue to exercise enforcement discretion only for an LDT where all of these elements are present.

(Response 238) FDA appreciates the support for its approach to 1976-Type LDTs; however FDA does not agree with expanding the policy for 1976-Type LDTs in the manner suggested by the comment. The purpose behind this policy is to recognize the tests that have the sort of mitigations in place that resulted in the emergence of FDA's general enforcement discretion approach for LDTs and to help focus FDA's regulatory oversight on more complex tests and tests posing higher risks. The factors proposed by the comment do not achieve the same purpose. FDA notes, however, that many of the factors identified by the comment have informed FDA's policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients (see section V.B.3).

(Comment 239) Comments requested clarification regarding whether adsorption of warm-reactive autoantibodies using allogeneic or autologous red blood cells to prepare samples for further immunohematology testing would be considered a 1976-Type LDT.

(Response 239) Adsorption of warm-reactive autoantibodies using allogeneic or autologous red blood cells to prepare samples for further immunohematology testing generally involves only manual techniques performed by laboratory personnel with specialized expertise, and therefore would generally be considered a 1976-Type LDT that would fall under the enforcement discretion policy for those tests provided it uses components legally marketed for clinical use and the design, manufacture, and use is all within a single CLIA-certified laboratory that meets the requirements under CLIA for high complexity testing.

4. Low-Risk IVDs Offered as LDTs

(Comment 240) FDA received several comments recommending FDA adopt a different approach for lower risk tests. One comment suggested FDA provide a ''tiered risk-based approach and have streamlined submission and approval options for simpler, lower risk LDTs'' to help reduce any negative consequences stemming from the phaseout policy. Another comment recommended the Agency ''adopt a new premarket review pathway'' for laboratories seeking FDA authorization for low- or moderate-risk tests. One comment stated that there should be an enforcement discretion policy for low-risk LDTs so that clinical microbiology laboratories would continue offering infectious disease LDTs to serve vulnerable communities.

(Response 240) FDA does not intend to have a separate policy for low-risk IVDs offered as LDTs. The statutory framework for device regulation is already risk-based and provides different premarket pathways for devices based on their risk, and FDA can neither change the review pathways established by statute nor create new review pathways not authorized by the statute. Most low-risk tests are exempt from premarket review, and moderate-risk tests are reviewed through the 510(k) and De Novo pathways rather than being subject to premarket approval.

With respect to infectious disease tests, FDA disagrees that all such tests are low-risk or that FDA should adopt an enforcement discretion policy for all clinical microbiology laboratories offering infectious disease LDTs. There are over 500 distinct product codes for infectious disease IVDs in FDA's classification database, and less than half of those are considered low-risk, or class I (most of which are exempt from premarket notification). Infectious disease IVDs pose risks that are not necessarily mitigated by other safeguards, and these tests have implications both for an individual patient and other members of the public. Therefore, FDA does not agree that it should continue the general enforcement discretion approach for all infectious disease LDTs offered by clinical microbiology laboratories. However, as described in section V.B, FDA generally intends to exercise enforcement discretion with respect to premarket review requirements for certain categories of tests, including currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3, and LDTs that are approved by NYS CLEP. FDA anticipates that these policies will help patients, including those in vulnerable communities, have continued access to existing beneficial tests on which they rely, and minimize undue disruption to the provision of care, while providing FDA with information about test performance through labeling, MDR reporting, and other applicable requirements.

(Comment 241) One comment expressed concern that the proposed phaseout policy could ''inadvertently result in millions of Americans abruptly losing access to much needed tests'' due to ''undue delay'' of FDA premarket review and recommended that FDA should continue the general enforcement discretion approach with respect to premarket review and QS requirements for low- and moderate-risk LDTs until FDA has demonstrated its ability to review and ''regulate'' high-risk LDTs.

(Response 241) Although FDA does not agree that FDA premarket review itself will cause ''undue delay,'' FDA is concerned that laboratories may stop

offering IVDs on which patients are currently relying if FDA expects compliance with premarket review and all QS requirements for currently marketed IVDs offered as LDTs. Therefore, as discussed elsewhere in the preamble, to address concern regarding potential disruption of access to currently marketed IVDs offered as LDTs, FDA generally intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3.

FDA disagrees with the comment's suggested approach for low- and moderate-risk IVDs offered as LDTs as it relates to IVDs introduced on or after the date of issuance of this rule. In general, low-risk devices are not subject to premarket review or the QS design control requirements (the main source of QS costs under the FRIA), so FDA does not consider the proposed enforcement discretion policy fitting with respect to those IVDs. In addition, FDA expects that compliance with premarket review and QS requirements for moderate-risk IVDs offered as LDTs will have substantial public-health benefits going forward. For example, FDA anticipates that oversight will help ensure the safety and effectiveness of tests that predict a person's risk of cancer, are used in newborn screening, provide information on the risk of adverse events from a therapeutic product, aid in the diagnosis of heart disease, aid in the diagnosis of chlamydia and gonorrhea, and aid in the diagnosis of neurodegenerative disease such as Alzheimer's, among others. Overall, IVDs that may be considered low- or moderate-risk still inform decisions by patients and their healthcare providers, and uncertainty about whether IVDs offered as LDTs provide accurate and reliable results can significantly impact public health. To the extent they apply, premarket review and QS requirements are valuable tools that will help to better ensure the safety and effectiveness of IVDs offered as LDTs by laboratories. Therefore, under the final phaseout policy, the general enforcement discretion approach with respect to premarket review requirements for low- and moderate-risk IVDs introduced on or after the date of issuance of this rule will end 4 years after publication of this final rule.

Further, to the extent this comment is suggesting FDA will lack sufficient resources or technical expertise to conduct premarket review of IVDs offered as LDTs in a timely manner, FDA disagrees as explained in sections VI.C.2, VI.C.3, and VI.N.

(Comment 242) One comment from a laboratory stated that results from its ''drugs of abuse screening tests'' are not used to ''diagnose, treat, or prevent any illness'' but rather ''provide accountability of patient use of controlled substances and are used as a means to monitor patient progress,'' and false positives or negatives are unlikely to result in patient harm. The comment concluded that such tests are low risk, and that low-risk tests should remain under the general enforcement discretion approach.

(Response 242) FDA disagrees with the blanket statement that ''drugs of abuse screening tests'' are low-risk tests. ''Drugs of abuse'' tests are used to diagnose a clinical condition (drug intoxication), which informs a state of health, and to monitor patient use of controlled substances or track patient progress with respect to substance use, which FDA does not consider to be low-risk. FDA generally regulates clinical toxicology tests for drugs of abuse as class II devices with special controls. *See, e.g.,* 21 CFR 862.3650 (opiates), 21 CFR 862.3250 (cocaine and metabolites). For additional information about drugs of abuse tests that FDA has cleared for marketing, we recommend consulting decision summaries in FDA's 510(k) database by searching under the toxicology panel. Although FDA has determined that it is appropriate to exercise enforcement discretion and generally not enforce any applicable requirements for drugs of abuse tests used solely for law enforcement purposes (see comment response 247), FDA does not see a reason to adopt an enforcement discretion policy for other drugs of abuse tests (see comment responses 248 and 249 for additional information).

(Comment 243) One comment urged FDA to establish classification panels that can act quickly to down-classify IVDs to class I or class II based on a risk assessment before enforcing any regulatory requirements related to LDTs. The comment noted that this would decrease regulatory burden on the Agency and laboratories and provide clarity on the number of class III IVDs offered as LDTs that would require premarket approval. As an example, the comment discussed CDx devices, which are generally class III devices. The comment also stated that ''it is critical that decisions regarding IVD risk classification be reexamined and that LDT device types be unambiguously assigned well before marketing application submission deadlines.''

(Response 243) Generally, FDA believes that IVDs offered as LDTs and other IVDs for the same indications should be under the same classification, so FDA intends to consider any reclassification efforts for IVDs holistically, rather than separating out IVDs offered as LDTs.

On January 31, 2024, FDA announced its intent to initiate the reclassification process for most IVDs that are currently class III into class II (Ref. 66). The majority of these tests are infectious disease and CDx IVDs. Reclassification would allow manufacturers of certain types of IVDs to seek clearance through the less burdensome 510(k) pathway rather than the PMA pathway, the most stringent type of FDA device review. The reclassification process will include opportunities for public comment and FDA aims to complete the process before stage 4 of the phaseout policy.

For discussion of the use of classification panels in the context of other IVDs offered as LDTs, please see comment response 195. In addition, FDA intends to continue taking a risk-based approach in the initial classification of individual IVDs (including IVDs offered as LDTs) to determine the appropriate level of regulatory controls and whether a new IVD may be classified into class II or class I through De Novo classification (and special controls established), rather than being class III and subject to the PMA pathway. FDA also regularly considers whether there are class II IVDs that can be reclassified to class I and intends to continue to do so.

5. IVDs Offered as LDTs for Rare Diseases/Unmet Needs

(Comment 244) Many comments reported that LDTs address unmet needs for which there are no FDA-authorized alternatives. For example, comments cited various tests for rare diseases, pediatric patients, infectious diseases including STIs, confirmation of drugs of abuse screening test results, candida auris, immunohistochemistry, and chimerism analysis for monitoring bone marrow transplants. Comments stated that in some cases, laboratories modify FDA-authorized IVDs to meet unmet needs, such as when an alternative specimen type must be used for a patient. One patient's parent wrote about their child's multiyear diagnostic journey that concluded when a whole genome sequencing LDT revealed a pathogenic genetic alteration. Several comments described challenges in rare disease test development, including the lack of potential profit due to low

volume use. Comments stated that most patients with rare diseases are treated at AMCs. Comments expressed concern that increased FDA oversight could further disincentivize rare disease test development, noting that the HDE program does not effectively address the issue, including because the 8,000 tests per year limit is too restrictive and the perceived burden of IRB and reporting requirements dissuade use of the program. Some comments recommended that FDA expand the HDE program. In addition, some comments claimed that the shorter turnaround time for results from certain LDTs (*e.g.,* LDTs for inflammatory cytokines and NK cell killing LDTs) compared to sending a sample to a reference laboratory can impact a physician's ability to cure a patient with a rare disease or condition.

(Response 244) FDA recognizes the challenges faced by patients with rare diseases, their families, and their treating physicians. FDA also recognizes that IVDs offered as LDTs play an important role in healthcare and may address various unmet needs including for rare diseases. We believe several of the enforcement discretion policies adopted in the final phaseout policy will help to address the concerns raised in the comments regarding the availability of IVDs for unmet needs and rare diseases. For example, for the reasons discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs, including IVDs for unmet needs and rare diseases, as long as they are not modified following the issuance of this final rule, or are modified as described in section V.B.3. In addition, for the reasons discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. This policy is intended, among other things, to address situations described in comments where there is no available FDA-authorized IVD for the disease or condition, where a laboratory needs to modify an FDA-authorized IVD to meet a specific patient need, or where the improved turnaround time of an LDT compared to an FDA-authorized IVD may be critical for the patient's care.

Several comments suggested FDA expand the HDE program. It is not clear what the comments meant by such an expansion, but to the extent this was a suggestion to change the criteria necessary for HDE approval, we note that such criteria are established by statute and cannot be expanded by FDA (see 21 U.S.C. 360j(m)).

FDA intends to consider whether issuing additional guidance regarding validation of tests, including those for rare diseases that takes into consideration the challenges in obtaining a robust number of samples for validation, would be helpful, as discussed in section V.B.3. In the event FDA were to issue any such guidance, FDA would do so in accordance with good guidance practices (see § 10.115).

(Comment 245) One comment expressed concern about applying the HUD program to IVDs offered as LDTs due to the program's complexity and constraints. This comment noted that tests for rare diseases are often developed and run at the request of clinicians, do not have an FDA-authorized alternative, and do not have the volume to support an FDA authorization. This comment recommended that tests for rare diseases remain under an enforcement discretion approach if they serve a local community, use a well-characterized standard test, and are offered in small volumes.

(Response 245) FDA acknowledges concerns regarding the constraints of the HUD program. For these and other reasons discussed in section V.B.3, FDA believes that an enforcement discretion policy for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system is appropriate. This policy should help avoid laboratories integrated within healthcare systems from no longer manufacturing LDTs to meet the unique needs of their patients, such as when there is no available FDA-authorized alternative (often the case for rare diseases).

FDA disagrees that an enforcement discretion policy for tests for rare diseases that serve a local community, use a well-characterized standard test, and are offered in small volumes would be appropriate as FDA has concerns that there would not be sufficient risk mitigations in such circumstances. Further, limiting an enforcement discretion policy for rare diseases to ''well-characterized standard tests'' would exclude certain LDTs for rare diseases that are critical to patients and that may not be manufactured by laboratories due to the limited market for such LDTs and the perceived costs of compliance with premarket review requirements.

6. IVDs Offered as LDTs Intended Only for Public Health Surveillance

(Comment 246) FDA received comments regarding our proposal that tests exclusively used for public health surveillance remain unaffected by the phaseout policy. Some comments supported this while others suggested oversight of such tests should be considered, regardless of whether results are returned to the patient or provider. One cited an example of a test that monitors for the presence or spread of a microorganism in a healthcare facility, which may not be used ''explicitly'' for patient management but is ''actionable'' by the facility and results may be made available to healthcare providers. The comment encouraged FDA to consider whether the phaseout policy should apply to certain surveillance tests, like this example.

(Response 246) FDA continues to believe that tests manufactured and offered for use exclusively for public health surveillance should remain unaffected by the phaseout policy. As described in the NPRM and this preamble, the scope of public health surveillance tests is limited to tests where results are not reported to patients or their healthcare providers (see section V.A.2, 88 FR 68006 at 68023). Where test results are not reported to patients or their healthcare providers, they are not informing the care of that patient, and increased FDA oversight is less critical. As to the comment's example of tests for microorganisms in a healthcare facility, if those tests are not on human specimens, they are not IVDs, and are therefore outside the scope of this rulemaking.

7. IVDs Offered as LDTs Intended To Detect the Presence of Drugs of Abuse

(Comment 247) FDA received several comments on ''drugs of abuse'' tests. Some suggested that FDA continue the general enforcement discretion approach for drugs of abuse IVDs offered as LDTs used in employment and insurance testing as well as for law enforcement purposes.

(Response 247) Drugs of abuse tests intended solely for employment and insurance testing and not for Federal drug testing programs are exempt from premarket review and would continue to be, regardless of whether they are

offered as an LDT (see 21 CFR 862.3100, 862.3150, 862.3170, 862.3250, 862.3270, 862.3580, 862.3610, 862.3620, 862,3630, 862.3640, 862.3650, 862.3700, 862.3870, 862.3910; *see also* 84 FR 71794 to 71819, December 30, 2019). With respect to other requirements applicable to drugs of abuse tests used in employment or insurance testing, FDA does not see a reason to treat IVDs offered as LDTs differently from other IVDs going forward; FDA believes it is important, for example, for such IVDs to be listed in FDA's database, labeled as required under FDA regulations, and manufactured in compliance with QS requirements, given their risks. FDA has not identified any characteristics that are unique to IVDs offered as LDTs intended to detect the presence of drugs of abuse tests that would justify treating them differently from other drugs of abuse tests.

With respect to drugs of abuse tests used solely for law enforcement purposes, FDA has explained elsewhere in this preamble that it is appropriate to exercise enforcement discretion and generally not enforce any applicable requirements for such tests. This reflects current policy, regardless of whether the tests are IVDs offered as LDTs (see sections V.B.1 and VI.L.2 for additional information).

(Comment 248) One comment stated that the general enforcement discretion approach should continue for all IVDs offered as LDTs intended as drugs of abuse tests because laboratories need to be able to adapt to combat modifications made to illicit drugs to evade detection. The comments stated, for example, that the FDA-cleared test for fentanyl does not detect modified versions of the drug.

(Response 248) FDA disagrees with the comment suggesting FDA continue the general enforcement discretion approach for all IVDs offered as LDTs to test for drugs of abuse. We acknowledge that such drugs may be modified and that tests for drugs of abuse may need to be modified in order to detect the new versions of these substances. However, FDA oversight does not preclude laboratory manufacturers from making such changes. FDA believes this oversight is important due to the risks to patients from false positive and false negative drugs of abuse test results. False positive results may delay treatment for the patient's true condition if that condition involves symptoms that overlap with drug intoxication (for example, missing a critical opportunity to treat cerebral hemorrhage or stroke). False negative results may put the patient at risk—for example, if they were to drive or were to need urgent treatment for overdose. Compliance with quality system requirements, such as design controls, will help assure that these drugs of abuse tests perform as intended, and compliance with premarket review, where applicable, will help assure that the drugs of abuse test's performance is suitable for the test's intended use.

Where a manufacturer may anticipate the types of changes it intends to make, it may consider seeking clearance or approval of a PCCP. Under section 515C of the FD&C Act, a PMA supplement or new 510(k) is not required for a modification to a device that would otherwise be required if the change is consistent with a PCCP previously approved or cleared by FDA. To the extent a PCCP is approved or cleared by FDA for a particular IVD, any changes within the bounds of that PCCP would not necessitate a new submission to FDA.

(Comment 249) Because the FDA-cleared drugs of abuse tests are only for screening, comments suggested that FDA continue the enforcement discretion approach for confirmatory LDTs intended as drugs of abuse tests, given that these tests are addressing an unmet need.

(Response 249) FDA acknowledges that in drugs of abuse testing, most confirmatory diagnostic tests are currently offered as LDTs. However, as discussed in response to comment 248, FDA oversight of drugs of abuse tests is important, including when such tests are confirmatory.

With respect to the comments' concerns, FDA notes that the final phaseout policy includes several new enforcement discretion policies that may help address those concerns. As explained in section V.B.3, FDA generally intends to exercise enforcement discretion with respect to premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule, including drugs of abuse IVDs offered as LDTs, and that are not modified, or that are modified as described in section V.B.3. In addition, going forward, LDTs may fall within the enforcement discretion policy for unmet needs when they are manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system (see section V.B.3).

8. Genetic IVDs Offered as LDTs/Next Generation Sequencing

(Comment 250) Comments asserted that the phaseout policy is problematic for genetic tests because if such tests are expected to comply with FDA requirements, that will hamper innovation and compromise patient care. One comment claimed that FDA's validation requirements for each variant are unmanageable for LDTs that analyze tens of thousands of variants from multiple sample types. The comment asserted that FDA requires 20 unique wildtype samples and 3–20 unique positive samples per variant per sample type. Other comments asserted that oversight is needed for genetic tests. One comment suggested FDA hire genetic counselors to facilitate decision-making focused on the risk of harm for genetic tests. Another expressed particular concern with pharmacogenomic tests making false claims.

(Response 250) FDA agrees with comments expressing the need for oversight of genetic tests. As illustrated by the pharmacogenomic example cited by comments, FDA is concerned that test offerings are outpacing the science that supports them. Technological advances have made it possible to sequence DNA in large volumes quickly, but there is not always evidence of clinical validity for the variants reported and used for clinical decision-making. FDA oversight will help ensure appropriate clinical validation. FDA's office that oversees in vitro diagnostics employs individuals with a wide range of expertise in genetics, currently including molecular pathologists, a genetic counselor, and Ph.D. trained scientists.

With respect to NGS tests for the detection of human genetic variants, FDA does not agree that its premarket expectations are unmanageable, and we do not necessarily require 20 unique positive samples for each variant for each specimen type. During premarket review, FDA considers prevalence when considering the number of samples necessary to validate an NGS assay and generally considers a representative approach to validation across variant types. For example, such an approach is described in FDA's final guidance document entitled ''Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases'' (Ref. 223). This is feasible to do as demonstrated by the many NGS tests, including IVDs manufactured by laboratories, that have received premarket authorization from FDA (see, *e.g.,* information available in FDA's PMA database (Ref. 165) for PMA numbers P210011, P160018, P190032,

P200011, and P190014; information available in FDA's De Novo database (Ref. 166) for De Novo numbers DEN170058 and DEN200059; and information available in FDA's 510(k) database (Ref. 224) for 510(k) numbers K210017, K202304, K192063, and K190661).

9. Antimicrobial Susceptibility Tests (ASTs)

(Comment 251) Comments asserted that susceptibility test panels for bacteria, fungi, Nocardia, and mycobacteria are mostly LDTs, as the few FDA-authorized panels have substantial limitations and there is a lack of FDA authorization for less common pathogens. Comments further asserted that there are no FDA breakpoints for susceptibility tests for many of the pathogens listed by CDC as urgent and serious antibiotic resistance threats, including, for example: *Candida auris,* drug resistant *N. gonorrhoeae,* and carbapenem-resistant *Acinetobacter baumannii.* Comments claimed that it would be unlikely that a laboratory would be able to get FDA authorization for a test that applies non-FDA interpretive breakpoints (CLSI or European Committee on Antimicrobial Susceptibility Testing (EUCAST)), which creates a ''catch-22'' situation given the Agency's role in breakpoint approval. The comment stated that laboratories will have to default to the breakpoints for which the assays received FDA approval, which are also out of sync with many of the CLSI updated breakpoints.

(Response 251) FDA recognizes the importance of using updated susceptibility test interpretive criteria (STIC), also referred to as breakpoints, when using antimicrobial susceptibility test (AST) systems. FDA's Center for Drug Evaluation and Research (CDER) maintains a website with the most up-to-date STIC for antibacterial and antifungal drugs, including FDA's recognition of STIC established by standards development organizations (SDOs) (Ref. 225). FDA has cleared hundreds of ASTs (addressing hundreds of individual organism/drug combinations) and has worked to ensure that the most up to date STIC are used, including having cleared more than 60 ASTs with breakpoint change protocols, allowing for the rapid adoption of updated breakpoints without further FDA review. To help address the importance of adopting updated breakpoints quickly, FDA recently issued a final guidance entitled ''Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling,'' which describes least burdensome approaches for AST manufacturers to update their device labeling with the updated breakpoints listed on the FDA's STIC website (see Refs. 225 and 226). This final guidance provides FDA's recommendations for submission of PCCPs for new AST systems, describes a policy regarding device manufacturers applying certain change protocols submitted to FDA in a separate 510(k) to implement breakpoint updates for the sponsor's legacy AST system device without a new 510(k) submission to FDA, and clarifies the process for incorporating by reference a cleared PCCP or breakpoint change protocol into a new submission. FDA believes these approaches will facilitate more timely adoption of updated breakpoints for numerous marketed devices with out-of-date breakpoints and streamline the process for future updated breakpoints to be incorporated quickly on an ongoing basis.

FDA disagrees that ''there are no FDA breakpoints for susceptibility tests for many of the pathogens listed as CDC urgent and serious antibiotic resistance threats (including *Candida auris,* drug resistant *N. gonorrhoeae,* carbapenem-resistant *Acinetobacter baumannii,* and more)'' as stated in the comment. The CDC list often includes qualifiers such as noting resistance to a particular drug. Generally, breakpoints are established for organism groups without resistance qualifiers, with notable exceptions like methicillin-resistant *S. aureus* and vancomycin-resistant Enterococci for which there is specific and significant data to support inclusion of the qualifiers. For other organisms, the same breakpoint is used regardless of the isolates. For example, there are FDA recognized breakpoints for *Acinetobacter* with many drugs; however, there are no separate breakpoints identified for drug-resistant *Acinetobacter* as the differentiation between drug-resistant and non-drug resistant *Acinetobacter* isolates has not been established in terms of breakpoint determination. It is important to note that CLSI and EUCAST similarly do not often have different breakpoints identified for drug-resistant and non-drug resistant isolates.

FDA also disagrees that ''[s]usceptibility test panels . . . are mostly LDTs'' and with the characterization that there are only a ''few FDA cleared panels.'' As noted, FDA has cleared ASTs addressing hundreds of organism/drug combinations and continues working towards assuring the breakpoints are updated expeditiously once recognized. In addition, referring to Table 2 in Simner *et al,* 2022, FDA notes that between 95.3 percent and 98.8 percent of surveyed CAP-accredited U.S. laboratories use automated AST devices (described in the paper as one of three commercial AST systems) (see Ref. 227). While some of these may be LDTs if the laboratory is modifying the original FDA-authorized AST device to use a different breakpoint or a non-cleared organism, the same study noted that between 37.9 percent and 70.5 percent of U.S. laboratories reported using out-of-date breakpoints for the antimicrobials that were queried. Therefore, this publication does not support the claim that the majority of ASTs are LDTs. This data supports the need for these tests to be updated with current breakpoints but does not support the claim that the majority of FDA-authorized AST devices are being modified and offered as LDTs in order to use updated breakpoints.

FDA notes in response to the statement that ''there is a lack of FDA clearance for less common pathogens,'' that there are FDA-authorized tests and FDA-recognized breakpoints for organism groups corresponding to commonly encountered pathogens described in CLSI M100 Table 1, ''Antimicrobial Agents That Should Be Considered for Testing and Reporting.'' While there are some drug/organism combinations that lack FDA-recognized breakpoints, this is due to the lack of adequate data (clinical, pharmacological, in vitro, etc.) to support the establishment of breakpoints. In most of these cases, as well as the above discussed cases of drug-resistant isolates, there are no breakpoints established by CLSI or EUCAST, either. It is important to note that any stakeholder, including a test manufacturer, also has the ability to submit a request to FDA requesting recognition of a particular breakpoint. This process is described in the docket to which these requests can be made (Ref. 228).

10. IVDs Offered as LDTs for Emergency Use

(Comment 252) Some comments stated that enforcement of premarket review requirements for emergency use tests is not appropriate while others stated it is necessary. Those opposed to such enforcement cited concerns with the ability of public health and AMC laboratories to respond to an outbreak quickly and the corresponding impact on patient access. Some also expressed concern about the impact of the phaseout policy on the availability of tests for emergent situations that do not

rise to the level of a declared public health emergency.

(Response 252) FDA agrees with comments that oversight of IVDs for emergency use is important. In this context, the potential for false results can have serious implications for disease transmission and public health decision-making, in addition to the individual patient's care. For these reasons, after all previous declarations under section 564(b) of the FD&C Act, FDA's general enforcement discretion approach generally has not applied to LDTs, and FDA is not changing its existing approach to tests for emergency use in this final rule (see section V.A.2). FDA issued EUAs to 116 IVDs from laboratories for COVID–19 and 1 IVD from a laboratory for Mpox.

We note that after a declaration is made under section 564 of the FD&C Act, FDA may issue EUAs to products that fall within the declaration and that meet certain statutory criteria. Notably, the statutory standard for EUAs is different than traditional premarket authorization. As discussed in FDA's final guidance entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' (Ref. 229), ''the 'may be effective' standard for EUAs provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals.'' This final guidance includes information on how to request an EUA.

FDA appreciates the need for immediate response to emergent situations (*e.g.,* harmful exposures or outbreaks) during the time between detection of the exposure or outbreak and either resolution of that exposure/outbreak or issuance of a declaration under section 564 of the FD&C Act. Accordingly, in parallel to this rulemaking, FDA is issuing draft guidance for an ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' This draft guidance includes an enforcement discretion policy that is limited to certain tests needed for immediate response and limited to certain laboratories, such as those that are USG laboratories, State or local public health laboratories, or other laboratories that have agreements with the USG.

FDA also appreciates that different emergency situations may present unique circumstances for which additional enforcement discretion policies should be considered. FDA has issued a draft guidance document describing ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency,'' which describes factors FDA intends to consider in determining whether to issue an enforcement discretion policy during an emergency declared under section 564 for certain tests.

11. IVDs Offered as LDTs by Public Health Laboratories

(Comment 253) We received several comments that expressed concerns regarding the phaseout of FDA's general enforcement discretion approach with respect to IVDs offered as LDTs by public health laboratories. Comments stated that public health laboratories develop tests for unmet needs for: infectious diseases (*e.g.,* STIs, biological and chemical threat agents), foodborne diseases, newborn screening, toxicology (*e.g.,* blood lead), drugs of abuse testing, and low volume tests for rare diseases. Multiple state public health laboratories expressed concern with increased oversight of IVDs offered as LDTs for newborn screening. They stated that they use LDTs because there is no FDA-authorized IVD for some disorders on the Recommended Uniform Screening Panel and, in other cases, their LDTs are less costly or provide faster turnaround times compared to available FDA-authorized IVDs. Comments also discussed the significant financial burden associated with premarket submissions to FDA and expressed concern regarding the impact of the phaseout policy on public health laboratories that develop LDTs that are not for profit. Various proposals were provided, including continuing the general enforcement discretion approach for existing public health laboratories' LDTs, making the FDA review and authorization processes similar to that of NYS CLEP or relying on that program, streamlining the regulatory process when a public health laboratory modifies an FDA-authorized IVD, FDA offering fee waivers or exemptions, and FDA providing additional guidance, templates, or other resources to facilitate compliance.

(Response 253) FDA appreciates the important role public health laboratories play in our healthcare system. As discussed further in section V.B, FDA is adopting various enforcement discretion policies that should address some of the concerns raised in these comments. For example, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that are not modified or that are modified as described in section V.B.3 (including those manufactured by public health laboratories) and generally not enforce premarket review requirements for LDTs approved by NYS CLEP (including those manufactured by public health laboratories).

We acknowledge that public health laboratories may manufacture LDTs for unmet needs and that compliance with premarket review and other requirements will impose compliance costs on those laboratories. As discussed further in section V.B.3, we are adopting a policy for unmet needs LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. We believe that in such circumstances there are important risk mitigations present, particularly in the case of unmet need LDTs. We understand that this policy does not apply to most public health laboratories (as they are not integrated into a healthcare system and their public health mandate is to serve patients beyond the hospital system). We think it would be inappropriate to extend the policy to unmet needs LDTs developed and performed by public health laboratories, or other laboratories that are not integrated within a healthcare system, as there are not the same risk mitigations present for such LDTs that would help address and avoid the use of problematic LDTs.

FDA disagrees with comments suggesting a streamlined process for when a public health laboratory modifies an FDA-authorized IVD. FDA does not think modifications by a public health laboratory to an FDA-authorized IVD merit a different approach or policy, and the comments did not explain why the considerations raised in the comments are unique to public health laboratories. We note, however, that FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements when a laboratory, including a public health laboratory, certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's lawfully marketed test that is not a PMA-approved or BLA-licensed test, in a manner that could not significantly affect the safety or effectiveness of the test or its intended use, as described in sections V.C.4 and V.C.5. Further, FDA intends to develop appropriately targeted enforcement discretion policies for certain common changes to IVDs (including those manufactured and offered by public health laboratories), such as extension of specimen stability

and certain alternative specimen types, following good guidance practices.

Regarding comments about fee waivers or exemptions, please refer to the response to comment 190 describing when payment of a user fee is required under the current MDUFA authorization. Exceptions from the requirement to pay a user fee are established by statute (see sections 738(a)(2)(B) and 738(a)(3)(B) of the FD&C Act). The statute also provides authority for FDA to waive some user fees for certain small businesses (see sections 738(a)(3)(B) and 738(d)(1) of the FD&C Act). More information about MDUFA fees, user fee exceptions, and how to request a fee waiver are available on FDA's website (Ref. 183).

Finally, FDA intends to consider making additional resources available over the course of the phaseout period, which could potentially include guidance documents and templates to facilitate compliance.

12. IVDs Offered as LDTs for Research Use Only

(Comment 254) FDA received multiple comments requesting that FDA establish reasonable requirements to incentivize companies to seek FDA authorization for RUO IVD reagents or test kits. One asserted that the majority of LDTs performed in clinical laboratories use test kits distributed by large companies and labeled for RUO. Another comment stated it is common practice for laboratories to modify FDA-authorized IVDs to use RUO instruments or reagents rather than the specified instruments or reagents in the FDA-authorized IVD instructions for use. This comment stated that, in the event a laboratory makes an LDT from RUO components, only the final LDT should be required to comply with regulatory requirements.

(Response 254) FDA has issued a final guidance document that addresses RUO products (see Ref. 176). As explained in the final guidance, the RUO labeling is meant to serve as a warning to prevent such products from being used in clinical diagnosis, patient management, or an investigation that is not exempt from part 812. In general, IVD products that are intended for clinical diagnosis or patient management must be labeled ''For In Vitro Diagnostic Use'' (§ 809.10(a)(4)) and be in compliance with all applicable requirements for in vitro diagnostic devices. In other words, if an IVD is intended for clinical diagnostic use, it should not be labeled RUO. RUO products are generally not manufactured under the QS requirements, and therefore, are not expected to have the quality controls necessary for clinical use. A manufacturer that labels their product RUO but intends it for clinical diagnostic use would be in violation of the FD&C Act, including misbranding the product under section 502(a) of the FD&C Act due to the labeling being false or misleading.

If a laboratory chooses to use one or more RUO components in its IVDs offered as LDTs, then the laboratory is responsible for qualifying such components in its IVDs. For those IVDs offered as LDTs for which the phaseout policy with respect to the QS requirements would apply, as long as the laboratory has implemented a quality system that meets the QS requirements, as applicable, and is able to appropriately manage the quality of these components under that quality system, then the components may be incorporated as part of an IVD offered as an LDT (see section V.C.3 for a discussion of when FDA generally expects compliance with the QS requirements for IVDs offered as LDTs). The RUO-labeled component(s) will be reviewed in the premarket submission for the IVD offered as an LDT, if applicable.

13. IVDs Offered as LDTs for Sexually Transmitted Infections

(Comment 255) Comments expressed concern that FDA's proposed phaseout of enforcement discretion would negatively affect access to STI tests currently in use. Multiple comments asserted that LDTs are ''the only or most appropriate, and most timely tests available'' for HIV and other STIs, and that the proposed phaseout policy would ''make it substantially more difficult to adopt new tests or modify existing tests to meet urgent and emerging public health needs.'' A comment also expressed that home-testing programs implemented by public health departments and community-based organizations ''provide critical access to HIV, viral hepatitis, and STI testing'' that includes testing associated with pre-exposure prophylaxis (PrEP).

(Response 255) FDA disagrees with comments predicting that phasing out the general enforcement discretion approach for LDTs will have negative impact on access to STI tests to meet ''urgent and emerging public health needs.'' As discussed in section VI.L.10 (IVDs Offered as LDTs for Emergency Use) and VI.L.11 (IVDs Offered as LDTs by Public Health Laboratories), FDA anticipates that several of the enforcement discretion policies adopted in the final phaseout policy will help to address the specific concerns raised in the comments regarding the availability of IVDs for emerging public health threats by facilitating timely access to STI IVDs.

FDA also disagrees with the comment that ''the most appropriate tests'' for HIV and other STIs are currently offered as LDTs. We acknowledge the critical importance of access to safe and effective HIV tests, including tests that may inform decisions about beginning or continuing use of antiretroviral medications for PrEP. However, FDA-authorized HIV diagnostic and supplemental tests and HIV viral load monitoring tests are available to provide such access. We note that there is an FDA-approved OTC HIV test that individuals may use to test themselves at home or in a private location (Ref. 221). FDA also acknowledges the importance of access to safe and effective tests for other STIs, such as chlamydia, gonorrhea, mycoplasma genitalium, and syphilis, for which FDA-authorized tests are also widely available (see, *e.g.,* Refs. 230 to 233). This includes STI tests for use with self-collected samples in clinical settings and one STI test with at-home sample collection for chlamydia and gonorrhea (see, *e.g.,* Ref. 222). As described in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs, including STI tests, that were first marketed prior to the date of issuance of this rule. FDA anticipates that this policy will help address the concerns expressed in the comments regarding the impact of the proposed phaseout policy on access to STI tests currently in use. However, for the reasons described in the NPRM and in section V.A.2, we note that FDA's general enforcement discretion approach for LDTs has not applied to direct-to-consumer tests, including direct-to-consumer HIV and other STI tests, and they are not included in this enforcement discretion policy (88 FR 68006 at 68022).

14. IVDs Offered as LDTs Conducted by and Within Blood Establishments, Transfusion Services, and Cell and Gene Therapy Laboratories

(Comment 256) Several comments requested that FDA ''exempt'' all tests conducted by and within blood establishments, hospitals' transfusion services, and accredited cell and gene therapy laboratories and services from FDA's proposed phaseout of the general enforcement discretion approach. In support of this request, a comment asserted that ''the existing regulatory

framework ensures that [these entities] provide high quality, safe, and effective care,'' noting that these entities offer LDTs in CLIA certified laboratories that are part of Federal, State, or locally licensed facilities. The comment also noted that ''[e]xtensive FDA regulatory requirements'' apply to such laboratories such as registration, licensure of donor screening tests, and premarket review (PMA, 510(k), or New Drug Application (NDA)) requirements for certain products, and that some of these laboratories are also subject to heightened State regulation, such as the NYS CLEP. Some comments expressed concerns that FDA's proposal could negatively affect laboratories' abilities to perform compatibility testing for patients in need of blood or testing that supports safe use of cell and gene therapies. Some comments also requested that FDA exclude immunohematology reference laboratories from the scope of the final phaseout policy as their LDTs involve ''highly educated and highly trained technologists perform[ing] specialized testing using manual techniques on select, complex samples'' and without which accurate and complete antibody identification would not be possible, resulting in ''missed antibodies leading to increased transfusion reactions, strains to the blood supply due to unnecessary phenomatching of Red Cells and many other issues.''

(Response 256) FDA disagrees with adopting an enforcement discretion policy for all tests used in blood establishments, transfusion services, and accredited cell and gene therapy (CGT) laboratories, and for all immunohematology reference laboratories. In the NPRM, FDA identified categories of tests that have not been part of the general enforcement discretion approach for LDTs. These categories of tests include those that are intended to screen donors of blood and HCT/Ps for infectious diseases under §§ 610.40 and 1271.80(c), or for determination of blood group and Rh factors required under § 640.5 (88 FR 68006 at 68021–22). Such tests may be conducted in blood establishments, transfusion services and/or CGT laboratories. Under the cited regulations, a blood or HCT/P establishment must not use a test for the purposes described in the regulation unless the test is authorized by FDA for such use, and in our experience, establishments have been generally complying with these requirements. Therefore, for these tests, we would not expect the phaseout policy to negatively affect the ability to perform blood compatibility testing or testing to determine HCT/P donor eligibility that supports safe use of HCT/Ps, such as cellular therapies. As described in section V.A.2, these tests are not subject to any enforcement discretion policies included in the phaseout policy.

For other tests conducted by blood establishments, transfusion services, or CGT laboratories (*i.e.,* those not subject to the requirements under §§ 610.40, 640.5, or 1271.80(c)), we disagree with the comment's assertion that enforcement discretion is appropriate because such tests are developed by laboratories that are CLIA certified and part of Federal, State, or locally licensed facilities. For discussion of why CLIA does not provide sufficient assurances of safety and effectiveness for IVDs offered as LDTs, see our responses to comments in section VI.C.2. While the comment did not provide details regarding which Federal, State, and local facility licensure requirements would be relevant, as a general matter, we note that the requirements against which a *facility* is assessed do not necessarily address the analytical and clinical validity of (or other issues affecting the safety and effectiveness of) IVDs offered as LDTs by a laboratory within that facility.

With respect to the argument that FDA should exercise enforcement discretion for all LDTs conducted by blood establishments, transfusion services, or CGT laboratories because these entities already comply with FDA requirements for certain other products, such entities should already have familiarity with FDA's requirements and thus be better positioned to transition to compliance in accordance with the phaseout policy. Regarding the comment that some blood establishment and CGT laboratories are subject to State requirements like NYS CLEP, FDA considered comments received regarding NYS CLEP and intends to exercise enforcement discretion and generally not enforce premarket review requirements (but intends to phase out enforcement discretion with respect to other requirements) for LDTs that are approved by NYS CLEP. For further discussion of this policy and other comments received related to NYS CLEP see sections V.B.2 and VI.F.5. The comment did not mention other, specific state programs.

Although we disagree with the comments' request for a broad enforcement discretion policy for all LDTs conducted by or within blood establishments or CGT laboratories and for all immunohematology reference laboratories' LDTs, we note that several of the targeted enforcement discretion policies described in section V may encompass some of these tests and help address the concerns raised in the comments. For example, as proposed in the NPRM and described in section V.B.1 of this preamble, FDA intends to exercise enforcement discretion and generally not enforce any applicable requirements for 1976-Type LDTs (88 FR 68006 at 68022). This includes some tests cited in the comments that are used in blood establishments and immunohematology laboratories such as adsorbing warm-reactive autoantibodies using allogeneic or autologous red blood cells, the Donath-Landsteiner test for aiding in the diagnosis of paroxysmal cold hemoglobinuria, Ham's test to aid in the diagnosis of paroxysmal nocturnal hemoglobinuria, tests to evaluate drug-induced hemolysis or interference in compatibility testing, monocyte-monolayer test to assess possible clinical significance of RBC alloantibodies, modified Kleihauer-Bethke, and SDa antigen neutralization with urine.

In addition, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. As noted above, FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP, and to exercise enforcement discretion with respect to premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

Finally, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for non-molecular antisera LDTs for rare RBC antigens when such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative available to meet the patient's need for a compatible blood transfusion as described in section V.B.3. This enforcement policy is based, in part, on FDA's recognition that there are occasions where licensed IVDs are not available for rare RBC antigens but

testing for such rare antigens is necessary to help ensure that patients receive a compatible blood transfusion and avoid potentially life-threatening reactions. We believe that this policy, in addition to some of the other enforcement discretion policies described above, helps mitigate the concern raised by one comment that a phaseout of enforcement discretion for immunohematology laboratories' LDTs will result in ''missed antibodies leading to increased transfusion reactions.''

15. IVDs Offered as LDTs Used in Manufacturing and Development of Cell or Gene Therapy Products

(Comment 257) One comment recommended enforcement discretion for tests used as part of cell therapy product manufacturing. Another comment recommended enforcement discretion for tests on banked cord blood.

(Response 257) We do not agree that it is appropriate to exercise enforcement discretion for all tests used as part of cell therapy product manufacturing or tests on banked cord blood. For example, as discussed in the NPRM, the general enforcement discretion approach for LDTs has not applied to HCT/P donor screening tests required for infectious disease testing under § 1271.80(c), including screening tests for banked cord blood (88 FR 68006 at 68021–22); FDA is not changing this approach in the final phaseout policy. Under the cited regulation, HCT/P establishments must not use a test for the purposes listed in that regulation unless the test is authorized by FDA for such use. With respect to other tests used as part of cell therapy product manufacturing or performed on banked cord blood, we note that this would span a wide variety of tests depending on the particular product and nature of the manufacturing process, including tests that do not meet the definition of an IVD under § 809.3 and are therefore outside the scope of this rulemaking and the phaseout policy. We note that FDA has mechanisms in place, such as ''Section 513(g) Requests for Information,'' for manufacturers to obtain information regarding the regulatory requirements applicable to a specific product under the FD&C Act (Ref. 65).

To the extent tests about which the comments are concerned would fall within the definition of an IVD, we note that several targeted enforcement discretion policies are included in the final phaseout policy, as described in section V.B. These policies may help address the comments' concerns. For example, to help address harms that could result from widespread loss of access to IVDs currently on the market, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3.

(Comment 258) A comment suggested we should continue the general enforcement discretion approach for premarket review and QS requirements for tests used in cell and gene therapy product development, particularly when screening for clinical trial eligibility and monitoring participant response to investigational treatments, since these tests are typically conducted in low volumes and reviewed in connection with therapeutic product sponsor INDs and NDAs. The comment stated that additional regulatory requirements would create additional burdens without countervailing benefits to trial participants and patients.

(Response 258) FDA recognizes that some clinical investigations of therapeutic products (including cell and gene therapy products) use investigational IVDs to guide the management of participants, such as to determine eligibility or monitor response of participants to the investigational therapeutic product. However, the comment appears to suggest that because of the phaseout policy described in the NPRM, premarket review requirements would apply to and be enforced for all such IVDs when used in clinical investigations. Devices intended for use in clinical investigations, including IVDs offered as LDTs, are exempt from most regulatory requirements applicable to devices, including premarket review, as long as the investigation complies with applicable requirements under part 812. As discussed in more detail in response to comment 175, FDA's regulations do not necessarily require submission of an IDE application to FDA for use of a device in a clinical investigation. To the extent submission of an IDE application is required for use of an investigational IVD in a clinical investigation of a drug or biological product, there are steps that sponsors can take to help simplify the process. For example, IDE and IND applications may cross-reference each other through a letter of authorization. While we disagree that it is appropriate to exercise enforcement discretion with respect to applicable QS requirements for all IVDs used in CGT product development, we note that an investigational device with an approved IDE application (or deemed to have an approved IDE under § 812.2(b)) is generally exempt from most QS requirements issued under section 520(f) of the FD&C Act (see § 812.1). As described in section V.C, FDA intends to phase out the general enforcement discretion approach with respect to QS requirements during stage 3, including, as applicable, QS requirements for investigational devices.

In all cases, FDA is committed to advancing CGT product development while protecting the safety of trial participants. Compliance with applicable investigational use requirements is important for the protection of participants. Under the phaseout policy described in section V.C, FDA expects compliance with applicable IDE requirements and other applicable requirements, such as parts 50 and 56, for investigations that involve investigational IVDs offered as LDTs 2 years after publication of this final rule. The Agency has resources available that may help sponsors designing trials of therapeutic products that involve the use of investigational IVDs, which are discussed further in our response to comment 175. Sponsors can also engage with FDA under the Q-Submission Program to address questions related to IVD risk, study design, and regulatory requirements.

16. Histocompatibility

(Comment 259) FDA received multiple comments regarding HLA tests. Many comments supported FDA's proposed approach to HLA tests for transplantation. Multiple comments that supported this approach indicated that the extensive and multilayer national system of regulatory oversight provided through United Network for Organ Sharing, OPTN, the Scientific Registry of Transplant Recipients, NMDP, FACT, and the Center for International Blood and Marrow Transplant Research for histocompatibility laboratories has ensured analytical and clinical validity and patient safety for decades. One comment noted that these tests often need to be ''customized'' to the needs of the patient, and that requiring premarket approval, or even notification, could prevent testing that is critical for patient care. One comment requested that FDA include HLA tests used for blood transfusion in its enforcement discretion approach. Another comment proposed that FDA broaden the scope of its continued enforcement discretion for HLA tests for transplantation to all histocompatibility tests. Another comment suggested that

other tests beyond HLA tests are ''generally performed in urgent, life-saving situations for the patient'' and therefore should be treated similarly.

(Response 259) FDA agrees with the comments to the extent that they support the Agency's proposed approach related to HLA tests for transplantation. As discussed in the NPRM, and consistent with the 2014 draft guidance document on oversight of LDTs (Ref. 38), FDA intends to exercise enforcement discretion and generally not enforce any applicable requirements for HLA tests for transplantation used in histocompatibility laboratories that meet the regulatory requirements under CLIA to perform high complexity histocompatibility testing, when used in connection with organ, stem cell, and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and ''virtual'' HLA crossmatch tests (88 FR 68006 at 68022). While other tests may be performed in urgent and life-threatening situations, we note that HLA tests for transplantation are often modified rapidly in response to urgent situations and individualized within each medical facility based on local HLA polymorphisms and patient demographics. Further, we do not agree to exercise enforcement discretion with respect to all applicable requirements for HLA tests for blood transfusion. As described in the NPRM, and in contrast to HLA tests for transplantation, HLA tests for blood transfusion are highly standardized across institutions (88 FR 68006 at 68022). In addition, as noted by some of the comments and explained in more detail in section V.B.1, in the context of HLA tests for transplantation, there are other Federal oversight mechanisms (such as OPTN and NMDP requirements for histocompatibility laboratories and HLA testing) that help mitigate risks of inaccurate results.

17. Antisera Used To Test for Rare Red Blood Cell Antigens

(Comment 260) Several comments recommended FDA continue to exercise enforcement discretion for unlicensed antisera that are used to test for rare RBC antigens. A comment also asserted that FDA's guidance document entitled ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results'' recognizes that blood establishments use unlicensed reagents or unapproved molecular tests for RBC antigen typing and that such tests did not appear to be included in the categories of tests for which FDA proposed to continue to apply its current general enforcement discretion approach going forward.

(Response 260) FDA recognizes there are occasions where licensed IVDs are not available for rare RBC antigens but testing for such rare antigens is necessary to help ensure that patients receive a compatible blood transfusion. While there are molecular tests approved for use in genotyping RBC antigens, there may not be an available approved molecular test to use as an alternative for all rare antigens. After considering the comments on this issue, as discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for non-molecular antisera LDTs for rare RBC antigens when such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative available to meet the patient's need for a compatible blood transfusion. However, for the reasons discussed in section V.B.3, FDA does not intend to extend this enforcement discretion policy to molecular tests used for genotyping red blood cell antigens.

M. IVD Modifications

(Comment 261) FDA received comments about modifications to IVDs in different scenarios. Some referred to modifications laboratories make to their own IVDs offered as LDTs for various reasons, including to improve their IVDs. Some stated that laboratories often make modifications to other manufacturers' FDA-authorized tests to accommodate different specimen types, different patient populations, various storage conditions, additional variants for genetic tests, and many other factors. Comments stated that laboratories cannot afford the expense or significant administrative burden associated with seeking FDA review for each such modification. One comment detailed the flexibilities under the VALID Act for CLIA-certified high-complexity laboratories to make certain modifications to approved in vitro clinical tests without seeking independent premarket review and suggested FDA adopt a similarly flexible policy for modifications through amendments to the FD&C Act and CLIA regulations or through continued enforcement discretion. The comment noted that a flexible modifications policy should extend to ''grandfathered tests'' because failure to do so would make a ''grandfathering'' policy ''obsolete as modifications are routinely made to improve performance and adjust to changing circumstances.''

(Response 261) As discussed below, we believe the existing requirements and policies and the enforcement discretion policies described in section V above generally address laboratory modifications of IVDs.

FDA's regulations describe when manufacturers must submit a premarket submission for a modification to their own device. Specifically, premarket review is required when: an approved device is modified in a way that changes the safety or effectiveness of the device, with certain exceptions (pursuant to § 814.39(a)); a cleared device, or a device classified through the De Novo process and subject to 510(k) requirements, is modified in a way that could significantly affect the safety or effectiveness of the device (pursuant to § 807.81(a)(3)); [93] or a 510(k)-exempt device is modified outside the scope of the 510(k) exemption. In the context of IVDs, these standards have generally been interpreted to include changes to the operating principle, intended use and other changes that impact performance (see, *e.g.,* Refs. 224 and 61). Post-approval changes to a licensed device must be submitted in accordance with § 601.12. Where the manufacturer may anticipate the types of changes they intend to make, they may consider seeking clearance or approval of a PCCP. Under section 515C of the FD&C Act, a PMA supplement or new 510(k) is not required for a modification to a device that would otherwise require such a submission if the change is consistent with a PCCP previously approved or cleared by FDA. To the extent a PCCP is approved or cleared by FDA for a particular IVD, any changes within the bounds of that PCCP would not necessitate a new submission to FDA.

In the final phaseout policy described in this preamble, FDA is also including several policies under which FDA generally does not intend to enforce the premarket review requirements for certain modified IVDs offered as LDTs. For example, if an IVD offered as an LDT was first marketed prior to the date of issuance of this rule, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements when the IVD is modified in certain limited ways as described in section V.B.3. As described in response to comment 124, this policy is intended to preserve access to beneficial IVDs on which patients and the healthcare community currently rely, including

[93] FDA has published several guidance documents to help stakeholders navigate this process, including ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' and ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device'' (Refs. 61 and 211).

versions of that IVD with minor changes. In addition, the final phaseout policy described in this preamble includes an enforcement discretion policy under which FDA generally does not intend to enforce premarket review requirements for certain LDTs for unmet needs, which may consist of a laboratory modification to an LDT or to another manufacturer's legally marketed test to meet an unmet need for use by a laboratory integrated within a healthcare system (see section V.B.3). Third, as described in sections V.C.4 and V.C.5, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements when a laboratory makes certain changes to another manufacturer's lawfully marketed 510(k) cleared or De Novo authorized test.

FDA also intends to develop appropriately targeted enforcement discretion policies for certain common changes, such as extension of specimen stability and certain alternative specimen types, following good guidance practices. Although FDA does not anticipate that such enforcement discretion policies will be analogous to certain provisions in the VALID Act, FDA nonetheless anticipates that such enforcement discretion policies will further help to address concerns regarding modifications as described in comments submitted to the docket. Moreover, the custom device exemption in the FD&C Act (21 U.S.C. 360j(b)), or enforcement discretion decisions for individual manufacturers, IVDs, or IVD modifications, may be appropriate to address unique patient needs or unforeseen circumstances.

(Comment 262) FDA received comments discussing the use of PCCPs as an option in complying with FDA requirements addressed in the phaseout policy. One comment inquired as to whether the PCCP process would extend to all assays or if it would be specific to sequencing assays, and whether FDA would issue a document explaining the PCCP process, including the type of change that would still require submission to FDA.

(Response 262) The use of PCCPs is not limited to certain types of devices, such as sequencing assays. FDA intends to issue draft guidance for stakeholders on Predetermined Change Control Plans for Medical Devices, as noted in the list of proposed guidances for fiscal year 2024 prepared by CDRH (Ref. 234).

(Comment 263) Another comment stated that PCCPs would not alleviate the need for new 510(k)s and PMA supplements for modifications because it would apply only to changes that a manufacturer makes to its own device and would not allow laboratories to adapt cleared or approved tests from other manufacturers to meet evolving clinical needs; and further, it would apply only to changes that the manufacturer can anticipate at the time of submission and does not enable laboratories to modify tests in response to other changing circumstances like reagent shortages or unique patient needs.

(Response 263) FDA agrees that the use of a PCCP would not be applicable in all circumstances in which a laboratory modifies an IVD. Inclusion of a PCCP in the clearance or approval of a device is based on FDA's review of the manufacturer's approach for validating certain types of modifications and associated acceptance criteria. While PCCPs are necessarily limited to the types of modifications the manufacturer can anticipate for a device that is under premarket review, use of the PCCP is just one approach to support the iterative improvement of a manufacturer's own devices. In addition, FDA has adopted or intends to adopt other enforcement discretion policies that may be relevant to the modifications described by the comments, which are described in the previous comment response. Otherwise, FDA believes premarket review of modifications as described in response to comment 261 is appropriate, consistent with the overall goal of this rulemaking to better assure the safety and effectiveness of IVDs offered as LDTs.

(Comment 264) FDA received a few comments that questioned the extent to which PCCPs would alleviate regulatory burdens for industry and how well they would function. One comment stated that, from experience with the current PCCP process, reaching agreement has been burdensome and lengthy, which limits the utility of PCCPs. Other comments stated that it is premature for FDA to assume that PCCPs will help laboratories as the program is still very new and it is unclear how well it will work for various categories of devices; and further, that it is unreasonable to expect laboratories that previously were generally not expected to comply with FDA requirements to leverage tools that still challenge more seasoned manufacturers.

(Response 264) FDA recognizes that efforts around PCCPs are relatively new and not all manufacturers may utilize PCCPs when making IVD modifications. In order to provide additional information to stakeholders on this topic, FDA has announced that it intends to issue draft guidance on PCCPs in fiscal year 2024 (Ref. 234). In addition, by the time of stages 4 and 5 of the final phaseout policy, FDA anticipates that it will have more experience with PCCPs, including in the context of IVDs, in order to facilitate manufacturer use of this tool. FDA may also provide additional guidance and educational opportunities for stakeholders, as appropriate. In any event, whether laboratories choose to use the PCCP process does not affect the public-health need for this rulemaking.

(Comment 265) FDA received comments expressing concern that premarket review requirements will cause disruption in access to tests and requesting the Agency take a more flexible approach or provide simplified submission requirements for specific types of assay modifications. Some comments suggested that FDA create a new submission pathway whereby low-risk modifications are reviewed on an expedited 45-day timeline and use this pathway when a PCCP may not be possible or available for low-risk modifications (*i.e.,* those that do not change the intended use, indications for use, or adversely affect the approved analytical or clinical performance) so that test manufacturers may implement low-risk modifications more expeditiously and ensure patient access to cutting-edge technology.

(Response 265) At the outset, FDA notes that compliance with premarket review requirements protects and promotes public health by helping assure that devices are safe and effective. In addition, not all modifications require premarket review. For modifications requiring premarket review, FDA will use the well-established premarket pathways set forth in the statute and regulations. With respect to the 45-day review period proposed by the comments, FDA declines to adopt a new policy expediting review of these modifications, which would divert resources from other priorities. However, for certain modifications that require premarket submission, FDA anticipates that the established expedited premarket pathways, such as the Special 510(k) program for moderate-risk devices with a 30-day timeline and the Real Time PMA program for high-risk devices with a 90-day timeline (see Refs. 235 and 236), will help laboratories implement these modifications in a timely manner. In addition, FDA has adopted or intends to adopt other enforcement discretion policies that may be relevant to such modifications. See the discussion in comment response 261.

(Comment 266) One comment proposed a continued enforcement discretion approach for modifications of certain FDA-approved (third-party) IVDs by appropriately trained and ''certified'' clinical scientists/pathologists at certain clinical laboratories, such as laboratories with high sample volume, reference laboratories, and laboratories serving ethnically diverse patient populations. This comment further proposed that qualified laboratory personnel would develop, review, and validate the modifications and submit a final report to FDA ''for information only,'' which would be used to facilitate FDA's review of the test characteristics when a submission for the modified IVD is submitted by the initial third-party manufacturer. The comment proposed that this approach should be limited to modifications of an FDA approved assay adapted for the local clinical need.

(Response 266) FDA does not agree that it should adopt the approach proposed in the comment. By ''FDA-approved'' IVD, we assume that the comment is referring to an IVD that is approved under a PMA. Such IVDs are class III devices that are considered high risk. When an IVD is high risk, changes to that IVD pose corresponding increased risks. Therefore, although FDA has adopted an enforcement discretion policy for certain laboratory changes to another manufacturer's lawfully marketed 510(k) cleared or De Novo authorized test (see sections V.C.4 and V.C.5), this policy does not apply to IVDs approved under a PMA.

However, FDA is adopting several other enforcement discretion policies that may be relevant to the comment's concern. As described in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)), for: (1) IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule, including versions of those IVDs with minor changes and (2) LDTs manufactured and performed by a laboratory integrated within a healthcare system to address an unmet need of patients receiving care within the same healthcare system.

(Comment 267) With respect to laboratory modifications to another manufacturer's FDA-authorized test, another comment suggested that FDA ''clarify through special controls what laboratories are expected to do when performing such validations and the extent to which the modified test's performance can change from the originally authorized version.'' The comment stated that it would be more practical for FDA to expect a premarket submission from a laboratory only when the modification is to another manufacturer's already cleared or approved device and a ''significant change'' has been made, as defined in FDA's guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (Ref. 61).

(Response 267) FDA agrees with this comment in that FDA intends to exercise enforcement discretion with respect to the premarket review requirements for certain modifications to certain lawfully marketed tests. Specifically, as described in sections V.C.4 and V.C.5, FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements when a laboratory certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's lawfully marketed 510(k) cleared or De Novo authorized test, following design controls and other quality system requirements for which FDA expects compliance as described in section V.C.3, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification. The guidance document mentioned in the comment applies to a manufacturer's modification of its own legally marketed device that is subject to 510(k) requirements. However, its description of changes that could significantly affect the safety or effectiveness of a test or constitute a major change or modification in intended use would be helpful and relevant for purposes of the enforcement discretion policy described in this paragraph.

Further, FDA intends to develop appropriately targeted enforcement discretion policies for certain common changes, such as extension of specimen stability and certain alternative specimen types, following good guidance practices.

In addition, to the extent the comment suggested that FDA should not expect premarket submissions from laboratories when a modification is made to a laboratory's own IVD, we disagree. Even if a laboratory is making a change to its own IVD, certain of those changes warrant premarket review in order to protect and promote public health. For example, for a 510(k)-cleared device, premarket review is expected when a change could significantly affect the safety or effectiveness of the device.

If a manufacturer needs assistance in understanding FDA's expectations for validation for a particular test, whether the test is designed initially by the laboratory manufacturer or whether the laboratory manufacturer is modifying another manufacturer's test, it may seek information through FDA's Pre-Submission program, which is further explained in FDA's guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65). Validation expectations may also be included in device-specific special controls, guidance documents, decision summaries, and recognized standards, all of which can be found on FDA's website. Further, FDA plans to consider what other resources may be helpful for laboratory manufacturers that modify another manufacturer's FDA-authorized test. Any future such resources will also be made available on FDA's website.

(Comment 268) FDA received several comments regarding test modifications in various areas of medicine, such as genetic testing, STI tests, and others that would be impacted by the phaseout policy. One comment asserted that the ability to rapidly update tests has improved the accuracy of genetic testing and provides improved sensitivity and specificity of testing across diverse populations in the United States. Another comment stated that increased oversight of LDTs would have significant implications for ongoing improvements using real-world evidence and continuous feedback loops, which allows for iterative enhancements to tests that greatly benefit patients. Another comment discussed the modifications to another manufacturer's FDA-authorized tests that are used in the pediatric population, where information in the labeling, such as intended use statements, are restrictive regarding patient population and specimen collection.

(Response 268) FDA agrees that test modifications, including those implemented based on real-world evidence information and to expand the indications for use of another manufacturer's FDA-authorized test to include pediatrics, can greatly benefit patients when the modified test remains safe and effective. FDA has seen modifications to tests that were intended to improve the test but did not actually do so; once the modified test underwent validation testing, the performance of the test was worse than the unmodified test and the test was no

longer safe and effective for its intended purpose. FDA has also seen modifications to tests that have not been supported by valid scientific evidence—for example, when there has been a lack of valid scientific evidence demonstrating the clinical validity of the modified test. FDA does not agree with the underlying implication of these comments that being able to modify IVDs without premarket review, regardless of the type of modification, best serves public health. FDA premarket review of modifications that could affect a test's safety and effectiveness helps ensure that modified IVDs are safe and effective. For example, FDA premarket review helps ensure appropriate clinical validation for modifications, among other things, including for genetic and STI tests, which were specifically raised by one comment.

(Comment 269) One comment expressed concern regarding the ''potential rigidity'' of the device regulatory scheme and its impact on the ability to ''routinely adjust DNA/RNA extraction processes to obtain more quality material for testing based on improving technology.'' The comment went on to propose FDA adopt an ''improved technology verification protocol'' that will allow a party to submit the reasons for modifications with a justification of improvements and demonstration that QC measures are being maintained.

(Response 269) The comment proposed a new regulatory approach to device modifications based on an ''improved technology verification protocol.'' Even assuming such an approach were within FDA's statutory authority, creating a new regulatory approach for all device or IVD modifications is not within the scope of this rulemaking, which is focused on phasing out the general enforcement discretion approach for LDTs. FDA notes that it may be appropriate to include certain changes, such as the modification to DNA/RNA extraction methods mentioned in the comment, in a PCCP in a premarket submission to FDA. For a more detailed discussion of PCCPs, see comment responses 262–264.

(Comment 270) Several comments discussed antimicrobial breakpoints and whether updates to breakpoints of ASTs should fall within the phaseout policy. One comment asserted that FDA's policy for requiring manufacturers of automated AST devices to wait for FDA to recognize updated breakpoints forces laboratories ''to choose between FDA's outdated breakpoints . . . or performing internal validation of CLSI's updated breakpoints.'' Another comment asserted that manufacturers of ''FDA-cleared or approved automated devices are not required to update breakpoints, and therefore modified FDA-cleared/approved (LDT) testing must be used'' and further asserted that their laboratory would not have the necessary staffing and financial resources to submit premarket submissions for revised breakpoints.

(Response 270) FDA disagrees with the premise that FDA's recognized breakpoints are outdated. Section 3044 of the Cures Act created a system to expedite the recognition of breakpoints, referred to in the Act as antimicrobial STIC (section 511A of the FD&C Act, 21 U.S.C. 360a–2). Since implementation of this statutory provision, FDA posts information online about FDA's recognition, or withdrawal from recognition, in whole or in part, of STIC established by an SDO and lists of exceptions or additions to the recognized STIC that the SDO established (Ref. 225). These online references are updated regularly. This approach allows FDA to more quickly communicate updated STIC than would be possible through updating and re-updating drug labeling. FDA has also created corresponding processes for rapid updates of breakpoints in AST devices. For example, FDA works with manufacturers to include PCCPs in their premarket submissions so that they can update their devices to address updated breakpoints without premarket review. In 2023, FDA issued a final guidance document, ''Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling'' (Ref. 226), in which FDA describes least burdensome approaches for AST system device manufacturers to update their device labeling with the updated breakpoints listed on FDA's STIC website (Refs. 225 and 226). Generally, updating the STIC could significantly affect the safety and effectiveness of the AST system device and would therefore require a 510(k) submission prior to updating the device labeling. However, the final guidance provides recommendations on the marketing submission content for PCCPs for new AST system devices, describes an enforcement policy regarding applying such updates to ''legacy'' AST system devices (AST system devices that were reviewed and cleared by FDA and did not include a breakpoint change protocol), and clarifies the process for incorporating by reference a cleared PCCP or breakpoint change protocol into a new 510(k) submission for an AST system device. FDA anticipates that this final guidance will facilitate timely adoption of updated breakpoints in AST system devices, which helps to maintain device safety and effectiveness. This should also reduce the burden on laboratories regarding the need to modify automated devices or submit premarket submissions where the manufacturers of the automated devices are using these streamlined approaches to quickly adopt updated breakpoints.

Additionally, for laboratories that are already offering AST devices as LDTs, as discussed in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule, and for certain modifications to such currently marketed IVDs offered as LDTs. In general, future updates to breakpoints of currently marketed ASTs offered as LDTs are within the scope of this enforcement policy, provided that such update is validated, does not change the indications for use of the AST, does not alter the operating principle of the AST, does not include significantly different technology, and does not adversely change the performance or safety specifications of the AST. For a modification to the breakpoint to an IVD currently offered as an LDT to be considered clinically validated, FDA expects the updated breakpoint to reflect that identified on the STIC website.

(Comment 271) Some comments stated that enforcing premarket review requirements for manufacturing changes will hamper process innovation, which will disincentivize changes that may improve laboratory operations and costs to patients, such as updating software, adding automation, and adjusting workflow to accommodate throughput needs of the institution.

(Response 271) As an initial matter, FDA notes that updating software, adding automation, and adjusting workflow to accommodate throughput could be examples of manufacturing process changes or changes to the design of an IVD, depending on how the change applies. For example, an update to the software used by a test would generally be considered a design change. For additional information regarding modifications to IVDs offered as LDTs, including design modifications, see the responses to comments 261 through 270. To the extent the comments are specific to changes made to the manufacturing

process, FDA requirements for premarket review of manufacturing process changes are calibrated to the significance of the change and risk of the device, such that premarket review (to the extent required) of minor changes is more streamlined than for major manufacturing changes. We believe this framework helps address some of the comments' concerns.

For example, for devices approved under a PMA or licensed under a BLA, FDA regulations require the submission of a supplement or a 30-day notice for certain manufacturing changes (see §§ 814.39 and 601.12). The appropriate type of submission varies with the nature of the change, as discussed in FDA's final guidance, ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process'' (Ref. 185) (see also § 601.12(b)–(c)). In some cases, which generally involve minor changes, manufacturing changes may be noted in a PMA or BLA annual report after they have been implemented (see §§ 814.39(b) and (e) and 601.12(e)). We also note that FDA estimates that premarket approval or licensure requirements will apply to only a small percentage of IVDs offered as LDTs (see Appendix A of the FRIA (Ref. 10)).

For devices subject to premarket notification, which are generally lower risk than those subject to PMA or BLA requirements, a change in the device manufacturing process would require a new 510(k) only if the change was one that could significantly affect the safety or effectiveness of the device (see § 807.81(a)(3)). Although, the need for premarket review of a manufacturing process change for an IVD is typically a case-specific evaluation, many changes implemented to improve laboratory operations may not trigger the requirement for a new 510(k) submission under FDA regulations. As discussed in FDA final guidance, manufacturers should consider the impact of manufacturing changes on device labeling, technology, engineering, performance, and/or materials to determine if a new 510(k) submission is required (Ref. 61).

In our experience, FDA premarket review of certain manufacturing changes is important to prevent adverse effects on device safety and effectiveness. For example, if a new manufacturing line is introduced that significantly alters the specificity of an antibody used for colon cancer screening, hundreds of individuals may receive false negative cancer screening results and miss critical early detection of colon cancer. In this example, even if introduction of the new manufacturing line was intended to improve operations, the change could have a significant, unintended adverse impact on the device's safety and effectiveness and, ultimately, on patients.

Moreover, as discussed in response to comment 261, FDA is issuing several policies under which FDA generally does not intend to enforce the premarket review requirements for certain modifications to IVDs offered as LDTs. The Agency anticipates these enforcement discretion policies will also help alleviate some of the concerns expressed in these comments.

(Comment 272) One comment stated that FDA should ''differentiate permitted off-label use from actions that create a 'new' or 'modified' test such that FDA would have jurisdiction'' and that FDA should ''ensure that it protects the legitimate (and statutorily protected) right of a healthcare professional to utilize a legally marketed test for an unapproved use.''

(Response 272) Section 1006 of the FD&C Act sets forth what conduct falls outside FDA's statutory authority as the ''practice of medicine,'' 21 U.S.C. 396, meaning Congress has already ''differentiate[d]'' in the manner suggested by the comment. For further discussion of the practice of medicine, see sections VI.D.6 and VI.D.7 of this preamble.

(Comment 273) One comment requested guidance ''on the use of specific IVD Cleared reagents and the conditions under which an LDT status is assigned.''

(Response 273) To the extent this comment is requesting clarification on whether the use of 510(k)-cleared reagents to develop a new test system would be considered manufacture of an IVD offered as an LDT, the answer is that it would. A test system is itself a device subject to applicable device requirements, regardless of whether the components of the system comply with FDA requirements.

N. FDA Resources

(Comment 274) Some comments expressed concerns that FDA would not have sufficient resources to conduct timely premarket review of IVDs offered as LDTs to meet the public health needs. Some recommended that FDA modify the phaseout policy to prolong the period of time prior to phasing out the general enforcement discretion approach with respect to premarket review requirements, and/or continue to apply the general enforcement discretion approach with respect to premarket review requirements for certain LDTs, to reduce the FDA resource needs.

(Response 274) FDA has considered Agency resources in developing the final phaseout policy (see section II.G of the FRIA (Ref. 10)). FDA disagrees that the Agency will lack sufficient resources to conduct premarket review of IVDs offered as LDTs in a timely manner.

First, FDA does not intend to phase out the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs offered as LDTs until 3½ years after publication of this final rule (stage 4 of the phaseout policy), and for moderate- and low-risk IVDs offered as LDTs (that require premarket submissions), until 4 years after publication of this final rule (stage 5 of the phaseout policy). This timeline aligns with the next reauthorization of MDUFA. This alignment will provide an opportunity for FDA and industry to negotiate regarding user fees and performance goals with the knowledge that laboratory manufacturers will be expected to comply with applicable premarket review requirements. Additional discussion regarding FDA's implementation of the phaseout policy is provided in response to comment 291. As discussed further in that response and in section V.C, for IVDs offered as LDTs for which a complete PMA, HDE application, 510(k) submission, BLA, or De Novo request has been received by the beginning of stage 4 or stage 5 of the phaseout policy (as applicable), FDA generally does not intend to enforce premarket review requirements until FDA completes its review of the application/submission. Thus, the timeliness of review of these submissions generally should not impact patient access.

Second, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs approved by NYS CLEP, and to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. These aspects of the phaseout policy are

discussed further in section V.B of this preamble, and collectively will significantly reduce the number of premarket submissions for IVDs offered as LDTs, as compared to the estimates in the PRIA. In particular, the total estimated number of affected tests has been reduced from 88,176 (see Ref. 60) to 7,606 (Ref. 10).

Third, FDA will gain more visibility into the universe of IVDs offered as LDTs through registration and listing in stage 2, which should help the Agency facilitate the efficient allocation of premarket review resources for those IVDs. As explained in the NPRM and discussed in the FRIA, FDA's device authorities require premarket review only for certain IVDs (88 FR 68006 at 68013). FDA estimates that approximately 50 percent of IVDs offered as LDTs will not require premarket review (see section II.F.2 of the FRIA (Ref. 10)). However, there are uncertainties surrounding the estimate of total numbers of IVDs offered as LDTs on the market because FDA generally has not enforced the registration and listing requirements for LDTs under section 510 of the FD&C Act and parts 607 and 807 (excluding subpart E). By 2 years after publication of this final rule, during stage 2 of the phaseout policy, FDA will obtain registration and listing information from laboratory manufacturers offering IVDs as LDTs. This information will help FDA assess and plan for the resources needed for premarket review of those IVDs before stages 4 and 5 of the phaseout policy. In addition, on January 31, 2024, FDA announced its intent to initiate the reclassification process for most IVDs that are currently class III into class II (Ref. 66). The majority of these tests are infectious disease and CDx IVDs. FDA aims to complete this reclassification process before stage 4 of the phaseout policy. Reclassification would allow manufacturers of certain types of tests to seek marketing clearance through the less burdensome 510(k) pathway rather than the PMA pathway, the most stringent type of FDA medical device review. FDA also intends to continue taking a risk-based approach in the initial classification of individual IVDs to determine the appropriate level of regulatory controls and whether a new test may be classified into class II through De Novo classification (and special controls established), rather than being class III and subject to the PMA pathway. Based on our experience, we believe that special controls could be developed, along with general controls, that could provide a reasonable assurance of safety and effectiveness for most future CDx and infectious disease IVDs. We therefore anticipate the percent of IVDs, including LDTs, eligible for 510(k) review to increase.

Fourth, other aspects of FDA's phaseout policy and related FDA actions will help to reduce premarket review resource needs. For example, FDA is currently working to enhance its Third Party review program to handle the review of low- and moderate-risk devices by 3P510k Review Organizations. This will free up Agency staff time to review more complex, innovative, high-risk devices. FDA estimates that half of the IVDs offered as LDTs subject to 510(k) requirements will be reviewed under the Third Party review program.

Fifth, FDA anticipates that laboratories may utilize PCCPs, and as discussed in response to comment 261, for certain common changes (like extension of reagent stability and certain alternative specimen types), FDA intends to develop appropriately targeted enforcement discretion policies, following good guidance practices. See additional discussion regarding test modifications in our responses to comments in section VI.M. FDA believes that PCCPs and targeted enforcement discretion policies will minimize the number of premarket submissions for modifications to IVDs offered as LDTs.

(Comment 275) Some comments questioned whether FDA would have adequate capacity to provide timely review of LDT applications/submissions because many EUA requests were not reviewed due to resource limitations during the COVID–19 pandemic. At least one comment cited FDA's review of a particular EUA request for an LDT during the COVID–19 pandemic, in which FDA's review of the request did not conclude until after the subject LDT had been removed from the market, as proof that FDA does not have adequate resources to conduct premarket review of LDTs.

(Response 275) FDA disagrees that its review of any one particular EUA request submitted for an LDT during the COVID–19 pandemic is indicative of how FDA will review premarket applications/submissions for IVDs offered as LDTs generally. FDA also disagrees that decision timelines on EUA requests, in general, are a good indicator to predict FDA's timelines for review of premarket applications/submissions for IVDs offered as LDTs.

First, EUAs differ substantially from standard premarket review pathways. FDA's authority to issue EUAs for LDTs is under a different statutory provision (section 564 of the FD&C Act) than traditional premarket reviews. Moreover, FDA is not required to review individual EUA requests submitted to FDA or review them on a specific timeline, or to authorize the emergency use of a medical product even if it meets the relevant criteria for an EUA, giving FDA flexibility to determine how to prioritize its efforts in emergencies to protect and promote public health. Second, during the COVID–19 pandemic, FDA received a large influx of submissions that had not been anticipated. In the context of the phaseout policy, FDA has estimated the number and type of premarket submissions we can expect in stages 4 and 5, and annually thereafter, and can prepare for those submissions.

Third, as noted in an FDA memorandum to file that was part of the record for this rulemaking (Ref. 18), FDA identified many issues with EUA requests from laboratories. When data are not presented clearly or data are inadequate to support authorization, FDA works with the submitter to address these issues and, in most cases, achieve authorization. This process extends review times. FDA anticipates that phasing out the general enforcement discretion approach for LDTs, combined with additional education or guidance, will ultimately lead to better submissions from laboratory manufacturers once they become familiar with FDA's expectations.

(Comment 276) Some comments referenced FDA's MDUFA IV performance report from FY2020 to 2022 (during the COVID–19 pandemic) and predicted that the increased volume of submissions from laboratory manufacturers that would result from the phaseout policy would affect FDA's overall ability to review premarket submission for all IVDs, meet its MDUFA performance goals, and conduct other essential work, including policy and post-market activities.

(Response 276) MDUFA performance goals include shared outcome goals agreed to by both FDA and representatives of the industry. FDA and applicants share the responsibility for achieving the Total Time to Decision objectives. Since premarket review of IVDs offered as LDTs is based on significant interaction between the Agency and applicants, high quality submissions will generally help reduce FDA's review time. FDA anticipates providing more targeted guidance on various topics, such as validation, and making additional resources available on the topic of premarket review of IVDs offered as LDTs over the course of the phaseout period. Further, as noted in

response to comment 274, the phaseout of enforcement discretion for premarket review requirements aligns with the next reauthorization of MDUFA, providing an opportunity for FDA and industry to negotiate regarding user fees and performance goals with the knowledge that laboratory manufacturers will be expected to comply with applicable premarket review requirements.

(Comment 277) Another comment referenced FDA's ''prolonged review'' of a particular consensus standard and suggested that ''such an extended review period raises concerns about the FDA's capacity to regulate and approve essential LDTs in a timely manner.''

(Response 277) FDA disagrees that our standards recognition process has any bearing on our ability to conduct timely premarket reviews, including reviews of LDTs. The premarket review process and the standards recognition process are independent and have different timelines and prioritization. Further, FDA's participation in standards writing committees does not automatically signal that FDA intends to recognize the standard. As these are consensus standards with many participants, FDA may or may not agree with the final published content and has a formal process for considering recognition.

(Comment 278) Some comments expressed concerns that a substantial increase in FDA staff and review capacity will be required to implement the phaseout policy, and workforce shortages will make it difficult to recruit and retain adequate numbers of qualified reviewers who are trained in laboratory diagnostics. Some comments stated that FDA lacks the personnel with relevant knowledge and expertise in laboratory medicine to effectively oversee molecular genetic IVDs offered as LDTs. One comment concluded that FDA had not kept up with the state-of-the-art methods for evaluating whole genome sequences, based on the fact that FDA declined to accept the Average Nucleotide Identity (ANI) results offered to correct the FDA–ARGOS database because the ANI results had not yet been standardized through the National Center for Biotechnology Information (NCBI).

(Response 278) FDA disagrees that the Agency lacks the knowledge and expertise to oversee IVDs offered as LDTs in the field of molecular genetics or in other fields. FDA has regulated IVDs under the comprehensive device authorities of the FD&C Act for almost 50 years, and it has the expertise and experience to regulate these tests, as discussed in response to comments 10 and 92. Specifically, OHT7 is staffed with scientific and medical experts who specialize in IVDs. OHT7 is responsible for overseeing total product lifecycle activities for IVDs. As noted previously, FDA also plans to utilize resources outside the Agency to support the implementation of the phaseout policy via the Third Party review program, and intends to exercise enforcement discretion and generally not enforce certain requirements for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3; LDTs approved by NYS CLEP; LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system; and LDTs manufactured and performed within VHA and DoD. Additional discussion can be found in response to comments in sections VI.F.5, VI.O, and VI.P of this preamble.

FDA also disagrees that its decision to follow the established quality control procedures for inclusion of genome sequences in the FDA–ARGOS database suggests that FDA's regulatory science in this area is outdated. Rather, the ongoing FDA–ARGOS project demonstrates FDA's investment in tools to support innovation of emerging technologies and commitment to regulatory science. The public FDA dAtabase for Reference Grade MicrObial Sequences (FDA–ARGOS) was established in 2014 and is a collaboration between FDA and DoD, the Institute for Genome Sciences at the University of Maryland, and NCBI (Ref. 237). FDA–ARGOS contains quality controlled and curated genomic sequence data to support research and regulatory decisions (Ref. 238). This is an evolving database that can be used as a tool for in-silico (computer simulation) performance validation and potentially reduce the testing burden on manufacturers of infectious disease NGS devices. There are ongoing projects focused on expanding the FDA–ARGOS database (Ref. 239). To maintain quality control of FDA–ARGOS as a reliable genome reference database, established quality metrics must be met and any updates to the quality control process are appropriately considered and vetted.

(Comment 279) Some comments expressed concerns related to whether FDA has sufficient resources to enforce compliance with requirements during stages 1 through 3 of the phaseout policy, which will occur before the next MDUFA reauthorization. Some of these comments stated that FDA would require additional resources before the next MDUFA reauthorization to support a significant increase in Pre-Submissions from laboratory manufacturers in anticipation of the phaseout of premarket review requirements for new and modified IVDs offered as LDTs. The comments suggested that FDA would need to hire more staff to review Pre-Submissions seeking FDA's input on the potential risk classification of many IVDs offered as LDTs for which there are no predicate devices. According to the comments, this increase in Pre-Submissions would not be addressed by issuing guidance documents, unless FDA issued those guidance documents expeditiously.

(Response 279) FDA believes that there will be adequate resources available from user fees (as permissible) and budget authority in stages 1 through 3 of the phaseout policy to provide advice, guidance, and education on premarket review and other regulatory requirements applicable to IVDs offered as LDTs. Also, during stages 1 through 3, FDA is phasing out the general enforcement discretion approach with respect to various requirements (*e.g.,* MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files) in stage 1; registration and listing, labeling, and investigational use requirements in stage 2; and QS requirements in stage 3 (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1)) and we believe information FDA receives as a result of compliance with those requirements will help FDA's allocation of anticipated available resources. FDA's estimate of the resources associated with stages 1 through 3 can be found in section II.G of the FRIA (Ref. 10).

FDA's projections do not presume a disproportionate increase in Pre-Submissions for IVDs offered as LDTs during stages 1 through 3 of the phaseout period in light of the enforcement discretion policies relating to premarket review described in section V.B, including for currently marketed IVDs offered as LDTs; LDTs approved by NYS CLEP; and LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.

For all of the foregoing reasons, FDA believes that the resources authorized under MDUFA V, combined with budget authority, are sufficient to fund the activities necessary for the review of voluntary Pre-Submissions received

during stages 1 through 3 of the phaseout policy.

(Comment 280) Some comments predicted that FDA's phaseout of the general enforcement discretion approach for LDTs will face challenges similar to those experienced in Europe in connection with the implementation of the In Vitro Diagnostic Medical Device Regulation, 2017/746 (IVDR). The IVDR was reported to cause significant delays in drug clinical trials by creating a bottleneck with respect to IVD approvals, as well as the discontinuation of certain rare disease diagnostics.

(Response 280) FDA disagrees that the phaseout policy will likely result in significant delays in clinical trials or disruption in patient access to LDTs for unmet needs, including tests for rare diseases, akin to what the comment claims has been observed during the implementation of the IVDR in Europe.

First, FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for currently marketed IVDs offered as LDTs, and thus does not anticipate disruption of patient access to such tests, including those for certain rare diseases, due to the phaseout policy. Going forward, FDA also intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA anticipates this policy will support continued innovation of new tests for rare diseases. For additional discussion regarding IVDs for unmet needs and IVDs for rare diseases, see our responses to comments in section VI.L.5.

With respect to use of IVDs offered as LDTs in clinical investigations of drugs, FDA does not anticipate that compliance with IDE requirements will meaningfully delay drug or IVD development activities, as described in response to comment 175. To the extent the comments are concerned about a potential review bottleneck due to resources, FDA disagrees that this will be the case for implementation of this rule, as described in response to comment 274.

O. 510(k) Third Party Review Program

(Comment 281) FDA received several comments supporting the use of FDA's Third Party review program to review 510(k) submissions for IVDs offered as LDTs. These comments stated that Third Party review will help to avoid strains on FDA's review capacity, streamline the timeline for review, limit redundancy with CLIA accreditation, and/or avoid detracting from other components of FDA's mission.

(Response 281) FDA agrees that use of the Third Party review program to review IVDs offered as LDTs could provide significant benefits to both industry and FDA, including by potentially reducing demand on FDA resources and facilitating timely review of 510(k) submissions. Under the MDUFA V commitment letter, FDA is currently working to enhance the Third Party review program, and the Agency anticipates interest in the Third Party review program among laboratories that manufacture IVDs offered as LDTs. As discussed in section II.G of the FRIA, FDA estimates that half of the IVDs offered as LDTs being submitted for 510(k) review will be reviewed under the Third Party review program. FDA also recognizes that if CLIA accreditation organizations seek accreditation under FDA's Third Party review program, there may be certain efficiencies or other advantages because the two programs are complementary, as described in response to comment 7.

(Comment 282) Some comments questioned the likelihood that a significant percentage of laboratories that manufacture IVDs offered as LDTs that require a 510(k) submission will use FDA's Third Party review program, based on historical utilization of the program. Comments suggested that the Third Party review program currently includes only a small number of Third Party reviewers, who review only a small subset of types of IVDs that require a 510(k) submission, and that laboratories may choose not to utilize the Third Party review program given that use of the program is voluntary.

(Response 282) Under the MDUFA V agreement, FDA committed to undertake several activities intended to enhance the Third Party review program with the objective of eliminating FDA's routine re-review of Third Party reviews. These activities include providing training to Third Parties seeking accreditation, auditing 3P510k Review Organizations, providing tailored retraining to 3P510k Review Organizations (based on the results of audits), and other activities (Ref. 240).

In addition, FDA has heard from entities interested in potentially serving as 3P510k Review Organizations for 510(k)s submitted for IVDs. Some of these entities are CLIA accreditation organizations with whom laboratories may already be familiar. We anticipate that when a laboratory already has a relationship with an organization, the laboratory may be inclined to work with that organization through the Third Party review program.

FDA anticipates that improving the Third Party review program, including through continued efforts to eliminate routine re-review of 510(k)s that have already been reviewed by a 3P510k Review Organization, as well as potential accreditation of organizations with whom laboratories may already be familiar, will increase use of the Third Party review program (as noted in response to comment 281 and discussed in section II.G of the FRIA, FDA estimates that half of the IVDs offered as LDTs being submitted for 510(k) review will be reviewed under the Third Party review program). FDA intends to continue efforts to enhance and facilitate greater use of the Third Party review program during implementation of the phaseout policy, including in advance of stage 5 of the phaseout policy.

FDA nonetheless acknowledges that participation in the Third Party review program is voluntary. Although FDA anticipates increased participation in the Third Party review program, as discussed in FDA's response to comment 284, FDA also anticipates that it will have sufficient resources to review 510(k) submissions for IVDs offered as LDTs even if participation in the Third Party review program is lower than estimated.

We also note that, as stated in FDA's final guidance document regarding the Third Party review program, ''[m]ost in vitro diagnostic (IVD) devices are eligible for [Third Party] review,'' provided they meet certain factors described in the final guidance (Ref. 56). About 75 percent of product codes for IVDs that are subject to 510(k) requirements (*i.e.,* ~750 out of 1,000 product codes) are currently eligible for submission to a 3P510k Review Organization, and FDA anticipates that this list may continue to grow as more IVDs are classified into class II (*i.e.,* through reclassification or De Novo classification) and as FDA gains experience with newer types of class II devices that are subject to 510(k) requirements.

(Comment 283) One comment noted that many devices do not qualify for Third Party review. Another comment noted that the Third Party review program does not extend to PMAs or De Novo submissions. These comments asserted that based in part on these factors, the Third Party review program does not sufficiently address concerns regarding the potential high volume of premarket submissions that may be submitted by laboratories as a result of the phaseout policy.

(Response 283) FDA agrees that PMA and De Novo submissions are not eligible for Third Party review under the Third Party review program as currently authorized under section 523 of the FD&C Act (21 U.S.C. 360m). In the FRIA, FDA has estimated the potential impact of the Third Party review program on costs and transfers associated with 510(k) submissions, but has not anticipated any impact from the program on costs or transfers associated with PMA or De Novo submissions (see sections II.G and II.H of the FRIA (Ref. 10)). FDA also recognizes that some devices that require a 510(k) submission are not eligible for Third Party review (see 21 U.S.C. 360m(a)(3)). However, as discussed in response to comment 282, about 75 percent of product codes for IVDs that are subject to 510(k) requirements (*i.e.,* ~ 750 out of 1,000 product codes) are currently eligible for submission to a 3P510k Review Organization, and FDA anticipates that this list may continue to grow as more IVDs are classified into class II (*i.e.,* through reclassification or De Novo classification) and as FDA gains experience with newer types of class II devices that are subject to 510(k) requirements. In addition, as discussed in response to comment 274, the Agency anticipates that certain enforcement discretion policies with respect to premarket review requirements, among other requirements, described in section V.B will also help to address concerns regarding the potential high volume of premarket submissions that may be submitted by laboratories as a result of the phaseout policy.

Further, as previously announced, FDA intends to initiate the reclassification process for most IVDs that have been previously classified in class III to class II (Ref. 66). FDA aims to complete this reclassification process before stage 4 of the phaseout policy. In addition, FDA intends to continue taking a risk-based approach in the initial classification of IVDs to determine the appropriate level of regulatory controls and whether a new test may be classified into class II through De Novo classification (and special controls established), rather than being class III and subject to the PMA pathway. Based on our experience, we believe that special controls could be developed that, along with general controls, could provide a reasonable assurance of safety and effectiveness for most future CDx and infectious disease IVDs, such that they could be regulated as class II devices. We therefore anticipate the percent of IVDs, including IVDs offered as LDTs, reviewed in a 510(k) submission to increase, and that the number of IVDs eligible for review by a 3P510k Review Organization may also increase. As shown in Table A.5 of the FRIA, the estimated numbers of PMAs and PMA supplements are lower after potential reclassification, while the estimated numbers of 510(k) submissions and De Novo requests are higher after potential reclassification.

(Comment 284) FDA received comments stating that a high rate of re-review of 510(k)s that have already been reviewed by a 3P510k Review Organization may extend premarket review times, and one comment stated that Third Party review should not be a substantial part of FDA's plans for managing the anticipated workload associated with premarket submissions for IVDs offered as LDTs until FDA has eliminated routine re-review of 510(k)s that have already been reviewed by a 3P510k Review Organization. One comment stated that if FDA intends to utilize the Third Party review program as a critical part of FDA's plans to manage the Agency's anticipated workload, FDA should not phase out the general enforcement discretion approach with respect to premarket submissions until FDA has demonstrated in a pilot program that 3P510k Review Organizations can apply FDA's requirements in a least burdensome manner. In addition, one comment suggested that FDA conduct a study to better understand the historical lack of utilization of the Third Party review program before making the program a core part of FDA's plans for managing the Agency's anticipated workload associated with premarket submissions for IVDs offered as LDTs.

(Response 284) FDA disagrees with the comments indicating that it is premature for the Agency to incorporate use of the Third Party review program into its plans for managing review of 510(k)s for IVDs offered as LDTs. FDA also disagrees that it should delay the phase out of enforcement discretion with respect to premarket review requirements prior to conducting a pilot to demonstrate application of least burdensome principles in the Third Party review program. As discussed in response to comment 282, under the MDUFA V agreement, FDA committed to undertake several activities intended to enhance the Third Party review program with the objective of eliminating FDA's routine re-review of Third Party reviews. These activities include providing training to Third Parties seeking accreditation, auditing 3P510k Review Organizations, and providing tailored re-training to 3P510k Review Organizations. FDA anticipates that these activities will advance FDA's efforts to eliminate routine re-review of 510(k)s that have already been reviewed by a 3P510k Review Organization and does not expect that there will be a ''high rate of re-review'' of 510(k)s submitted for IVDs offered as LDTs as some comments suggest. We also expect that these activities will facilitate 3P510k Review Organizations' consistent application of FDA's requirements for 510(k) review in a least burdensome manner. Further, we note that FDA provides training materials on its ''least burdensome'' approach to medical device regulation as part of its training curriculum for 3P510k Review Organizations (Ref. 241).

As discussed in response to comment 282, FDA anticipates that improving the Third Party review program will increase the program's use and estimates that approximately half of IVDs offered as LDTs being submitted for 510(k) review will be reviewed under the Third Party review program (see section II.G of the FRIA (Ref. 10)). However, even if the majority of submitters do not choose to use the Third Party review program, FDA anticipates that the Agency will be able to effectively manage review of 510(k) submissions for IVDs offered as LDTs. As described in section V.B.3, FDA intends to exercise enforcement discretion and generally not enforce premarket review and QS requirements (except for requirements under part 820, subpart M (Records)) for currently marketed IVDs offered as LDTs. FDA also intends to exercise enforcement discretion and generally not enforce premarket review requirements for LDTs that are approved by NYS CLEP, and to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. Collectively, these policies significantly reduce the estimated number of premarket submissions for IVDs offered as LDTs, as compared to the preliminary estimates in the PRIA (see sections II.F and II.G of the FRIA (Ref. 10)). In addition, as noted in our response to comment 274, FDA does not intend to phase out enforcement discretion with respect to premarket review requirements for moderate- and low-risk IVDs offered as LDTs that require 510(k) submissions until after the next reauthorization of MDUFA. This will

provide an opportunity for FDA and industry to negotiate regarding user fees taking into consideration FDA's anticipated resource needs to review 510(k) and other submissions for IVDs offered as LDTs.

(Comment 285) Some comments stated that the Third Party review program should utilize 3P510k Review Organizations that are accustomed to CLIA, or that FDA should encourage laboratory accreditation bodies to become 3P510k Review Organizations, to facilitate integration of the two programs, ensure the involvement of expert reviewers, and be less burdensome for laboratories.

(Response 285) As discussed in section V.C, FDA recognizes that a laboratory may be particularly inclined to use the Third Party review program when the laboratory is already familiar with a 3P510K Review Organization. FDA is aware of certain CLIA accreditation organizations that may be interested in becoming 3P510k Review Organizations, and the Agency encourages such organizations to continue exploring potential participation in the Third Party review program. To the extent the comments advocating for ''integration'' of CLIA accreditation and FDA's Third Party review programs were suggesting that CLIA accreditation and review of a 510(k) overlap, we note that, while there may be certain efficiencies or other advantages associated with CLIA accreditation organizations also serving as 3P510k Review Organizations, these are separate programs with complementary but distinct purposes (see, *e.g.,* response to comment 7).

(Comment 286) Several comments raised concerns about potential conflicts of interest among 3P510k Review Organizations, given that 3P510k Review Organizations are paid by the laboratories whose submissions they review. One comment asserted that the potential conflicts of interest among 3P510k Review Organizations may be particularly significant when the 3P510k Review Organization is also a CLIA accrediting organization.

(Response 286) FDA recognizes that avoiding conflicts of interest among 3P510k Review Organizations is critical to the success of the Third Party review program. With respect to the fact that laboratories would pay 3P510k Review Organizations to review 510(k)s for their IVDs offered as LDTs, we note that section 523(b)(5) of the FD&C Act (21 U.S.C. 360m(b)(5)) specifically provides that compensation for 3P510k Review Organizations to review a 510(k) ''shall be paid by the person who engages such services.'' However, the FD&C Act also contains provisions related to conflicts of interest for 3P510k Review Organizations, including provisions concerning the minimum qualifications for 3P510k Review Organizations and certain recordkeeping requirements (see sections 523 and 704(f) of the FD&C Act). In addition, FDA's final guidance document entitled ''510(k) Third Party Review Program'' addresses safeguards against potential conflicts of interest among 3P510k Review Organizations. As explained in FDA's final guidance document, ''FDA expects 3P510k Review Organizations to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of a conflict of interest. Therefore, FDA will consider whether the potential 3P510k Review Organization has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest or the appearance of a conflict of interest, including conflicts of interests pertaining to their external Technical Experts'' (Ref. 56). FDA's final guidance document also explains, among other things, that ''conflict of interest policies for a 3P510k Review Organization should be fully implemented and there should be an attestation that those policies have been implemented that is signed by the most responsible individual at the organization before any 510(k) is accepted for review.'' While FDA appreciates that concerns regarding potential conflicts of interest may be heightened when a 3P510k Review Organization is also a CLIA accreditation organization, the statutory provisions regarding the Third Party review program and FDA's implementation thereof already take potential conflicts of interest into account.

(Comment 287) One comment stated that FDA's discussion in the NPRM regarding use of the Third Party review program was vague. Another comment stated that with respect to Third Party review, FDA should provide ''better clarity and more information as to the participating entities, their capacities, throughput and turnaround time to review submissions by such entities.'' A third comment stated that FDA should ''formally withdraw inconsistent and outdated guidance,'' in particular FDA's draft guidance document regarding in vitro diagnostic multivariate index assays (IVDMIAs), as such guidance documents will create confusion among 3P510k Review Organizations and others if not withdrawn.

(Response 287) In the NPRM, FDA's discussion of the Third Party review program: (1) provided a general description of the program; (2) stated that FDA anticipated interest in the Third Party review program among test manufacturers and new 3P510k Review Organizations; and (3) explained the basis for anticipating that interest (see 88 FR 68006 at 68027). FDA does not agree that these statements were vague. However, to the extent stakeholders seek additional information regarding the Third Party review program, stakeholders may consult FDA's ''510(k) Third Party Review Program'' final guidance document (Ref. 56), which was cited as a reference in the NPRM (see 88 FR 68006 at 68027), as well as information available on FDA's website regarding the Third Party review program (Ref. 67). This includes information regarding current 3P510k Review Organizations and the devices they may review (Ref. 242). FDA publishes quarterly reports on the performance of 3P510k Review Organizations (Ref. 243). These reports include, among other things, data on the total number of submissions, review times, and decisions. FDA notes that 3P510k Review Organizations are best situated to address specific questions from potential submitters regarding their capacity and turnaround time for review of 510(k) submissions.

FDA agrees that inconsistent or outdated guidance documents may cause confusion among stakeholders. The Agency strives to maintain consistency across its final guidance documents and to update those documents when appropriate, consistent with good guidance practices (§ 10.115). We note that the specific guidance mentioned in the comment is a draft guidance. Draft guidance documents are not for implementation and explicitly state (on their title pages) that they are distributed for comment purposes only. Thus, the draft guidance mentioned in the comment should not cause confusion among stakeholders. With respect to final guidance documents, the Agency undertakes retrospective review of previously issued final guidance documents (21 CFR 10.115(k)) and is interested in receiving external feedback about final guidance documents that should be revised or withdrawn (see § 10.115(f)(4)). Stakeholders can submit comments on any guidance document at any time (§ 10.115(g)(5)).

(Comment 288) One comment stated that the ISO 15189 standard should be considered a viable alternative for quality management system requirements for laboratories that manufacture IVDs, and suggested that for specific provisions of the ISO 13485

standard that may not be covered in ISO 15189, FDA should include the provisions as a requirement (or through guidance) as part of the Third Party review program.

(Response 288) FDA does not agree that ISO 15189 is a viable alternative for quality management system requirements for laboratories that manufacture IVDs offered as LDTs, or that the Third Party review program is an appropriate mechanism to address any differences between the ISO 13485 [94] and ISO 15189 standards. For additional discussion of the ISO 15189 standard, see our response to comment 183. Further, the Third Party review program addresses 510(k) premarket review by accredited persons (see section 523 of the FD&C Act). It is not a mechanism to add or change the requirements that apply to a device manufacturer's quality system.

(Comment 289) FDA received a comment stating that FDA ''should leverage device performance reviews or external quality assessments of LDTs conducted by certified and creditable third parties'' as an alternative to premarket review by FDA for LDTs offered by AMCs.

(Response 289) The comment did not provide additional detail on what would constitute a ''certified and creditable'' third party that could provide such assessments. However, we note that FDA intends to continue supporting the use of its Third Party review program authorized under section 523 of the FD&C Act, as described in our responses to comments 281 through 288. The statute authorizes FDA to recognize Third Parties to review 510(k) submissions for certain types of devices and imposes various requirements on those organizations. We also note that FDA discusses comments received related to LDTs manufactured and performed by AMCs, including an enforcement discretion policy that may apply to certain LDTs manufactured and performed by AMC laboratories, in section VI.F.4 (see also section V.B.3).

P. Implementation

(Comment 290) FDA received comments suggesting that the Agency provide additional information regarding how FDA will be implementing the final phaseout policy. One comment recommended that the phaseout policy include timelines and ''criteria'' for transitioning from the general enforcement discretion approach for LDTs.

(Response 290) FDA agrees with the comment suggesting that FDA include timelines for transitioning from the general enforcement discretion approach for LDTs, and notes that section V.C of this preamble addresses this issue. As set forth more fully in that section:

- *Stage 1:* beginning 1 year after the publication date of this final rule, FDA will expect compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files) for IVDs offered as LDTs;
- *Stage 2:* beginning 2 years after the publication date of this final rule, FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements, for IVDs offered as LDTs;
- *Stage 3:* beginning 3 years after the publication date of this final rule, FDA will expect compliance with QS requirements (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1) for IVDs offered as LDTs;
- *Stage 4:* beginning 3½ years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs, unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review; and
- *Stage 5:* beginning 4 years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.

(Comment 291) Comments requested that FDA publish clear guidance document(s), including regarding: practical instructions, examples, and case studies; definitions of and other information regarding LDT risk categories; guidance on how laboratories can tailor their validation processes based on the complexity and potential impact of their LDTs; scenarios addressing how the phaseout policy affects specialized LDTs, such as those for rare diseases; and other topics. Comments requested that stakeholders be offered the opportunity to participate in guidance document development. FDA also received questions regarding the content and format for premarket submissions.

(Response 291) FDA agrees with comments that recommended that FDA provide additional resources on specific topics that may be useful as laboratories come into compliance with applicable requirements. FDA anticipates issuing a small entity compliance guide and/or making additional resources available on topics such as applicable labeling requirements over the course of the phaseout period. FDA also anticipates offering robust educational resources, potentially including but not limited to a webinar, a Town Hall meeting, Frequently Asked Questions web pages, and other materials designed to guide laboratories and other stakeholders. FDA also intends to consider issuing additional guidance during the phaseout period as appropriate, and would do so in accordance with good guidance practice regulations, which set forth the processes for participating in the development and issuance of guidance documents (§ 10.115).

In response to the comments seeking information regarding how laboratories can determine the risk categories of their IVDs offered as LDTs, we note that this rule does not change the statutory framework under which FDA regulates medical devices, including the risk-based classification of devices. FDA has previously provided multiple resources intended to help manufacturers determine the classification of their devices, including on FDA's web page entitled ''Classify Your Medical Device'' (Ref. 201), and in FDA's classification database (Ref. 200). In addition, laboratory manufacturers may request feedback from FDA regarding the potential regulatory pathway for a device through a Pre-Submission, described in FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65). Laboratory manufacturers may also consider submitting a request for information regarding the class in which a device is classified or the requirements applicable to a device under section 513(g) of the FD&C Act, the process for which is further described in FDA's final guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act'' (Ref. 244). For further information, you may view the training module available on FDA's website, entitled ''513(g) Requests for Information'' (Ref. 245).

[94] As noted elsewhere in this preamble, FDA recently finalized amendments to part 820, which take effect in February 2026. These amended QS requirements incorporate by reference the 2016 edition of ISO 13485 (see 89 FR 7496).

In response to comments seeking information regarding the content and format for premarket submissions, FDA offers Device Advice on Premarket Submissions: Selecting and Preparing the Correct Submission on FDA's web page (Ref. 246).

As discussed in section V.C, for IVDs offered as LDTs for which a complete PMA, HDE application, 510(k), BLA, or De Novo request has been received by the beginning of stage 4 or stage 5 of the phaseout policy (as applicable), FDA generally does not intend to enforce premarket review requirements until FDA completes its review of the submission.

(Comment 292) A comment stated that hospital and health system laboratories cannot currently assess how each part of the device regulations would apply to their LDTs under the phaseout policy. The comment noted that the uncertainty is problematic and underscores the need for continued enforcement discretion, most particularly in certain areas, such as for low- and moderate-risk tests.

(Response 292) As discussed further in the response to comment 162, FDA believes the information included in the phaseout policy, including the timeline for the various stages in the phaseout policy and information regarding enforcement discretion policies described in this preamble, provides clear expectations for laboratories that offer IVDs as LDTs. FDA appreciates that additional guidance regarding implementation of the phaseout policy may facilitate efforts by laboratories to comply with applicable requirements.

We note that FDA intends to exercise enforcement discretion and generally not enforce premarket review requirements and QS requirements (except for requirements under part 820, subpart M (Records)) for LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. For further discussion of this policy, refer to section V.B.3. As discussed further in the responses to comments in section VI.L.4, FDA is not adopting an enforcement discretion policy in the final phaseout policy for low- and moderate-risk tests.

Notably, and as set forth more fully in response to comment 291, FDA is not changing the statutory framework under which FDA regulates medical devices. In this rule, FDA has made explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. IVDs, as defined in § 809.3, are devices intended for human use and are subject to the FD&C Act. They include class I, class II, and class III devices, as well as both preamendments and postamendments devices. Like other devices, IVDs are subject to general controls, including premarket notification, reporting requirements regarding adverse events and corrections and removals, IDE requirements (though some investigations of IVDs are exempt from most provisions of the IDE regulation), and other applicable requirements under the FD&C Act and FDA's regulations. IVDs are also subject to specific labeling requirements in part 809. FDA has made numerous resources available to assist device manufacturers, including laboratories, in understanding device requirements.

(Comment 293) A comment stated that the phaseout policy does not provide enough guidance for laboratories to determine what data laboratories must submit for premarket review of existing or new LDTs.

(Response 293) Where premarket review is expected, the particular data required may vary based on the type of test at issue. There are multiple resources available to help IVD manufacturers, including laboratories, understand the type of data and information that is included in support of premarket submissions for IVDs. For example, FDA posts on its website the decision summaries for each IVD authorized (see Refs. 66, 166, 224, 247, and 248). These decision summaries describe the data and information that was provided to support the authorization and can be used as a model for manufacturers of the same types of tests. FDA also has issued general and device specific final guidance documents that describe recommendations for the data and information to be submitted in premarket submissions (see, *e.g.,* Refs. 234, 165, 190, and 249 to 253)), and has partially or fully recognized 110 CLSI consensus standards for In Vitro Diagnostics (Ref. 254). Many of these FDA recognized consensus standards describe recommendations for validation study designs. Manufacturers may also submit a Pre-Submission for specific feedback on individual tests (Ref. 65).

We note that FDA intends to exercise enforcement discretion and generally not enforce premarket review and most QS requirements for currently marketed IVDs offered as LDTs that were first marketed as of the date of issuance of this rule and that are not modified, or that are modified as described in section V.B.3. Thus, FDA generally does not expect laboratories to submit data for existing LDTs in a premarket review submission. FDA has also included several other enforcement discretion policies with respect to premarket review for certain LDTs as described in section V.B.

Further, we note that as more fully described elsewhere in this preamble, under FDA's device authorities, FDA premarket review is required only for certain IVDs (generally those classified into class II or class III), and FDA estimates that approximately 50 percent of IVDs offered as LDTs would not require premarket review.

In addition, when tests are modified, premarket review is required only in certain circumstances, as discussed elsewhere in this preamble (see response to comments 215 and 261).

(Comment 294) A number of comments suggested that FDA should assess the LDT marketplace to determine which LDTs present the ''highest risk,'' and implement the phaseout policy by risk category.

(Response 294) As described in section V.C, FDA's phaseout policy prioritizes the review of applications for high-risk IVDs offered as LDTs (stage 4) over those for moderate- and low-risk IVDs offered as LDTs that require premarket review (stage 5). For the reasons set forth in our response to comment 155, we do not believe the other stages of the phaseout should be ordered or dictated by the level of risk of an IVD offered as an LDT.

(Comment 295) FDA received a comment inquiring whether facilities that manufacture LDTs will be inspected in the same manner as other devices.

(Response 295) All domestic and foreign device establishments, including those that manufacture IVDs offered as LDTs, are subject to inspection. Section 704(a) of the FD&C Act provides FDA authority for inspections, specifically providing authority for duly designated officers or employees of FDA to enter, at reasonable times, and inspect, at reasonable times and within reasonable limits and in a reasonable manner, facilities subject to regulation under the FD&C Act.

FDA uses a risk-based evaluation to select device manufacturing facilities for inspection. *See* section 510(h)(2) of the FD&C Act (stating that the Secretary ''shall inspect establishments . . . that are engaged in the manufacture, propagation, compounding, or processing of a device or devices . . . in accordance with a risk-based schedule established by the Secretary.''). The Agency prioritizes device surveillance inspections deemed high-risk based on a variety of specific criteria, such as: (1)

facility type, such as manufacturer, control laboratory; (2) the facility's compliance history, including whether it has been inspected in the last 4 years; (3) hazard signals, including the record of signals, history and nature of product recalls linked to the facility; and (4) inherent risks of the device manufactured at a facility (Ref. 255). FDA does not intend to have a different approach for selecting laboratory manufacturing facilities for inspection.

(Comment 296) We received several comments that FDA should include industry experts and solicit outside expertise at various points during the implementation of the phaseout policy and in the regulation of IVDs offered as LDTs going forward. Comments suggested FDA solicit input on test classifications on an ongoing basis, convene expert panels to recommend risk categories and advise on specific types of technology and tests, and allow experts to participate in reviewing and approving premarket submissions in the areas of their expertise, and to ''have a seat at the table during the implementation of the FDA regulations, as well as long-term monitoring/approval'' of IVDs offered as LDTs.

(Response 296) To the extent the comments recommended that FDA seek input from stakeholders and outside experts, we agree that such input is important, and in fact required, in certain circumstances. For device classification, FDA follows the procedures required under section 513 of the FD&C Act and outlined in part 860. When classifying a preamendments device for the first time, for example, FDA provides a public process as required under section 513(d) of the FD&C Act. This process involves a public meeting of the appropriate advisory committee panel and notice and comment rulemaking.

More generally, FDA uses panels of the Medical Devices Advisory Committee (MDAC) to provide advice and recommendations to FDA on various regulatory issues. This may include advice on particular submissions, general issues, and device type classifications, among other things. The MDAC consists of 18 panels, including the following panels with established rosters reflecting expertise regarding IVDs, including LDTs: Clinical Chemistry and Clinical Toxicology Devices Panel (Ref. 256), Hematology and Pathology Devices Panel (Ref. 257), Immunology Devices Panel (Ref. 258), Microbiology Devices Panel (Ref. 259), and Molecular and Clinical Genetics Panel (Ref. 260). The rosters, calendars, and materials from past meetings are available on FDA's website as noted in the references above. For example, in September 2023, FDA convened the Microbiology Devices Panel to seek preliminary input on potential reclassification of certain types of IVDs for hepatitis B virus, human parvovirus B19, and M. tuberculosis from class III to class II with special controls (Ref. 261). In another recent example, FDA convened the Molecular and Clinical Genetics Panel in November 2023 to discuss and make recommendations on the design of multicancer detection in vitro diagnostic devices (tests) as well as potential study designs and study outcomes of interest that could inform the assessment of the probable benefits and risks of such tests (Ref. 262). The committee's discussion and recommendations from these meetings will help inform future Agency regulatory efforts for these tests.

FDA can also seek external expertise through its Network of Experts program, which is a vetted network of partner organizations and their members, scientists, clinicians, and engineers who can provide FDA rapid access to expertise when it is needed to supplement existing knowledge and expertise within CDRH (Ref. 263). There are multiple organizations within the Network of Experts with expertise relevant to IVDs. As has been FDA's practice, and when appropriate, FDA will continue to engage with experts and stakeholders through conferences, meetings, industry roundtables, town halls, and through collaborative communities in which we participate.

We note that FDA has long solicited and considered input from stakeholders regarding the Agency's oversight of LDTs. In 2010, FDA held a public meeting and requested comments on the ''Oversight of Laboratory Developed Tests'' (75 FR 34463, June 17, 2010). In 2014, FDA issued and requested comments on two draft guidance documents entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' (Ref. 38) and ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)'' (Ref. 112), and subsequently held and requested comments on a 2015 Public Meeting regarding the Agency's proposed oversight framework (Ref. 116). In 2017 we issued the 2017 Discussion Paper synthesizing the feedback that had been provided to the Agency (Ref. 57).

Furthermore, our Q-Submission program, in addition to providing IVD manufacturers with an opportunity to provide input to and request feedback from FDA on specific devices or submissions, also includes an opportunity to request an Informational Meeting to share with FDA information, among other purposes, to familiarize the FDA review team with new device(s) with significant differences in technology from currently available devices and provide an overview of ongoing or upcoming device development (see FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65)).

We note, however, that industry participation in certain activities referenced in the comments, such as the review and authorization of premarket submissions, would raise issues related to confidentiality and conflicts of interest (*e.g.,* if IVD manufacturers, including those who may be developing similar or competitor products, review or influence the outcome of other IVD manufacturers' premarket submissions). FDA has obligations to maintain confidentiality of certain aspects of premarket submissions and to make decisions about whether to authorize devices without undue influence.

Q. Interplay With Oncology Drug Products Used With Certain In Vitro Diagnostic Tests Pilot Program

(Comment 297) Several comments addressed FDA's ongoing pilot described in the final guidance document entitled ''Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program'' (Ref. 264). Most comments indicated support for the pilot; one did not. Supporters thought the model described in the pilot is valuable and should be considered in other disease areas, including rare diseases. Another comment suggested that the pilot's model should be used for tests used as part of cell and gene therapy product development. One suggested that FDA delay finalizing the rule until the pilot is completed and expanded.

(Response 297) FDA agrees that the concept of establishing performance expectations is valuable for test development generally, including for tests for rare disease. Such goals could be developed by the community and used to support premarket review submissions.

We note that the pilot program was initiated as one step that may be helpful in reducing the risks associated with LDTs used for oncology drug treatment decisions (then under the general enforcement discretion approach for LDTs), while the Agency continued to work on a broader approach for LDTs, including moving forward with this rulemaking. As discussed further in the

response to comment 298, the phasing out of the general enforcement discretion approach for LDTs means that FDA generally will expect compliance with applicable requirements for IVDs offered as LDTs, including those IVDs described in the oncology pilot program.

(Comment 298) Some comments asked for clarification regarding the impact of the phaseout policy on the pilot. One comment suggested pilot participants should be ''exempt'' from the phaseout. One comment asked if an unapproved clinical trial assay could be used upon approval of the therapeutic with a postmarket commitment to obtain approval of a CDx.

(Response 298) FDA disagrees with the suggestion to ''exempt'' unapproved assays used in the pilot from the phaseout policy. The types of LDTs discussed in the pilot program may provide information that is essential for the safe and effective use of a corresponding therapeutic product. As described in the NPRM, we have seen variability in performance among LDTs offered for a use that is the same as a CDx such that, in some cases, selection of a treatment for a given patient can be impacted by which test is used (see 88 FR 68006 at 680209–10). For example, the same patient may receive a particular therapeutic if they are tested with one LDT and not receive the therapeutic if they are tested with another LDT due to differences in test performance. For these reasons, the phaseout of the general enforcement discretion approach generally applies to LDTs offered for a use that is the same as a CDx, including the types of LDTs discussed in the pilot program.

(Comment 299) One comment asserted that the pilot program will amplify risks to patients by encouraging the use of tests that are not clinically validated.

(Response 299) The pilot program was initiated as one step that may be helpful in reducing the risks associated with using LDTs for oncology drug treatment decisions while the Agency continued to work on a broader approach for LDTs, including moving forward with this rulemaking. For the reasons in this preamble, FDA is phasing out the general enforcement discretion approach for LDTs, including the types of LDTs discussed in the pilot program final guidance.

(Comment 300) One comment suggested that FDA's general approach to CDx approvals is a barrier to innovation in that it requires clinical concordance studies to other PMA-approved devices or clinical trials in partnership with drug companies. The comment explained that there is no incentive for a drug company to conduct additional clinical trials to support diagnostic approvals and no incentive for the laboratory with the approved CDx to conduct clinical concordance studies with additional laboratories to support other diagnostic approvals. This comment expressed concern that increased oversight of LDTs is likely to put significant constraints on CDx availability, where doctors and patients would be forced to send samples to specific laboratories.

(Response 300) As discussed in response to comment 298, FDA has seen variability in performance among LDTs offered for a use that is the same as a CDx such that, in some cases, selection of a treatment for a given patient can be impacted by which test is used. For this reason, and for the reasons further discussed throughout this preamble, FDA believes that increased oversight for these and others IVDs offered as LDTs is generally necessary and appropriate. FDA understands the current system presents challenges for development of additional tests to select patients for a drug once one CDx is authorized. FDA seeks to engage with the community on additional efforts to create standardization, such as through reference materials, so that clinical validity can be extrapolated to other tests of the same type in more cases.

R. Miscellaneous

(Comment 301) We received many comments regarding the impacts that FDA's proposal would have on the medical education of those training in pathology. Comments noted that the increased financial and regulatory burdens on smaller teaching laboratories would reduce the number of tests available at those laboratories, which would eliminate, significantly delay, or make less attractive the opportunities for training clinical pathologists and additionally fewer laboratories would be able to meet the criteria for training programs prescribed by ACGME. Comments additionally stated that without robust opportunities to learn pathology principles and the skills needed to pass the pathology board certification exam, fewer trainees may be able to pass.

Comments stated that fewer learning opportunities would, in turn, exacerbate existing pathologist workforce burnout and shortages, and lead to fewer and less qualified and competent pathologists, which would lead to a decline in the practice of pathology that would reduce the quality and timeliness of patient care, and potentially the ability for healthcare to address advanced or new disease altogether. Additional comments noted that for-profit reference laboratories are not obligated to train pathology residents and fellows and that the pipeline of medical students who train at small laboratories is also an important pool of talent for IVD manufacturers, other clinical laboratory affiliated industries, and regulatory agencies, which will be similarly negatively affected.

Some comments stated that reduced medical training opportunities would particularly affect genetic and genomic medicine, an area of increasing demand and worsening workforce shortages, because it relies so heavily on LDTs. Another comment noted that if data available from LDTs was limited, then genomics and genetics biomedical research training at the Ph.D. graduate and postgraduate levels that depend on that data would also suffer and ultimately affect the health of the U.S. population and the competitiveness of the U.S. research enterprise.

(Response 301) As set forth in section V.B, FDA is adopting several enforcement discretion policies in the phaseout policy that reflects a balancing of the important public health considerations at issue in the rule (see further discussion of these considerations in section III.B). We anticipate the impact of these policies will address some of the concerns expressed in comments related to the impact on medical education, insofar as the financial burdens on laboratories will be reduced, resulting in fewer laboratories scaling back operations, exiting the market, or otherwise limiting educational opportunities. As a result of these policies and other adjustments, the FRIA estimates a 78 percent reduction in cost to industry compared to the PRIA. Specifically, the FRIA estimates a $1,166M 20-year annualized cost to industry—a reduction of $4,170M.

(Comment 302) A comment requested clarity about how FDA considers its potential enforcement actions or remedies when the Agency identifies a violation of the law. In particular, the comment was interested in whether enforcement actions apply to the laboratory activity, revenue, and operations or only the manufacturing of the test.

(Response 302) This comment was not entirely clear; we have interpreted this comment as seeking more information about FDA's approach to device enforcement. Such enforcement by FDA is taken on a case-by-case basis and the specifics of each enforcement action depend on the specific facts at issue. FDA generally seeks to work with

device manufacturers to address issues where the manufacturer or device is in noncompliance with requirements. FDA may issue a warning letter or take other advisory actions where appropriate. Administrative and enforcement actions authorized under the FD&C Act include: seizure of adulterated or misbranded devices (see section 304 of the FD&C Act); injunction against a manufacturer (see section 302 of the FD&C Act); and civil monetary penalties (see section 303 of the FD&C Act).

(Comment 303) One comment stated that FDA's characterization of LDTs as simple devices was incorrect, because all tests require professional interpretation given that test results should be interpreted in the context of a patient's overall clinical status and the specifics of a particular test. The comment stated that two tests assessing the same parameter may measure different things (*i.e.,* hot spot testing vs. sequencing of the entire coding region of a gene), while the same result may mean different things in different patients.

(Response 303) FDA is not clear what the comment is referencing when it states that FDA characterized LDTs as ''simple.'' FDA did not include such a description in the NPRM. Rather, FDA noted in the NPRM that many LDTs rely on high-tech or complex instrumentation and software to generate results and clinical interpretations (88 FR 68006 at 68008). Nevertheless, FDA agrees that test results should be interpreted in the context of overall clinical status and the specifics of a particular test. This is one reason why it is important that IVDs have appropriate assurance of safety and effective for their specific intended uses.

(Comment 304) FDA received comments discussing part 11 (21 CFR part 11). One comment asked whether IVDs offered as LDTs would be subject to part 11 and, if so, what type of documentation would be required for software associated with an IVD offered as an LDT, and requested guidance on how to treat software that analyzes results for automatic release or that analyzes sequencing data to identify mutations or other targets of interest.

(Response 304) This rule does not change the framework under which FDA regulates devices, including the scope and application of electronic records and electronic signatures regulations found at part 11.

The comment that asked about the applicability of part 11 and requested guidance does not appear to be speaking for or against any aspect of this rulemaking, or presenting any matter which is relevant to this rulemaking. FDA notes nevertheless that it has issued final guidance on part 11. For example, FDA's final guidance document entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' (Ref. 265) provides guidance to persons who, in fulfillment of a requirement in a statute or another part of FDA's regulations to maintain records or submit information to FDA, have chosen to maintain the records or submit designated information electronically and, as a result, have become subject to part 11. People can comment on that final guidance document or any other at any time, and FDA will revise guidance documents in response to comments when appropriate (§ 10.115(g)(5)). FDA also periodically reviews existing final guidance documents to determine among other things whether they need to be changed (§ 10.115(k)(1)).

(Comment 305) One comment stated that it could be overly burdensome to meet the requirements of part 11 for systems that were designed to be used for clinical care but would now be used as the system of record for data that is included in a premarket submission.

(Response 305) It is not clear what particular submission requirements are being referred to by the comment that said it could be overly burdensome to comply, or what legal or policy changes, if any, this comment would recommend. While this comment talked about the requirements of part 11, FDA notes that submission requirements might arise under the FD&C Act, the PHS Act, and FDA regulations other than part 11, and that FDA's policies regarding part 11 would not affect such requirements. And, of course, this rulemaking does not change part 11.

In any event, in the ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' final guidance, FDA observed that some broad interpretations of the scope of part 11 ''could lead to unnecessary controls and costs and could discourage innovation and technological advances without providing added benefit to the public health.'' Accordingly, in that final guidance document, FDA stated that it ''intends to interpret the scope of part 11 narrowly.'' Moreover, FDA currently exercises enforcement discretion with respect to certain part 11 requirements. In particular, and as described in that final guidance, FDA currently does ''not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 as explained in this guidance'' and does ''not intend to take (or recommend) action to enforce any part 11 requirements with regard to systems that were operational before August 20, 1997, the effective date of part 11 (commonly known as legacy systems) under the circumstances described in section III.C.3 of this guidance.'' FDA believes that its interpretation of and enforcement policies regarding part 11 strike an appropriate balance between public health and innovation, without being overly burdensome. Nevertheless, and consistent with the ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' final guidance, as a result of its re-examination of part 11, FDA anticipates initiating rulemaking to change part 11 as appropriate.

(Comment 306) One comment asked if FDA will establish a fund to compensate physicians who face malpractice lawsuits that may result from misdiagnoses as a result of phasing out the general enforcement discretion approach for LDTs.

(Response 306) Malpractice lawsuits are outside the scope of this rulemaking.

(Comment 307) Some comments stated that FDA should work with Congress to advance new legislation regarding the regulation of IVDs more broadly, such as the VALID Act. These comments generally acknowledged that FDA has a role to play in the oversight of LDTs, but suggested that legislation could better balance a variety of considerations and objectives—such as promoting patient safety, ensuring flexibilities, facilitating innovation, and supporting patient access—as compared to what is possible with FDA's existing authorities. One comment suggested that legislation could better take into consideration unique characteristics of the diagnostics industry and the ''multitude of stakeholders'' affected by the regulation thereof, while other comments stated that new legislation could provide ''unequivocal'' statutory authority, as well as the resources necessary to effectively oversee diagnostics.

(Response 307) These comments are outside the scope of this rulemaking. The ability to enact new legislation rests with Congress. This rulemaking is focused on FDA's oversight of devices under the current statutory authorities set forth in the FD&C Act. Based on the evidence currently available to the Agency, FDA has determined that there is a public health need to better assure the safety and effectiveness of IVDs offered as LDTs, and FDA has determined to address that need consistent with our existing authorities by amending our regulations to make explicit that IVDs are devices under the

FD&C Act including when the manufacturer of the IVD is a laboratory, and by phasing out the general enforcement discretion approach for LDTs.

FDA recognizes that the Agency's current statutory authorities could be amended or supplemented to establish a different regulatory framework for IVDs than the one that currently exists. FDA notes that this rulemaking does not prevent Congress from enacting new legislation.

VII. Effective Date

This rule is effective July 5, 2024.

VIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

E.O.s 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under E.O. 12866 Section 3(f)(1) (as amended by E.O. 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is a significant regulatory action under E.O. 12866 Section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule falls within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because most facilities that will be affected by this rule are defined as small businesses and the final rule is likely to impose a substantial burden on the affected small entities, we find that the rule will have a significant economic impact on a substantial number of small entities.

We prepared an analysis consistent with the Unfunded Mandates Reform Act of 1995 (section 202(a)), which requires the preparation of a written statement that includes estimates of anticipated impacts before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in at least one year that meets or exceeds this amount.

This final rule amends FDA's regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. As discussed in section V of the preamble to the final rule, FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs.

We anticipate that the benefits of phasing out FDA's general enforcement discretion approach for LDTs includes a reduction in healthcare costs associated with unsafe or ineffective IVDs offered as LDTs (generally referred to in this document as ''problematic IVDs''), including IVDs offered as LDTs that are promoted with false or misleading claims, and from therapeutic decisions based on unreliable results of those tests. Quantified benefits are the annualized sum of both health and non-health benefits. Unquantified benefits include the reduction in costs from lawsuits. We discuss the benefits of the phaseout of FDA's general enforcement discretion approach for IVDs offered as LDTs in section II.E of the FRIA.

This phaseout policy will result in compliance costs for laboratories that are ensuring their IVDs offered as LDTs are compliant with statutory and regulatory requirements, as described in section V. We discuss the costs of the phaseout policy in section II.F of the FRIA. These costs overlap somewhat with effects associated with this phaseout policy in the form of user fees, including annual registration fees, fees for premarket applications/submissions, and annual fees for periodic reporting concerning PMA-approved devices, which are paid from laboratories to FDA. These fees are paid by laboratories but are revenue for FDA; the approach to estimating fee effects is distinct from the approaches for either benefits or costs, so they will be presented as transfers. We discuss transfers in section II.H of the FRIA.

Table 1 summarizes the annualized benefits, costs, and transfers of the phaseout policy. At a 7 percent discount rate, 20-year annualized benefits range from about $0.99 billion to $11.1 billion, with a primary estimate of $3.51 billion per year. At a 3 percent discount rate, 20-year annualized benefits range from $1.24 billion to $13.62 billion, with a primary estimate of $4.34 billion per year. At a 7 percent discount rate, 20-year annualized costs range from about $566 million to $3.56 billion, with a primary estimate of $1.29 billion per year. At a 3 percent discount rate, annualized costs range from about $603 million to $3.79 billion, with a primary estimate of $1.37 billion per year. At a 7 percent discount rate, 20-year annualized transfers range from $20 million to $81 million, with a primary estimate of $41 million per year. At a 3 percent discount rate, 20-year annualized transfers range from $29 million to $115 million, with a primary estimate of $58 million per year. These estimates do not include anticipated offsets from user fees. At a 7 percent discount rate, 20-year annualized costs to FDA range from $61 million to $243 million, with a primary estimate of $121 million per year. At a 3 percent discount rate, 20-year annualized costs to FDA range from $65 million to $259 million, with a primary estimate of $129 million per year. Factoring in offsets from user fees at current levels, estimated costs to FDA are reduced to $40 million to $162 million at a 7 percent discount rate, with a primary estimate of $81 million, and to $36 million to $144 million at a 3 percent discount rate, with a primary estimate of $72 million, covering approximately 30 to 40 percent of the estimated costs to FDA.

BILLING CODE 4164–01–P

Table 1.--Summary of Benefits, Costs and Transfers of the Final Rule (millions of 2022 U.S. dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$3,509	$988	$11,096	2022	7%	20 years	Major sources of benefits will be the avoidance of harms to patients from use of problematic IVDs offered as LDTs and the avoidance of spending on such IVDs.
		$4,341	$1,244	$13,619	2022	3%	20 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized ($m/year)	$1,287	$566	$3,559	2022	7%	20 years	A portion of foreign costs will be passed on to domestic consumers. We estimate that up to $147 million in annualized costs (7%, 20 years) to foreign facilities could be passed on to domestic consumers.
		$1,372	$603	$3,789	2022	3%	20 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)	$41	$20	$81	2022	7%	20 years	The main portion of transfers will be user fees for premarket submissions.
		$58	$29	$115	2022	3%	20 years	
		From: Device Industry			To: FDA			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local, or Tribal Government: No significant effects Small Business: The phaseout policy will have a significant economic impact on a substantial number of small laboratories that manufacture IVDs offered as LDTs. Wages: N/A Growth: N/A							

BILLING CODE 4164–01–C

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the phaseout policy. The full analysis of economic impacts is available in the docket for this phaseout policy (Ref. 10) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human

environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA concludes that this rule contains no new collections of information. However, we expect that the phaseout of our general enforcement discretion approach for LDTs will necessitate adjustment to the burden estimates for several approved information collections, before the relevant phaseout stage begins. Such adjustments will account for an anticipated increase in the number of responses due to the expected compliance of laboratory manufacturers with applicable requirements for which FDA previously exercised enforcement discretion under the general enforcement discretion approach. Such adjustments will be submitted for review and clearance by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521).

In section II.D.1 of the FRIA for this rulemaking, we estimate a range of 590 to 2,362 affected laboratories and 47 to 189 new affected laboratories entering the market per year. We intend to adjust the applicable information collection burden estimates to reflect additional responses to correspond with the phaseout policy.

As discussed in section V.C of this preamble, FDA has determined to gradually phase out its current general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes targeted enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs, as described in section V.B of this preamble. FDA has structured the phaseout policy to contain five key stages. In the following paragraphs, we include a brief description of the stages and the OMB control numbers under which the related information collections (corresponding to the requirements for which FDA will expect compliance in each stage) are approved.

In stage 1, beginning 1 year after the publication date of this final rule, FDA generally will expect compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files). Information collections associated with the MDR requirements under 21 U.S.C. 360i(a) through (c) and part 803 are approved under OMB control number 0910–0437. Information collections associated with correction and removal reporting requirements under 21 U.S.C. 360i(g) and part 806 are approved under OMB control number 0910–0359. Information collections associated with QS requirements under part 820, including § 820.198 (complaint files), are approved under OMB control number 0910–0073. Costs associated with stage 1 are discussed in section II.F.1 of the FRIA.

In stage 2, beginning 2 years after the publication date of this final rule, FDA generally will expect compliance with requirements not covered during other stages of the phaseout policy. These other requirements include registration and listing requirements under 21 U.S.C. 360 and parts 607 and 807 (excluding subpart E) (related information collections are approved under OMB control numbers 0910–0052, and 0910–0625, respectively); labeling requirements under 21 U.S.C. 352 and parts 801 and 809, subpart B (related information collections are approved under OMB control number 0910–0485); investigational use requirements under 21 U.S.C. 360j(g) and part 812 (related information collections are approved under OMB control number 0910–0078); and, for certain devices that are biological products, investigational use requirements under 42 U.S.C. 262 and 21 CFR part 312 (related information collections are approved under OMB control number 0910–0014). Costs associated with stage 2 are discussed in section II.F.2 of the FRIA.

Additionally, for questions that are specific to a particular IVD, laboratory manufacturers may request feedback from FDA through a Pre-Submission, which is further explained in FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 65) (related information collections are approved under OMB control number 0910–0756).

In stage 3, beginning 3 years after the publication date of this final rule, FDA generally will expect compliance with QS requirements under part 820 (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1). Information collections associated with QS requirements under part 820 are approved under OMB control number 0910–0073. Costs associated with stage 3 are discussed in section II.F.3 of the FRIA.

In stage 4, beginning 3½ years after the publication date of this final rule, FDA generally will expect compliance with premarket review requirements for high-risk IVDs. The premarket review requirements for PMAs are set forth in 21 U.S.C. 360e and part 814 (related information collections are approved under OMB control number 0910–0231). Premarket review requirements specific to HDE applications are set forth in 21 U.S.C. 360j(m) and part 814, subpart H (related information collections are approved under OMB control number 0910–0332). Licensure requirements are set forth in 42 U.S.C. 262 and 21 CFR part 601 (related information collections are approved under OMB control number 0910–0338). Costs associated with stage 4 are discussed in section II.F.4 of the FRIA.

In stage 5, beginning 4 years after the publication date of this final rule, FDA generally will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions). These premarket submissions include 510(k) submissions, the requirements for which are set forth at 21 U.S.C. 360(k), 360c(i), and part 807, subpart E (related information collections are approved under OMB control number 0910–0120). These submissions also include De Novo requests, which laboratories may submit for IVDs offered as LDTs for which there is no legally marketed device upon which to base a determination of substantial equivalence, and for which the laboratory seeks classification into class I or class II. These requirements are set forth at 21 U.S.C. 360c(f)(2) and part 860, subpart D (related information collections are approved under OMB control number 0910–0844). Costs associated with stage 5 are discussed in section II.F.4 of the FRIA.

FDA also anticipates that laboratories may seek to utilize FDA's Third Party review program. FDA currently operates a Third Party review program for medical devices, and multiple organizations are accredited to conduct reviews of 510(k) submissions for certain IVDs (see Ref. 67). We anticipate interest in the Third Party review program among laboratory manufacturers, as well as potential new 3P510k Review Organizations. Information collections associated with the Third Party review program are approved under OMB control number 0910–0375.

XI. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that have substantial direct effects on the

States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

One comment stated that FDA failed to conduct the required federalism analysis under E.O. 13132 and that the Agency erroneously stated in the NPRM that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Another comment stated that the conclusions in the NPRM regarding federalism ''do not reflect the impact on practice of medicine'' given that, in the comment's view, FDA's proposal conflicts with certain state medical practice acts as well as NYS CLEP, which currently permits the review, approval, and use of LDTs.

As discussed in response to comment 101, the requirement for a federalism summary impact statement applies to the proposed amendment to § 809.3 (and not the phaseout policy), and because the proposed regulation would not establish any new requirements, it would not have any federalism implications under E.O. 13132. Moreover, even if the requirement for a federalism summary impact statement were to apply to the phaseout policy, the policy does not have federalism implications because it is not establishing any new requirements. For further discussion on the relationship between this rule and state medical practice acts and NYS CLEP, as raised in the comments summarized above, see comments 76 and 101 and the responses to those comments.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA received one comment on the NPRM that expressed concern that the rule, if implemented, would have significant tribal implications, resulting from loss of access to IVDs offered as LDTs that address special needs of the Native American population. As discussed in response to comment 223 (section VI.K), FDA does not anticipate that the Native American population will lose access to such IVDs offered as LDTs based on the final phaseout policy. We conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. CMS, ''List of Exempt States Under the Clinical Laboratory Improvement Amendments (CLIA).'' Available at *https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/exemptstateslist.pdf* (last accessed on January 30, 2024).
* 2. Congressional Research Service, ''FDA Regulation of Laboratory-Developed Tests (LDTs),'' December 7, 2022. Available at *https://crsreports.congress.gov/product/pdf/IF/IF11389*.
3. The Pew Charitable Trusts, ''The Role of Lab-Developed Tests in the In Vitro Diagnostics Market,'' October 22, 2021. Available at *https://www.pewtrusts.org/en/research-and-analysis/reports/2021/10/the-role-of-lab-developed-tests-in-the-in-vitro-diagnostics-market*.
4. Grand View Research, ''Laboratory Developed Tests Market Size, Share & Trends Analysis Report By Technology (Immunoassay, Molecular Diagnostics), By Application (Oncology, Nutritional & Metabolic Disease), By Region, and Segment Forecasts, 2023–2030: Report Summary,'' 2021. Available at *https://www.grandviewresearch.com/industry-analysis/laboratory-developed-tests-market-report* (last accessed on January 30, 2024).
* 5. Warning Letter to deCODE Genetics re: deCODEme Complete Scan (June 10, 2010). Available at *https://www.fda.gov/media/79216/download*.
* 6. Warning Letter to 23andMe, Inc. re: 23andMe Personal Genome Service (June 10, 2010). Available at *http://web.archive.org/web/20191214010336/https:/www.fda.gov/media/79205/download*.
7. UC San Diego, Jacobs School of Engineering, ''How Unsecured, Obsolete Medical Record Systems and Medical Devices Put Patient Lives at Risk,'' August 28, 2018. Available at *https://jacobsschool.ucsd.edu/news/release/2619?id=2619* (last accessed on March 19, 2024).
* 8. FDA, ''Illumina Cybersecurity Vulnerability May Present Risks for Patient Results and Customer Networks: Letter to Health Care Providers,'' June 2, 2022. Available at *https://www.fda.gov/medical-devices/letters-health-care-providers/illumina-cybersecurity-vulnerability-may-present-risks-patient-results-and-customer-networks-letter* (last accessed on March 19, 2024).
* 9. FDA, ''Illumina Cybersecurity Vulnerability Affecting the Universal Copy Service Software May Present Risks for Patient Results and Customer Networks: Letter to Health Care Providers,'' July 7, 2023. Available at *https://www.fda.gov/medical-devices/letters-health-care-providers/illumina-cybersecurity-vulnerability-affecting-universal-copy-service-software-may-present-risks* (last accessed on March 19, 2024).
* 10. Final Regulatory Impact Analysis; Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. 2024. Information available at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria*.
11. Grennan, M. and Town, R.J., ''Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices,'' *American Economic Review,* 110(1): 120–161, 2020. Available at: *https://www.aeaweb.org/articles?id=10.1257/aer.20180946*.
12. Carpenter, D., Grimmer, J., and Lomazoff, E., ''Approval Regulation and Endogenous Consumer Confidence: Theory and Analogies to Licensing, Safety, and Financial Regulation,'' *Regulation & Governance,* 4:383–407, 2010. Available at: *https://doi.org/10.1111/j.1748-5991.2010.01091.x*.
13. Alliance for a Stronger FDA, ''The US Food and Drug Administration: A Cornerstone of America's Economic Future.'' Available at: *https://fdaalliance.files.wordpress.com/2009/11/fda_cornerstone_of_american_economy_final.pdf* (last accessed on February 28, 2024).
14. Fleming, T.R., D.L. Demets, and L.M. McShane, ''Discussion: The Role, Position, and Function of the FDA—The Past, Present, and Future,'' *Biostatistics.* 18(3): 417–421, 2017. Available at *https://doi.org/10.1093/biostatistics/kxx023*.
15. Singhal, U., C. Horrow, A. Kesselheim, et al., ''Modernizing Federal Oversight of Laboratory-Developed Tests—Toward Safety, Validity, and Utility,'' *New England Journal of Medicine,* 389:1735–

1737, 2023. Available at *https://www.nejm.org/doi/full/10.1056/NEJMp2307585*.

* 16. Memorandum to File from Brittany Schuck, Ph.D., Deputy Office Director, Office of In Vitro Diagnostics (OHT7), Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration, RE: Examples of In Vitro Diagnostic Products (IVDs) Offered as Laboratory Developed Tests (LDTs) that Raise Public Health Concerns (September 22, 2023).
* 17. FDA, ''Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products,'' January 2017. Available at *https://www.regulations.gov/document/FDA-2016-N-1149-0040*.
* 18. Memorandum to File from Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration, RE: Summary of 2020 Assessment of the First 125 EUA Requests from Laboratories for Molecular Diagnostic Tests for SARS-CoV–2 (September 22, 2023).
* 19. Comment to the Docket from New York State Department of Health Re: Docket No. FDA–2023–N–2177 (November 22, 2023). Available at *https://www.regulations.gov/document/FDA-2023-N-2177-4963*.
20. Pfeifer, J.D., R. Loberg, C. Lofton-Day, et al., ''Reference Samples to Compare Next-Generation Sequencing Test Performance for Oncology Therapeutics and Diagnostics,'' *American Journal of Clinical Pathology,* 157(4):628–638, 2022. Available at *https://doi.org/10.1093/ajcp/aqab164*.
21. The Pew Charitable Trusts, ''Fact Sheet: Americans Support Increased FDA Oversight to Ensure Accuracy of Diagnostic Tests,'' May 5, 2022. Available at *https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2022/05/americans-support-increased-fda-oversight-to-ensure-accuracy-of-diagnostic-tests*.
22. AdvaMed, ''Press Release: In Congressional Testimony, AdvaMed Urges Passage of Diagnostic Regulatory Reform,'' March 21, 2024. Available at *https://www.advamed.org/industry-updates/news/in-congressional-testimony-advamed-urges-passage-of-diagnostic-regulatory-reform/* (last accessed March 25, 2024).
23. Kang, S., J. Woo, N. Kim, et al., ''Necessity of Strengthening the Current Clinical Regulatory for Companion Diagnostics: An Institutional Comparison of the FDA, EMA, and MFDS,'' *Molecular Therapy: Methods & Clinical Development,* 30: 447–458, 2023. Available at *https://doi.org/10.1016/j.omtm.2023.08.008*.
* 24. New York State Department of Health Wadsworth Center, Clinical Evaluation Program ''Test Approval.'' Available at *https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval* (last accessed on January 26, 2024).
* 25. FDA, ''FDA News Release: FDA Issues Warning Letter to Genomics Lab for Illegally Marketing Genetic Test That Claims to Predict Patients' Responses to Specific Medications,'' April 4, 2019. Available at *https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letter-genomics-lab-illegally-marketing-genetic-test-claims-predict-patients*.
* 26. CMS, ''Laboratory Developed Tests (LDTs) Frequently Asked Questions,'' October 22, 2013. Available at *https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf*.
* 27. FDA, ''Monkeypox (mpox) and Medical Devices.'' Available at *https://www.fda.gov/medical-devices/emergency-situations-medical-devices/monkeypox-mpox-and-medical-devices* (last accessed on January 30, 2024).
* 28. Warning Letter to Magellan Diagnostics, Inc., October 23, 2017. Available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/magellan-diagnostics-inc-532743-10232017* (last accessed March 19, 2024).
* 29. Warning Letter to Atossa Genetics, February 20, 2013. Available at *https://web.archive.org/web/20140103034305/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm341601.htm* (last accessed March 19, 2024).
* 30. FDA, ''Compliance Program Guidance Manual 7341.002; Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' Available at *https://www.fda.gov/media/73949/download*.
* 31. FDA, ''Compliance Program Guidance Manual 7342.002; Inspection of Source Plasma Establishments, Brokers, Testing Laboratories, and Contractors,'' January 31, 2019. Available at *https://www.fda.gov/media/80179/download*.
* 32. FDA, ''Policy for Monkeypox Tests to Address the Public Health Emergency; Guidance for Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff,'' September 7, 2022. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-monkeypox-tests-address-public-health-emergency*.
* 33. FDA, ''Policy for Coronavirus Disease-2019 Tests (Revised); Guidance for Developers and Food and Drug Administration Staff,'' January 12, 2023. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised*.
* 34. Government Accountability Office, ''COVID–19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed,'' May 2022. Available at *https://www.gao.gov/assets/gao-22-104266.pdf*.
* 35. ''It Has Come to Our Attention'' Letter to Texas Children's Hospital and Houston Methodist Hospital re: Zika Direct Test (March 4, 2016). Available at *https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/96740/download*.
* 36. It Has Come to Our Attention'' Letter to MD Biosciences re: the Zika Virus RNA by RT–PCR Assay (March 4, 2016). Available at *https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/96214/download*.
* 37. ''It Has Come to Our Attention'' Letter to First Diagnostic Corp. re: ATFirst One Step Zika Antibody Test (March 10, 2016). Available at *https://public4.pagefreezer.com/content/FDA/04-10-2022T10:19/https://www.fda.gov/media/96739/download*.
* 38. FDA, ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs); Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories,'' October 3, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/framework-regulatory-oversight-laboratory-developed-tests-ldts*.
* 39. Untitled Letter to Navigenics Corp re: the Navigenics Health Compass. (June 10, 2010). Available at *https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/79235/download*.
* 40. FDA, ''Direct-to-Consumer Tests.'' Available at *https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests* (last accessed on January 30, 2024).
* 41. Untitled Letter to Interleukin Genetics, Inc. (November 4, 2015). Available at *https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/94365/download*.
* 42. Untitled Letter to Pathway Genomics, Inc. (September 21, 2015). Available at *https://public4.pagefreezer.com/browse/FDA/30-12-2022T07:46/https://www.fda.gov/media/93493/download*.
* 43. Transcript of the Molecular and Clinical Genetics Panel meeting, March 8, 2011. Available at *https://wayback.archive-it.org/7993/20170404140959/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249857.pdf*.
* 44. Transcript of the Molecular and Clinical Genetics Panel meeting, March 9, 2011. Available at *https://wayback.archive-it.org/7993/20170404141000/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249858.pdf*.
* 45. Health Resources & Services Administration (HRSA) Blood Stem Cell, ''Joining the Registry.'' Available at *https://bloodstemcell.hrsa.gov/donor-information/donate-bone-marrow/joining-registry* (last accessed on March 27, 2024).

46. NMDP, ''NMDP Standards.'' Available at *https://bethematch.org/about-us/global-transplant-network/standards/* (last accessed on March 27, 2024).
47. NMDP Policy for HLA Confirmatory Typing Requirements for Unrelated Adult Donors and HLA Typing Requirement for Patients, National Marrow Donor Program, Number P00079, Revision 2. Available at *https://bioinformatics.bethematchclinical.org/WorkArea/DownloadAsset.aspx?id=21474837962*.
48. Health Resources and Services Administration, ''Organ Procurement and Transplantation Network, Policies.'' Available at *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf*.
49. National Marrow Donor Program HLA Typing Discrepancy Review Process (Updated June 2008). Available at *https://bioinformatics.bethematchclinical.org/WorkArea/DownloadAsset.aspx?id=6635*.
50. OPTN Membership Application for Histocompatibility Laboratories. Available at *https://unos.org/wp-content/uploads/FORM-OPTN-Membership-App-HistoLab.pdf*.
51. U.S. Transplant Center Participation Criteria (AOO228), 2023. Available at *https://bethematch.org/workarea/downloadasset.aspx?id=10143*.
52. U.S. Donor Center Participation Criteria (AOO371), 2022. Available at *https://bethematch.org/WorkArea/DownloadAsset.aspx?id=10146*.
* 53. New York State Department of Health Wadsworth Center, Clinical Evaluation Program Tiered Evaluation of Laboratory Developed Tests Policy. Available at *https://www.wadsworth.org/sites/default/files/WebDoc/Tiered-LDT_Review_Policy_Nov%202023.pdf* (last accessed on January 26, 2024).
* 54. New York State Department of Health Wadsworth Center, Clinical Evaluation Program General Checklist for Full Method Validation Submission. Available at *https://www.wadsworth.org/sites/default/files/WebDoc/General_Assay_Checklist_0.pdf* (last accessed on January 26, 2024).
* 55. New York State Department of Health Wadsworth Center, Clinical Evaluation Program Risk Attestation Form for Laboratory Developed Tests. Available at *https://www.wadsworth.org/sites/default/files/WebDoc/Risk_Attestation_Form_Jan%202024_0.pdf* (last accessed January 26, 2024).
* 56. FDA, ''510(k) Third Party Review Program; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations,'' March 12, 2020. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program*.
* 57. FDA, ''Discussion Paper on Laboratory Developed Tests (LDTs),'' January 13, 2017. Available at *https://www.fda.gov/media/102367/download*.
58. Lundberg, G.D., ''Acting on Significant Laboratory Results,'' *JAMA* 1;245(17): 1762–1763, 1981. Available at *https://pubmed.ncbi.nlm.nih.gov/7218491/*.
59. Shaw, S.T., Jr., and J.M. Miller, ''Cost-Containment and the Use of Reference Laboratories,'' *Clinics in Laboratory Medicine,* 5(4):725–752, 1985. Available at *https://pubmed.ncbi.nlm.nih.gov/4085191/*.
* 60. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis. 2023. Information available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.
* 61. FDA, ''Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff,'' October 25, 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device*.
* 62. FDA, ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers; Guidance for Industry,'' June 2018. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-product-communications-are-consistent-fda-required-labeling-questions-and-answers*.
63. International Society of Blood Transfusion, ''Red Cell Immunogenetics and Blood Group Terminology.'' Available at *https://www.isbtweb.org/isbt-working-parties/rcibgt.html#:~:text=The%20International%20Society%20of%20Blood%20Transfusion%20(ISBT)%20Working%20Party%20for,cell%20antigens%20(November%202023)*. (last accessed March 19, 2024).
* 64. FDA, ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry,'' December 2018. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-red-blood-cell-units-historical-antigen-typing-results*.
* 65. FDA, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff,'' June 2, 2023. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program*.
* 66. FDA, ''CDRH Announces Intent to Initiate the Reclassification Process for Most High Risk IVDs,'' January 31, 2024. Available at *https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-intent-initiate-reclassification-process-most-high-risk-ivds*.
* 67. FDA, ''510(k) Third Party Review Program.'' Available at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/510k-third-party-review-program* (last accessed on January 29, 2024).
68. Rychert, J., R.L. Schmidt, and J.R. Genzen, ''Laboratory-Developed Tests Account for a Small Minority of Tests Ordered in an Academic Hospital System,'' *American Journal of Clinical Pathology,* 160(3):297–302, 2023. Available at *https://pubmed.ncbi.nlm.nih.gov/37265129/*.
* 69. FDA, ''Public Workshop—Cardiac Troponin Assays, November 28, 2017.'' Available at *https://wayback.archive-it.org/7993/20201222130122/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-cardiac-troponin-assays-november-28-2017* (last accessed on January 28, 2024).
70. Morgan, D., ''What the Tests Don't Show: Doctors Are Surprisingly Bad at Reading Lab Results. It's Putting Us All at Risk,'' *Washington Post,* October 5, 2018. Available at *https://www.washingtonpost.com/news/posteverything/wp/2018/10/05/feature/doctors-are-surprisingly-bad-at-reading-lab-results-its-putting-us-all-at-risk/*.
* 71. CMS, ''FDA and CMS Statement: Americans Deserve Accurate and Reliable Diagnostic Tests, Wherever They Are Made,'' January 18, 2024. Available at *https://www.cms.gov/newsroom/press-releases/fda-and-cms-statement-americans-deserve-accurate-and-reliable-diagnostic-tests-wherever-they-are*.
* 72. FDA, ''CDRH Learn.'' Available at *https://www.fda.gov/training-and-continuing-education/cdrh-learn* (last accessed on January 26, 2024).
* 73. FDA, ''Quarterly Update on Medical Device Performance Goals MDUFA V CDRH Performance Data—Actions through 30 September 2023,'' November 16, 2023. Available at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports*.
* 74. CDC, ''Clinical Laboratory Improvement Advisory Committee Summary Report,'' April 12–13, 2023. Available at *https://www.cdc.gov/cliac/docs/april-2023/CLIAC_SUMMARY_APR2023_1.pdf*.
* 75. FDA, ''The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and FDA Staff,'' February 5, 2019. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles*.
* 76. FDA Form 483 Issued to Theranos, Inc. Re: FEI Number 3006231732 (September 16, 2015). Available at *https://www.fda.gov/files/about%20fda/published/Theranos--Inc.--Newark--CA-483-Issued-09-16-2015.pdf*.
77. COLA, ''COLA Accreditation.'' Available at *https://www.cola.org/accreditation/* (last accessed on January 26, 2024).
78. College of American Pathologists, ''Laboratory Accreditation: Guide to CAP Accreditation,'' 2018. Available at

https://uatcap.objects.frb.io/documents/2018-guide-to-accreditation.pdf.
79. Association for Molecular Pathology, ''Clinical Practice—Practice Guidelines.'' Available at *https://www.amp.org/clinical-practice/practice-guidelines/* (last accessed on January 26, 2024).
80. Clinical and Laboratory Standards Institute, ''CLSI Standards: Guidelines for Health Care Excellence.'' Available at *https://clsi.org/standards/* (last accessed on January 28, 2024).
81. International Organization for Standardization, ISO Standards Catalogue search page. Available at *https://www.iso.org/standards.html* (last accessed on January 28, 2024).
82. Palmetto GBA, ''MolDx Program (Administered by Palmetto GBA).'' Available at *https://www.palmettogba.com/moldx* (last accessed on January 28, 2024).
* 83. CDC, ''NSQAP: Newborn Screening Quality Assurance Program,'' March 9, 2023. Available at *https://www.cdc.gov/labstandards/nsqap.html.*
* 84. Washington State Department of Health, ''Medical Test Sites (MTS) State Authority and Responsibilities.'' Available at *https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/medical-test-site-program/state-authority-and-responsibilities* (last accessed on January 28, 2024).
* 85. State of New Jersey, Department of Health, ''Clinical Laboratory Licensing Program.'' Available at *https://www.nj.gov/health/phel/clinical-lab-imp-services/state_licensing/* (last accessed March 27, 2024).
86. Richards, C.S., G.E. Palomaki, F.L. Lacbawan, et al., ''Three-Year Experience of a CAP/ACMG Methods-Based External Proficiency Testing Program for Laboratories Offering DNA Sequencing for Rare Inherited Disorders,'' *Genetics in Medicine,* 16:25–32, 2014. Available at *https://www.nature.com/articles/gim201365.*
87. Harrison, B. and B. Charrow, ''The FDA's Lab-Test Power Grab,'' *The Wall Street Journal,* December 15, 2022. Available at *https://www.wsj.com/articles/the-fdas-lab-test-power-grab-verifying-accurate-leading-edge-ivct-development-act-valid-covid-pandemic-11671145483.*
88. Al-Faruque, F., ''FDA Won't Extend LDT Rule Comment Period,'' *Regulatory Focus,* October 31, 2023. Available at *https://www.raps.org/news-and-articles/news-articles/2023/10/fda-won%E2%80%99t-extend-ldt-rule-comment-period.*
89. Kuzma, J., ''Implementing Responsible Research and Innovation: A Case Study of U.S. Biotechnology Oversight,'' *Global Public Policy and Governance,* 2:306–325, 2022. Available at *https://doi.org/10.1007/s43508-022-00046-x.*
90. Wittrock, C., E.-M., Forsberg, A. Pols, et al., ''Implementing Responsible Research and Innovation: Organisational and National Conditions,'' *Springer Briefs in Ethics,* 2021. Available at *https://rring.eu/wp-content/uploads/2020/10/2021_Book_Implementing ResponsibleResearc.pdf.*
91. Quy, P.N., K. Fukuyama, M. Kanai, et al., ''Inter-Assay Variability of Next-Generation Sequencing-Based Gene Panels,'' *BMC Medical Genomics,* 15:86, 2022. Available at *https://doi.org/10.1186/s12920-022-01230-y.*
92. Vega, D.M., L.M. Yee, L.M. McShane, et al., ''Aligning Tumor Mutational Burden (TMB) Quantification Across Diagnostic Platforms: Phase II of the Friends of Cancer Research TMB Harmonization Project,'' *Annals of Oncology,* 32(12):1626–1636, 2021. Available at *https://doi.org/10.1016/j.annonc.2021.09.016.*
93. Offit, K., C.M. Sharkey, D. Green, et al., ''Regulation of Laboratory-Developed Tests in Preventive Oncology: Emerging Needs and Opportunities,'' *Journal of Clinical Oncology,* 41(1):11–21, 2022. Available at *https://doi.org/10.1200/jco.22.00995.*
94. Coffey, D., ''Blood Test Positive for Cancer, but Is There Really a Tumor?'' *Medscape,* February 17, 2023. Available at *https://www.medscape.com/viewarticle/988431.*
95. Manrai, A.K., B.H. Funke, H.L. Rehm, et al., ''Genetic Misdiagnoses and the Potential for Health Disparities,'' *New England Journal of Medicine,* 375(7):655–665, 2016. Available at *https://doi.org/10.1056/NEJMsa1507092.*
96. Kliff, S. and A. Bhatia, ''When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong,'' *New York Times,* January 1, 2022. Available at *https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html.*
* 97. FDA, ''Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication,'' April 19, 2022. Available at *https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication.*
98. Benayed, R., M. Offin, K. Mullaney, et al., ''High Yield of RNA Sequencing for Targetable Kinase Fusions in Lung Adenocarcinomas with no Mitogenic Driver Alteration Detected by DNA Sequencing and Low Tumor Mutation Burden,'' *Clinical Cancer Research,* 25(15):4712–4722, 2019. Available at *https://pubmed.ncbi.nlm.nih.gov/31028088/.*
99. Keegan, A., J.A. Bridge, N.I. Lindeman, et al., ''Proficiency Testing of Standardized Samples Shows High Interlaboratory Agreement for Clinical Next-Generation Sequencing-Based Hematologic Malignancy Assays with Survey Material-Specific Differences in Variant Frequencies,'' *Archives of Pathology & Laboratory Medicine,* 144(8), 959–966, 2020. Available at *https://pubmed.ncbi.nlm.nih.gov/31986076/.*
100. Kim, A.S., A.N. Bartley, J.A. Bridge, et al., ''Comparison of Laboratory-Developed Tests and FDA-Approved Assays for BRAF, EGFR, and KRAS Testing,'' *JAMA Oncology,* 4(6), 838–841, 2018. Available at *https://pubmed.ncbi.nlm.nih.gov/29242895/.*
101. Merker, J.D., K. Devereaux, A.J. Iafrate, et al., ''Proficiency Testing of Standardized Samples Shows Very High Interlaboratory Agreement for Clinical Next-Generation Sequencing-Based Oncology Assays,'' *Archives of Pathology & Laboratory Medicine,* 143(4):463–471, 2019. Available at *https://pubmed.ncbi.nlm.nih.gov/30376374/.*
102. Moncur, J.T., A.N. Bartley, J.A. Bridge, et al., ''Performance Comparison of Different Analytic Methods in Proficiency Testing for Mutations in the BRAF, EGFR, and KRAS Genes: A Study of the College of American Pathologists Molecular Oncology Committee,'' *Archives of Pathology & Laboratory Medicine,* 143(10), 1203–1211, 2019. Available at *https://pubmed.ncbi.nlm.nih.gov/30969158/.*
103. Zehir, A., V. Nardi, E.Q. Konnick, et al., ''SPOT/Dx Pilot Reanalysis and College of American Pathologists Proficiency Testing for KRAS and NRAS Demonstrate Excellent Laboratory Performance,'' *Archives of Pathology & Laboratory Medicine,* 148(2):139–148, 2023. Available at *https://pubmed.ncbi.nlm.nih.gov/37776255/.*
104. Zhang, B.M., A. Keegan, P. Li, et al., ''An Overview of Characteristics of Clinical Next-Generation Sequencing-Based Testing for Hematologic Malignancies,'' *Archives of Pathology & Laboratory Medicine,* 145(9), 1110–1116, 2021. Available at *https://pubmed.ncbi.nlm.nih.gov/33450747/.*
105. Clark, A., ''For a Host of Vital Lab Tests, No FDA Oversight Exists,'' *Undark Magazine,* February 1, 2023. Available at *https://undark.org/2023/02/01/for-a-host-of-vital-lab-tests-no-fda-oversight-exists/.*
106. Clark, A., A. Gallardo, J. Deam, et al., ''They Trusted Their Prenatal Test. They Didn't Know the Industry Is an Unregulated 'Wild West,''' *ProPublica,* December 6, 2022. Available at *https://www.propublica.org/article/how-prenatal-screenings-have-escaped-regulation.*
107. Robinson, S.A., A.R. Carter, and D.A. Brindley, ''The Changing Regulatory Landscape for Laboratory Developed Tests,'' *Regulatory Focus,* August 30, 2021. Available at *https://www.raps.org/news-and-articles/news-articles/2021/8/the-changing-regulatory-landscape-for-laboratory-d.*
108. Adashi, E.Y. and I.G. Cohen, ''SARS–CoV–2 Laboratory-Developed Tests: Integrity Restored,'' *JAMA,* 327(13):1229–1230, 2022. Available at *https://doi.org/10.1001/jama.2022.3382.*
109. Rogus, S. and P. Lurie, ''FDA Is Letting Harmful Lab-Developed Tests Fall Through the Cracks,'' *MedPage Today,* December 9, 2022. Available at *https://www.medpagetoday.com/opinion/second-opinions/102161.*
110. Damon, A., ''The COVID Testing Company That Missed 96% of Cases,'' *ProPublica,* May 16, 2022. Available at *https://www.propublica.org/article/covid-testing-nevada-false-negatives-northshore.*
* 111. FDA, ''Draft CPG: Commercialization of Unapproved In Vitro Diagnostic

Devices Labeled for Research and Investigation,'' August 3, 1992. Available at *https://www.thefdalawblog.com/wp-content/uploads/2022/08/RUO-CPG-1992.pdf*.

* 112. FDA, ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs); Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories,'' October 3, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-notification-and-medical-device-reporting-laboratory-developed-tests-ldts*.
* 113. FDA, ''Laboratory Developed Tests.'' Available at *https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests*.
* 114. Letter from FDA/CDRH to Hyman Phelps & McNamara P.C., Docket No. FDA–1992–P–0047 (September 2, 1998). Available at *https://www.regulations.gov/document/FDA-1992-P-0047-0001*.
* 115. Letter from Leslie Kux, Assistant Commissioner for Policy, FDA, to Alan Mertz, American Clinical Laboratory Association, Docket No. FDA–2013–P–0667 (July 31, 2014). Available at *https://www.regulations.gov/document/FDA-2013-P-0667-0008*.
* 116. Framework for Regulatory Oversight of Laboratory Developed Tests; Public Workshop; Request for Comments, 79 FR 69860 (2014). Available at *https://www.federalregister.gov/documents/2014/11/24/2014-27713/framework-for-regulatory-oversight-of-laboratory-developed-tests-public-workshop-request-for*.
* 117. FDA, ''In Vitro Diagnostic Multivariate Index Assays; Draft Guidance for Industry, Clinical Laboratories, and FDA Staff,'' July 26, 2007. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/in-vitro-diagnostic-multivariate-index-assays-draft-guidance-industry-clinical-laboratories-and-fda*.
* 118. Warning Letter to Inova Genomics Laboratory re: MediMap Tests (April 4, 2019). Available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/inova-genomics-laboratory-577422-04042019*.
* 119. FDA, ''The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies,'' November 16, 2015. Available at *http://web.archive.org/web/20151122235012/https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf*.
120. Shuren, J. and T. Stenzel, ''Covid-19 Molecular Diagnostic Testing—Lessons Learned,'' *New England Journal of Medicine,* 383(17): e97, 2020. Available at *https://doi.org/10.1056/nejmp2023830*.
* 121. FDA, ''The FDA Warns Against the Use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications: FDA Safety Communication,'' October 31, 2018. Available at *http://web.archive.org/web/20190909184258/https://www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-many-genetic-tests-unapproved-claims-predict-patient-response-specific*.
122. Greely, H.T., ''The Future of DTC Genomics and the Law,'' *Journal of Law, Medicine & Ethics,* 48(1):151–160, 2020. Available at *https://pubmed.ncbi.nlm.nih.gov/32342782/*.
123. Eisenberg, R.S., ''Opting into Device Regulation in the Face of Uncertain Patentability,'' *Marquette Intellectual Property Law Review,* 23(1):10, 2019. Available at *https://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1335&context=iplr*.
124. Paradise, J., ''Cultivating Innovation in Precision Medicine Through Regulatory Flexibility at the FDA,'' *New York University Journal of Law & Liberty,* 11(2):672, 707, 2017. Available at *https://www.nyujll.com/volume-11/blog-post-title-one-m44st-6fn5r-xg22c-8k4cd-s9kwt*.
* 125. Memorandum to File from Stephen Cha, Counselor to the Secretary, HHS, RE: Withdrawal of August 2020 Policy Regarding Laboratory-Developed Tests (November 14, 2021).
126. Merriam-Webster, Contrivance. Available at *https://www.merriam-webster.com/dictionary/contrivance* (last accessed on January 31, 2024).
127. Oxford English Dictionary, Contrivance. Available at *https://www.oed.com/dictionary/contrivance_n?tl=true* (last accessed on March 21, 2024).
128. Merriam-Webster, Apparatus. Available at *https://www.merriam-webster.com/dictionary/apparatus* (last accessed on January 31, 2024).
129. Oxford English Dictionary, Apparatus. Available at *https://www.oed.com/search/advanced/Meanings?textTermText0=apparatus&textTermOpt0=WordPhrase* (last accessed on February 1, 2024).
130. Cambridge Dictionary, Apparatus. Available at *https://dictionary.cambridge.org/us/dictionary/english/apparatus* (last accessed on March 21, 2024).
131. Merriam-Webster, Article. Available at *https://www.merriam-webster.com/dictionary/article* (last accessed on January 31, 2024).
132. Merriam-Webster, Product. Available at *https://www.merriam-webster.com/dictionary/product* (last accessed on March 25, 2024).
* 133. FDA, ''Compliance Policy Guide (CPG) Sec. 300.600 Commercial Distribution with Regard to Premarket Notification (Section 510(k)),'' September 1987. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300600-commercial-distribution-regard-premarket-notification-section-510k*.
134. Merriam-Webster, Commercial. Available at *https://www.merriam-webster.com/dictionary/commercial* (last accessed on January 31, 2024).
135. Cambridge Dictionary, Distribute. Available at *https://dictionary.cambridge.org/us/dictionary/english/distribute* (last accessed on March 21, 2024).
136. Merriam-Webster, Distribution. Available at *https://www.merriam-webster.com/dictionary/distribution* (last accessed on January 31, 2024).
137. Merriam-Webster, Commodity. Available at *https://www.merriam-webster.com/dictionary/commodity* (last accessed on March 25, 2024).
138. Merriam-Webster, Include. Available at *https://www.merriam-webster.com/dictionary/include* (last accessed on January 31, 2024).
139. Merriam-Webster, Distribute. Available at *https://www.merriam-webster.com/dictionary/distribute* (last accessed on January 31, 2024).
* 140. FDA, ''Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff,'' February 3, 2016. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices*.
141. Fortune, ''Fortune 500—The Largest Companies in the U.S. by Revenue,'' 2023. Available at *https://fortune.com/ranking/fortune500/*.
142. Noah, L., ''Ambivalent Commitments to Federalism in Controlling the Practice of Medicine,'' *University of Kansas Law Review,* 53(1):149–194, 2004. Available at *https://heinonline.org/HOL/P?h=hein.journals/ukalr53&i=161*.
* 143. CMS, ''Medicare State Operations Manual 100–07; Appendix C—Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services,'' October 3, 2014. Available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms1201984* (last accessed on January 31, 2024).
* 144. FDA, PMA Approval, FoundationOne® Liquid CDx (F1 Liquid CDx), P190032, Decision Date August 26, 2020. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190032A.pdf*.
* 145. FDA, De Novo Decision Summary, MSK–IMPACT (Integrated Mutation Profiling Of Actionable Cancer Targets): A Hybridization-Capture Based Next Generation Sequencing Assay, DEN 170058, Decision Date November 15, 2017. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN170058*.
* 146. FDA, De Novo Decision Summary, Adaptive Biotechnologies ClonoSEQ Assay, DEN170080, Decision Date September 28, 2018. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN170080*.
* 147. FDA, Premarket Approval, AAV5 DetectCDx, P190033, Approval Date June 29, 2023. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190033*.

* 148. FDA, Humanitarian Device Exemption, PDGFRB FISH assay, H140005, Approval Date December 18, 2015. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=375585*.
* 149. FDA, Premarket Approval, Foundation Medicine, Inc. FoundationOne CDx, P170019, Approval Date November 30, 2017. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p170019*.
* 150. FDA, PMA Approval, xT CDx, P210011, Approval Date June 7, 2023. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210011S001*.
* 151. FDA, 510(k) Premarket Notification, NYU Langone Genome PACT (Genome Profiling of Actionable Cancer Targets), K202304, Decision Date July 14, 2021. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202304*.
* 152. FDA, De Novo Decision Summary, PMC/PCSK1//LEPR CDx panel, DEN200059, Decision Date January 21, 2022. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200059*.
* 153. FDA, 510K Premarket Notification, Laboratory Corporation of America Holdings, K181373, Extended Lipid Panel Assay, Decision Date October 18, 2018. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181373.pdf*.
* 154. FDA, Emergency Use Authorization, UMass Molecular Virology Laboratory 2019-nCoV rRT–PCR Dx Panel, Decision Date October 1, 2020. Available at *https://www.fda.gov/media/142689/download*.
* 155. FDA, Emergency Use Authorization, Stanford Health Care Clinical Virology Laboratory SARS-CoV–2 RT–PCR Assay, Decision Date November 24, 2020. Available at *https://www.fda.gov/media/136817/download*.
* 156. FDA, ''FDA at a Glance,'' January 2024. Available at *https://www.fda.gov/media/175664/download*.
157. Myriad Genetics, ''Myriad Receives FDA Approval of BRACAnalysis CDx as Companion Diagnostic for Lynparza(TM) (olaparib) in Ovarian Cancer Patients,'' December 19, 2014. Available at *https://investor.myriad.com/news-releases/news-release-detail/11736/*.
* 158. FDA, ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers; Draft Guidance for Industry,'' October 2023. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses*.
* 159. FDA, ''Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices; Draft Guidance,'' December 2011. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/responding-unsolicited-requests-label-information-about-prescription-drugs-and-medical-devices*.
160. Kapczynski, A., ''Free Speech and Pharmaceutical Regulation—Fishy Business,'' *JAMA Internal Medicine,* 176(3):295–296, 2016. Available at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2484907*.
* 161. FDA Response to Request for Comment Period Extension, Docket No. FDA–2023–N–2177, November 2, 2023. Available at *https://www.regulations.gov/document/FDA-2023-N-2177-1149*.
* 162. FDA, ''Webinar—Proposed Rule: Medical Devices; Laboratory Developed Tests,'' October 31, 2023. Available at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-proposed-rule-medical-devices-laboratory-developed-tests-10312023*.
* 163. Office of the Federal Register, ''A Guide to the Rulemaking Process.'' Available at *https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf* (last accessed January 31, 2024).
* 164. FDA, ''FDA Proposes Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests,'' September 29, 2023. Available at *https://www.fda.gov/news-events/press-announcements/fda-proposes-rule-aimed-helping-ensure-safety-and-effectiveness-laboratory-developed-tests*.
*165. FDA, ''Premarket Approval (PMA) Database.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm* (last accessed on January 29, 2024).
*166. FDA, ''Device Classification Under Section 513(f)(2)(De Novo) Database.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm* (last accessed on January 29, 2024).
*167. FDA, ''Establishment Registration & Device Listing Database.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm* (last accessed on March 25, 2024).
*168. FDA, ''Custom Device Exemption; Guidance for Industry and Food and Drug Administration Staff,'' September 24, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption*.
*169. FDA, ''Expanded Access for Medical Devices.'' Available at *https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices* (last accessed on January 29, 2024).
*170. Comment to the Docket from Association of Pathology Chairs Re: Docket No. FDA–2023–N–2177 (December 1, 2023). Available at *https://www.regulations.gov/comment/FDA-2023-N-2177-6057*.
*1171. Fargen, K.M, D. Frei, D. Fiorella, et al., ''The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?'' *Journal of Neurointerventional Surgery,* 5(4):269–275, 2013. Available at *https://pubmed.ncbi.nlm.nih.gov/22764203/*.
*172. FDA, ''Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff,'' November 8, 2016. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-manufacturers*.
*173. FDA, ''Medical Device Reporting (MDR): How to Report Medical Device Problems.'' Available at *https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems* (last accessed on January 29, 2024).
*174. FDA, ''Recalls, Corrections and Removals (Devices),'' Available at *https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#:~:text=Under%20 21%20CFR%20806% 2C%20Medical,the%20 Act%20caused%20by%20the* (last accessed on February 27, 2024).
*175. FDA, ''Device Registration and Listing.'' Available at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing* (last accessed on January 29, 2024).
*176. FDA, ''Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only; Guidance for Industry and FDA Staff,'' November 25, 2013. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/distribution-in-vitro-diagnostic-products-labeled-research-use-only-or-investigational-use-only*.
*177. FDA, ''In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions; Guidance for Industry and FDA Staff,'' June 25, 2010. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/in-vitro-diagnostic-ivd-device-studies-frequently-asked-questions*.
*178. FDA, ''Investigational IVDs Used in Clinical Investigations of Therapeutic Products; Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards.'' December 18, 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-ivds-used-clinical-investigations-therapeutic-products*.
*179. FDA, ''Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination; Guidance for Industry,'' October, 2019. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-in-vitro-diagnostics-oncology-trials-streamlined-submission-process-study-risk*.

*180. FDA, ''Labeling: Regulatory Requirements for Medical Devices,'' August, 1989. Available at *https://www.fda.gov/media/74034/download*.
*181. CMS, ''List of Non-Waived Testing for Which PT is Required,'' January 19, 2018. Available at *https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/list-of-non-waived-testing-which-pt-is-required.pdf*.
*182. CMS, ''Clinical Laboratory Improvement Amendments (CLIA) Proficiency Testing and PT Referral Do's and Don'ts,'' September 2017. Available at *https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliabrochure8.pdf*.
*183. FDA, ''Medical Device User Fee Amendments (MDUFA).'' Available at *https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa* (last accessed on January 29, 2024).
*184. FDA, ''Contact Us—Division of Industry and Consumer Education (DICE).'' Available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice* (last accessed on January 29, 2024).
*185. FDA, ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process; Guidance for Industry and FDA Staff,'' December 11, 2008. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process*.
*186. FDA, Recognized Consensus Standards: CLSI EP35 standard (1st Edition), ''Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures,'' Date of Entry July 6, 2020. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=41031*.
*187. FDA, ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics; Guidance for Stakeholders and Food and Drug Administration Staff,'' April 13, 2008. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-public-human-genetic-variant-databases-support-clinical-validity-genetic-and-genomic-based-vitro*.
*188. FDA, ''Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff,'' September 28, 2022. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software*.
*189. FDA, ''General Principles of Software Validation; Guidance for Industry and FDA Staff,'' January 11, 2002. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation*.
*190. FDA, ''Content of Premarket Submissions for Device Software Functions; Guidance for Industry and Food and Drug Administration Staff,'' June 14, 2023. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions*.
*191. FDA, De Novo Reclassification Order, Sepsis ImmunoScore, DEN230036, Decision Date May 5, 2023. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf23/DEN230036.pdf*.
*192. FDA, De Novo Decision Summary, Paige Prostate, DEN200080, Decision Date September 21, 2021. Available at *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200080.pdf*.
*193. FDA, PMA Approval, Agilent Resolution ctDx FIRST, P210040, Decision Date December 12, 2022. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210040A.pdf*.
*194. FDA, De Novo Decision Summary, The 23andME Personal Genome Service (PGS) Pharmacogenetic Reports, DEN180028, Decision date October 31, 2018. Available at *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180028.pdf*.
*195. FDA, 510(k) Substantial Equivalence Determination Decision Summary, BD Respiratory Viral Panel (BD RVP) for BD MAX System; BD Respiratory Viral Panel-SCV2 (BD RVP–SCV2) for BD MAX System, K230956, Decision Date July 31, 2023. Available at *https://www.accessdata.fda.gov/cdrh_docs/reviews/K230956.pdf*.
*196. FDA, De Novo Classification Order, KidneyIntelX.dkd, DEN200052, Decision Date June 29, 2023. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200052.pdf*.
*197. FDA, 510(k) Substantial Equivalence Determination Decision Summary, Selux AST System; Model AST Gen 1.0, K211748, Decision Date April 19, 2023. Available at *https://www.accessdata.fda.gov/cdrh_docs/reviews/K211748.pdf*.
*198. FDA, 510(k) Substantial Equivalence Determination Decision Summary, NantHealth Next Generating Sequencing Tumor Profiling Test, K190661, Decision Date November 9, 2019. Available at *https://www.accessdata.fda.gov/cdrh_docs/reviews/K190661.pdf*.
*199. FDA, De Novo Reclassification Order, Helix Laboratory Platform, DEN190035, Decision date December 23, 2020. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190035.pdf*.
*200. FDA, Product Classification Database. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm* (last accessed on January 30, 2024).
*201. FDA, ''Classify Your Medical Device.'' Available at *https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device* (last accessed on January 29, 2024).
*202. FDA, ''Device Master Files.'' Available at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/device-master-files* (last accessed on January 29, 2024).
*203. FDA, ''De Novo Classification Process (Evaluation of Automatic Class III Designation); Guidance for Industry and Food and Drug Administration Staff,'' October 5, 2021. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation*.
*204. FDA, ''Acceptance Review for De Novo Classification Requests; Guidance for Industry and Food and Drug Administration Staff.'' Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests*.
*205. Comment to the Docket from American Society for Microbiology Re: Docket No. FDA–2023–N–2177 (December 4, 2023). Available at *https://www.regulations.gov/comment/FDA-2023-N-2177-6631*.
*206. FDA, ''List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).'' Available at *https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools* (last accessed on January 28, 2024).
207. Tachibana, C., ''What Makes an Innovative Academic Medical Center?,'' UPenn LDI Health Care Access & Coverage Blog Post, March 17, 2023. Available at *https://ldi.upenn.edu/our-work/research-updates/what-makes-an-innovative-academic-medical-center/* (last accessed on March 21, 2024).
208. Silva, P.J., V.M. Schaibley, and K.S. Ramos, ''Academic Medical Centers as Innovation Ecosystems to Address Population—Omics Challenges in Precision Medicine,'' *Journal of Translational Medicine,* 16:28, February 15, 2018. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5815198/*.
209. Harpool, A., ''How Academic Medical Centers Can Innovate During Tough Times,'' *Oliver Wyman Health.* Available at *https://www.oliverwyman.com/our-expertise/perspectives/health/2023/june/how-academic-medical-centers-can-innovate-during-tough-times.html* (last accessed on March 21, 2024).
210. Meer, E., I. Ezzeddine, J. Chao, et al., ''Pursuing Innovation in Academic Medical Centers: Models, Activities, and Influential Factors,'' *Health Care Management Review,* 48:161–174, April-June 2023. Available at *https://pubmed.ncbi.nlm.nih.gov/36728435/*.
*211. FDA, ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff,'' October 25, 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device*.

212. 360Dx, ''Arima Genomics to Offer NGS-Based Gene Fusion Test Through Protean BioDiagnostics CLIA Lab,'' January 31, 2023. Available at *https://www.360dx.com/cancer/arima-genomics-offer-ngs-based-gene-fusion-test-through-protean-biodiagnostics-clia-lab#.Y9pjZ3DMInI*.
213. 360Dx, ''Myriad Genetics, MD Anderson Partner to Study MRD Testing in Renal Cell Carcinoma,'' June 12, 2023. Available at *https://www.360dx.com/cancer/myriad-genetics-md-anderson-partner-study-mrd-testing-renal-cell-carcinoma#.ZIijlu3MJPZ*.
214. Burky A., ''Simple HealthKit Inks Deal with Walmart to Expand Access to At-Home Tests,'' *Fierce Healthcare,* June 12, 2023. Available at *https://www.fiercehealthcare.com/retail/simple-healthkit-inks-deal-walmart-rollback-prices-increase-access-home-test* (last accessed on March 21, 2024).
215. Zhang H., ''Bionano Genomics Keeps Focus on Clinical Applications for Optical Genome Mapping,'' *GenomeWeb,* May 6, 2022. Available at *https://www.genomeweb.com/business-news/bionano-genomics-keeps-focus-clinical-applications-optical-genome-mapping#.Y9wGO3bMJPY* (last accessed on March 21, 2024).
216. Gerhard, G.S., S.G. Fisher, and A.M. Feldman, ''Genetic Testing for Inherited Cardiac Diseases in Underserved Populations of Non-European Ancestry: Double Disparity,'' *JAMA Cardiology,* 3(4):273–274, 2018. Available at *https://jamanetwork.com/journals/jamacardiology/fullarticle/2673291*.
217. Martin, A.R., M. Kanai, Y. Kamatani, et al., ''Clinical Use of Current Polygenic Risk Scores May Exacerbate Health Disparities,'' *Nature Genetics,* 51:584–591, 2019. Available at *https://doi.org/10.1038/s41588-019-0379-x*.
218. Wang, Y., K. Tsuo, M. Kanai, et al., ''Challenges and Opportunities for Developing More Generalizable Polygenic Risk Scores,'' *Annual Review of Biomedical Data Science,* 5:293–320, 2022. Available at *https://doi.org/10.1146%2Fannurev-biodatasci-111721-074830*.
219. Duncan, L., H. Shen, B. Gelaye, et al., ''Analysis of Polygenic Risk Score Usage and Performance in Diverse Human Populations,'' *Nature Communications,* 10(1):3328, 2019. Available at *https://doi.org/10.1038%2Fs41467-019-11112-0*.
220. Hoskins, K.F., O.C. Danciu, N.Y. Ko, et al., ''Association of Race/Ethnicity and the 21-Gene Recurrence Score with Breast Cancer-Specific Mortality Among U.S. Women,'' *JAMA Oncology,* 7(3):370–378, 2021. Available at *https://doi.org/10.1001%2Fjamaoncol.2020.7320*.
*221. FDA, Premarket Approval, OraQuick In-Home HIV Test, BP120001, Approval Date July 3, 2012. Available at *https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/oraquick-home-hiv-test*.
*222. FDA, ''FDA Grants Marketing Authorization of First Test for Chlamydia and Gonorrhea with At-Home Sample Collection.'' Available at *https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-test-chlamydia-and-gonorrhea-home-sample-collection#:~:text=Today%2C%20the%20U.S.%20Food%20and,to%20be%20granted%20marketing%20authorization*. (last accessed on February 27, 2024).
*223. FDA, ''Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)—Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases; Guidance for Stakeholders and Food and Drug Administration Staff,'' April 13, 2018. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-development-and-analytical-validation-next-generation-sequencing-ngs-based*.
*224. FDA, ''510(k) Premarket Notification Database.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm* (last accessed on January 29, 2024).
*225. FDA, ''FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria.'' Available at *https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria* (last accessed on January 28, 2024).
*226. FDA, ''Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling; Guidance for Industry and Food and Drug Administration Staff,'' September 29, 2023. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/antimicrobial-susceptibility-test-ast-system-devices-updating-breakpoints-device-labeling*.
227. Simner, P.J., C.A. Rauch, I.W. Martin, et al., ''Raising the Bar: Improving Antimicrobial Resistance Detection by Clinical Laboratories by Ensuring Use of Current Breakpoints,'' *Open Forum Infectious Diseases,* 9(3), 2022. Available at *https://academic.oup.com/ofid/article/9/3/ofac007/6523695*.
228. ''Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive web page; Reopening of a Public Docket; Request for Comments,'' 83 FR 8883 (2018). Available at *https://www.federalregister.gov/documents/2018/03/01/2018-04175/susceptibility-test-interpretive-criteria-recognized-and-listed-on-the-susceptibility-test*.
*229. FDA, ''Emergency Use Authorization of Medical Products, Guidance for Industry and Other Stakeholders,'' January 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities*.
*230. FDA, 510(k) Premarket Notification, Aptima® Chlamydia trachomatis Assay, K230451, Decision Date November 16, 2023. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230451*.
*231. FDA, 510(k) Premarket Notification, BD Probetec Chlamydia Trachomatis (Ct) Qx Amplified DNA Assay, K140446, Decision Date May 20, 2014. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140446*.
*232. FDA, 510(k) Premarket Notification, Elecsys Syphilis, K211302, Decision Date July 20, 2021. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K211302*.
*233. FDA, 510(k) Premarket Notification, Architect Syphilis TP Reagent, Architect Syphilis Tp Calibrator, Architect Syphilis TP Control, K153730, Decision Date June 15, 2016. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153730*.
*234. FDA, ''CDRH Proposed Guidances for Fiscal Year 2024 (FY2024).'' Available at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024* (last accessed on January 28, 2024).
*235. FDA, ''The Special 510(k) Program; Guidance for Industry and Food and Drug Administration Staff,'' September 13, 2019. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program*.
*236. FDA, ''Real-Time Premarket Approval Application (PMA) Supplements; Guidance for Industry and FDA Staff,'' December 16, 2019. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-time-premarket-approval-application-pma-supplements*.
*237. FDA, ''Database for Reference Grade Microbial Sequences (FDA–ARGOS).'' Available at *https://www.fda.gov/medical-devices/science-and-research-medical-devices/database-reference-grade-microbial-sequences-fda-argos* (last accessed on January 28, 2024).
238. Sichtig, H., T. Minogue, Y. Yan, et al., ''FDA–ARGOS is a Database with Public Quality-Controlled Reference Genomes for Diagnostic Use and Regulatory Science,'' *Nature Communications,* 10: 3313, 2019. Available at *https://www.nature.com/articles/s41467-019-11306-6*.
*239. FDA, ''Expanding Next-Generation Sequencing Tools to Support Pandemic Preparedness and Response.'' Available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/expanding-next-generation-sequencing-tools-support-pandemic-preparedness-and-response* (last accessed on January 28, 2024).
*240. FDA, ''MDUFA Performance Goals and Procedures Fiscal Years 2023 Through 2027.'' Available at *https://www.fda.gov/media/158308/download*.
*241. FDA, ''Training Curriculum for Third-Party Reviewers,'' May 10, 2022.

Available at *https://www.fda.gov/medical-devices/510k-third-party-review-program/training-curriculum-third-party-reviewers* (last accessed March 19, 2024).

*242. FDA, ''Current List of FDA-Recognized 510(k) Third Party Review Organizations.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm* (last accessed on January 29, 2024).

*243. FDA, ''510(k) Third Party Performance Metrics and Accreditation Status.'' Available at *https://www.fda.gov/about-fda/cdrh-transparency/510k-third-party-performance-metrics-and-accreditation-status* (last accessed on March 27, 2024).

*244. FDA, ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff,'' December 16, 2019. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic*.

*245. FDA, ''CDRH Learn; CDRH Industry Basics Workshop: 513(g) Requests for Information and Custom Device Exemption,'' November 5, 2019. Available at *https://fda.yorkcast.com/mediasite/Play/01b9a71491b54a2c9603f01443a477d61d* (last accessed on January 29, 2024).

*246. FDA, ''Premarket Submissions: Selecting and Preparing the Correct Submission.'' Available at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/premarket-submissions-selecting-and-preparing-correct-submission* (last accessed February 27, 2024).

*247. FDA, ''Humanitarian Device Exemption (HDE) Database.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm* (last accessed on January 29, 2024).

*248. FDA, ''In Vitro Diagnostics EUAs.'' Available at *https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas* (last accessed on January 29, 2024).

*249. FDA, ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff,'' July 28, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k*.

*250. FDA, ''Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Guidance for Industry and FDA Staff,'' March 13, 2007. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-guidance-reporting-results-studies-evaluating-diagnostic-tests-guidance-industry-and-fda*.

*251. FDA, ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices; Guidance for Industry and Food and Drug Administration Staff,'' August 31, 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices*.

*252. FDA, ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Guidance for Industry and Food and Drug Administration Staff,'' September 15, 2017. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-performance-characteristics-in-vitro-diagnostic-devices-detection-or-detection-and-0*.

*253. FDA, Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff,'' August 27, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/highly-multiplexed-microbiologicalmedical-countermeasure-in-vitro-nucleic-acid-based-diagnostic-devices*.

*254. FDA, ''Recognized Consensus Standards: Medical Devices, Specialty Task Group Area: In Vitro Diagnostics Clinical Laboratory Standards Institute.'' Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=101&sortcolumn=pdd&productcode+&category=InVitro&title=&supportingdocsyn=off&ascapilotyn=off&organization=25&referencenumber=&regulationnumber=&recognitionnumber=&effectivedatefrom=&effectivedateto=&pagenum=100* (last accessed on January 29, 2024).

*255. FDA, ''FDA's Risk-Based Approach to Inspections,'' January 17. 2024. Available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/fdas-risk-based-approach-inspections* (last accessed March 19, 2024).

*256. FDA, ''Roster of the Clinical Chemistry and Clinical Toxicology Devices Panel,'' March 5, 2024. Available at *https://www.fda.gov/advisory-committees/clinical-chemistry-and-clinical-toxicology-devices-panel/roster-clinical-chemistry-and-clinical-toxicology-devices-panel* (last accessed on March 21, 2024).

*257. FDA, ''Hematology and Pathology Devices Panel,'' November 18, 2021. Available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/hematology-and-pathology-devices-panel* (last accessed on March 21, 2024).

*258. FDA, ''Immunology Devices Panel.'' Available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/immunology-devices-panel* (last accessed on March 21, 2024).

*259. FDA, ''Microbiology Devices Panel.'' Available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/microbiology-devices-panel* (last accessed on March 21, 2024).

*260. FDA, ''Molecular and Clinical Genetics Panel.'' Available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/molecular-and-clinical-genetics-panel* (last accessed on March 21, 2024).

*261. FDA, ''September 7–8, 2023: Microbiology Devices Panel of the Medical Devices Advisory Committee Meeting Announcement.'' Available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar/september-7-8-2023-microbiology-devices-panel-medical-devices-advisory-committee-meeting* (last accessed on March 21, 2024).

*262. FDA, ''November 29, 2023: Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee Meeting Announcement.'' Available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-29-2023-molecular-and-clinical-genetics-panel-medical-devices-advisory-committee-meeting* (last accessed on March 21, 2024).

*263. FDA, ''Network of Experts Program: Connecting the FDA with External Expertise.'' Available at *https://www.fda.gov/about-fda/center-devices-and-radiological-health/network-experts-program-connecting-fda-external-expertise* (last accessed on March 21, 2024).

*264. FDA, ''Oncology Drug Products Used with Certain In Vitro Diagnostics Pilot Program.'' Available at *https://www.fda.gov/medical-devices/in-vitro-diagnostics/oncology-drug-products-used-certain-in-vitro-diagnostics-pilot-program* (last accessed on January 30, 2024).

*265. FDA, ''Part 11, Electronic Records; Electronic Signatures—Scope and Application; Guidance for Industry,'' September 2003. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application*.

List of Subjects in 21 CFR Part 809

Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 809 is amended as follows:

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

■ 1. The authority citation for part 809 is revised to read as follows:

Authority: 21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, 381, and 42 U.S.C. 262.

■ 2. In § 809.3, revise the last sentence of paragraph (a) to read as follows:

§ 809.3 Definitions.

(a) * * * These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory.

* * * * *

Dated: April 22, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–08935 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 89 Monday,

No. 88 May 6, 2024

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 112

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2021–N–0471]

RIN 0910–AI49

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is issuing a final rule to amend the agricultural water provisions of the produce safety regulation. This rule replaces the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with a regulatory approach that incorporates recent science and Food and Drug Administration outbreak investigation findings to achieve improved public health protections as compared to the earlier requirements. The rule requires systems-based assessments, with required testing in certain circumstances, that focus on key risk factors for contamination by pre-harvest agricultural water and will enable farms to implement effective preventive measures. The rule requires farms to take timely action based on risk and includes a new requirement for expedited mitigation for certain hazards. The requirements are adaptable to future scientific advancements and provide sufficient flexibility to be practicable for all sizes and types of farms to implement across the wide variety of agricultural water systems, uses, and practices. These revisions to the produce safety regulation will more comprehensively address a known route of microbial contamination that can lead to preventable foodborne illness that is a significant public health problem.

DATES: This rule is effective July 5, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: *With regard to the final rule:* Samir Assar, Director, Division of Produce Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317) 5001 Campus Dr., College Park, MD 20740, 240–402–1636, email: *samir.assar@hhs.fda.gov*.

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Coverage of the Final Rule

In this final rule, the Food and Drug Administration (FDA, the Agency, or we) is amending the ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' rule (2015 produce safety final rule), which was established in accordance with the FDA Food Safety Modernization Act (FSMA) and sets forth science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables for human consumption. This rule revises certain provisions in the 2015 produce safety final rule applicable to agricultural water[1] for covered produce other than sprouts, using a direct application method during growing activities (commonly referred to as ''pre-harvest agricultural water''[2]). It establishes a regulatory framework of systems-based assessments and risk-tiered outcomes through which farms subject to the 2015 produce safety final rule (covered farms) are required to identify known and potential hazards and implement effective preventive measures within specific timeframes based on risk.

The written assessments focus on agricultural water systems, including sources, and agricultural water practices that are key determinants of contamination risks associated with agricultural water, together with crop characteristics and environmental conditions that can impact the survival of pathogens. The assessments include a requirement to test pre-harvest agricultural water in certain circumstances—that is, when doing so would not delay action most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary. Moreover, the assessments are designed for use in diverse circumstances and require covered farms to evaluate a broad range of factors that impact pre-harvest agricultural water quality, providing results that are tailored to address hazards unique to their respective

[1] ''Agricultural water'' is defined at 21 CFR 112.3 as water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). Related to this definition is our definition of ''direct water application method,'' which means agricultural water used in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. If a specific use of water does not fit within the definition of agricultural water, then the requirements in subpart E do not apply to that specific use of water. See 80 FR 74354 at 74429.

[2] The 2015 produce safety final rule refers to pre-harvest agricultural water used during sprout production as ''sprout irrigation water.''

operations. This approach will be feasible to implement across the wide variety of agricultural water systems, practices, and uses, and it is adaptable to future advancements in agricultural water quality science.

Farms must use the information evaluated to make a written determination on the outcomes of their assessments. The outcomes are based on risk, and include the actions farms must take within a specific timeframe to ensure that their pre-harvest agricultural water is safe and is of adequate sanitary quality for the intended use(s). Within this framework for risk-tiered outcomes is a new expedited mitigation requirement relating to the impacts of certain adjacent and nearby land uses on pre-harvest agricultural water.

These amendments to the 2015 produce safety final rule are supported by scientific literature published since FDA promulgated the 2015 produce safety final rule and findings from FDA's outbreak investigations since FDA promulgated the 2015 produce safety final rule. These amendments are also supported by information and insights shared by an array of stakeholders through a variety of means since FDA promulgated the 2015 produce safety final rule (including through meetings, educational farm visits, and listening sessions), as well as information shared through the notice-and-comment process for this rulemaking. Feedback shared by stakeholders included information about the complexity of the previous pre-harvest agricultural water testing requirements, the practical implementation challenges associated with the uniform nature of those requirements, and findings from scientific studies demonstrating the need for additional testing in highly variable water with previously unaccounted for costs (see section III.C.). We have carefully considered the new information as we considered revisions to the 2015 produce safety final rule necessary to achieve our intended public health goals.

After considering available information, FDA has concluded this final rule will achieve improved public health protections by setting forth requirements for comprehensive pre-harvest agricultural water assessments. Those assessments will better enable covered farms to implement effective measures that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated due to those hazards. Moreover, these revisions provide sufficient flexibility to be practicable for all sizes and types of farms and to account for differences in risk across varying agricultural water systems, uses, and practices.

B. Summary of the Major Provisions of the Final Rule

FDA is amending the 2015 produce safety final rule by revising certain provisions relating to pre-harvest agricultural water for covered produce other than sprouts, while retaining the existing standards applicable to agricultural water for sprouts and for harvest and post-harvest activities conducted by covered farms.

For pre-harvest agricultural water for non-sprout covered produce, we are:

- Replacing the microbial quality criteria and uniform testing requirements in the 2015 produce safety final rule with new provisions for conducting pre-harvest agricultural water assessments for hazard identification purposes (including consideration of agricultural water sources, distribution systems, and practices, as well as adjacent and nearby land uses, and other relevant factors), and using the results of the assessments in making risk management decisions;
- Including a requirement to test pre-harvest agricultural water in certain circumstances (that is, when doing so would not delay action most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary) for generic *Escherichia coli* (*E. coli*) (or other appropriate indicator organism, index organism, or analyte) to help inform covered farms' agricultural water assessments;
- Adding new options for mitigation measures, providing covered farms additional flexibility in responding to findings from their pre-harvest agricultural water assessments;
- Requiring expedited implementation of mitigation measures for known or reasonably foreseeable hazards related to certain adjacent and nearby land uses;
- Requiring management review of pre-harvest agricultural water assessments; and
- Adding new definitions of ''agricultural water assessment'' and ''agricultural water system.''

We are making additional amendments, such as adding examples and making other edits that are designed to provide clarity, such as reorganizing subpart E to group provisions of a similar nature. We are also making conforming changes elsewhere in the 2015 produce safety final rule.

C. Legal Authority

We are issuing this final rule under FDA's authorities in sections 402, 419, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342, 350h, and 371(a)) and sections 311, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 243, 264, and 271). We discuss our legal authority in greater detail in section IV.

D. Costs and Benefits

Our primary estimates of annualized costs are approximately $17.5 million at a 3 percent discount rate and approximately $17.7 million at a 7 percent discount rate over 10 years.

Our primary estimates of annualized benefits are approximately $10.3 million at a 3 percent discount rate and approximately $10.1 million at a 7 percent discount rate over 10 years. We discuss non-quantified benefits of the rule stemming from recalls averted and increased flexibility for covered farms to comprehensively evaluate their agricultural water systems.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

TABLE 1—TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation/acronym	What it means
BSAAO	Biological Soil Amendment of Animal Origin.
CAFO	Concentrated Animal Feeding Operation.
CAN	California Agricultural Neighbors.
CDC	Centers for Disease Control and Prevention.
CEA	Controlled Environment Agriculture.
CFR	Code of Federal Regulations.
CFU	Colony Forming Units.
CWA	Clean Water Act.

TABLE 1—TABLE OF ABBREVIATIONS AND ACRONYMS—Continued

Abbreviation/acronym	What it means
E. coli	*Escherichia coli.*
EIS	Environmental Impact Statement.
EPA	U.S. Environmental Protection Agency.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FRIA	Final Regulatory Impact Analysis.
FSMA	FDA Food Safety Modernization Act.
GAP	Good Agricultural Practices.
GM	Geometric Mean.
HACCP	Hazard Analysis and Critical Control Point.
H–GAP	USDA Harmonized Good Agricultural Practices.
HHS	Health and Human Services.
IFSAC	Interagency Food Safety Analytics Collaboration.
LGMA	Leafy Greens Marketing Agreement.
L. monocytogenes	*Listeria monocytogenes.*
mL	Milliliters.
MPN	Most Probable Number.
MWQP	Microbial Water Quality Profile.
NASDA	National Association of State Departments of Agriculture.
NOP	USDA National Organic Program.
NASS	USDA National Agricultural Statistics Service.
NPDWR	U.S. EPA National Primary Drinking Water Regulations.
PCR	Polymerase Chain Reaction.
PHS Act	Public Health Service Act.
PRIA	Preliminary Regulatory Impact Analysis.
QAR	Qualitative Assessment of Risk.
RWQC	Recreational Water Quality Criteria.
STV	Statistical Threshold Value.
USDA	U.S. Department of Agriculture.
UV	Ultraviolet.

III. Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA transformed the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it.

FSMA enables FDA to establish a prevention-oriented framework that focuses effort where food safety hazards are reasonably likely to occur and is flexible and practical in light of current scientific knowledge and food safety practices. The law also provides enforcement authorities for responding to food safety problems when they do occur. In addition, FSMA gives FDA important tools to help ensure the safety of imported foods and encourages partnerships with State, local, Tribal, and territorial authorities, as well as foreign regulatory counterparts.

FDA has issued nine foundational rules that create risk-based standards and provide oversight at various points in the supply chain for domestic and imported human and animal food. The produce safety regulation, established in the 2015 produce safety final rule (80 FR 74354, November 27, 2015), is one of the nine foundational rules.

B. 2015 Produce Safety Final Rule

In November 2015, FDA finalized the produce safety regulation, which establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption (codified in the Code of Federal Regulations (CFR) at part 112 (21 CFR part 112)). In accordance with section 419 of the FD&C Act (21 U.S.C. 350h), the 2015 produce safety final rule sets forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into produce and to provide reasonable assurances that produce is not adulterated on account of such hazards. The regulation focuses on biological hazards (defining a ''known or reasonably foreseeable hazard'' as a biological hazard that is known to be, or has the potential to be, associated with the farm or the food) and major routes of microbial contamination—including agricultural water; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools. Farms subject to the requirements of part 112 are ''covered farms''; however, for purposes of readability, we use the term ''farms'' to mean ''covered farms'' within the meaning of part 112 in this document.

Subpart E of the 2015 produce safety final rule includes a general requirement that agricultural water must be safe and adequate for its intended uses (§ 112.41). It also included microbial water quality criteria (§ 112.44) and requirements for testing certain water sources (§ 112.46). The microbial quality criteria were based on the intended use of the agricultural water—*i.e.,* for growing activities for covered produce other than sprouts (including irrigation water applied to covered produce, other than sprouts, using a direct water application method and water used in preparing crop sprays) (commonly referred to as ''pre-harvest agricultural water'')[3], and for certain other specified uses, including sprout irrigation water and water applications that directly contact covered produce during or after harvest (commonly referred to as ''harvest and post-harvest agricultural water'').[4] For pre-harvest agricultural water for non-sprout covered produce, the microbial

[3] The 2015 produce safety final rule refers to pre-harvest agricultural water used during sprout production as ''sprout irrigation water.''

[4] Because sprouts present a unique safety risk, the 2015 produce safety final rule establishes sprout-specific requirements on multiple topics, including agricultural water. Sprouts are not the subject of this rulemaking.

water quality criteria consisted of a geometric mean (GM) of 126 or less colony forming units (CFU) generic *E. coli* per 100 milliliters (mL), and a statistical threshold value (STV) of 410 or less CFU generic *E. coli* per 100 mL. The 2015 produce safety final rule preamble explained that we established the pre-harvest agricultural water microbial criteria based on our analysis of the then-current scientific information; we also explained that that scientific information relied on an underlying dataset that had the necessary scientific rigor and described illness rates due to incidental ingestion generalized across different bodies of water (see 80 FR 74534 at 74416 and 74441–74442).

For untreated surface waters, farms were required to establish an initial microbial water quality profile (MWQP) of at least 20 samples collected over a 2 to 4-year period, followed by at least 5 annual samples thereafter; and for untreated ground water sources, this would consist of an initial profile of at least 4 samples collected during the growing season or over a period of 1 year, followed by at least 1 annual sample thereafter (80 FR 74354 at 74452) (Ref. 1).

In the 2015 produce safety final rule, we explained that the pre-harvest agricultural water microbial criteria and testing requirements were not a direct indicator of the safety of agricultural water for immediate use; rather, they were designed as a long-term water quality management tool for use in understanding the microbial quality of water over time and determining how to appropriately use water from that source. 80 FR 74354 at 74430. Moreover, we acknowledged gaps in the then-current science related to use of indicator organisms for monitoring water quality and predicting pathogen presence and/or fecal contamination. 80 FR 74354 at 74427–74428. We discussed that while testing water for pathogens has the obvious advantage of directly targeting microorganisms in water that are a risk to public health, doing so is not without significant challenges. 80 FR 74354 at 74427–74428. In response to comments received during that earlier rulemaking, we considered, and declined, the option to establish a qualitative standard alone in lieu of a quantitative microbial quality requirement for pre-harvest agricultural water. 80 FR 74354 at 74443. However, since 2015, new scientific findings as well as findings from FDA outbreak investigations have demonstrated the need for an updated systems-based approach.

Table 2 lists the key FSMA 2015 produce safety final rule documents published in the **Federal Register**. The complete set of **Federal Register** documents associated with the FSMA 2015 produce safety final rule, including supporting materials, are available in the docket folders at *https://www.regulations.gov/docket?D=FDA-2011-N-0921* and *https://www.regulations.gov/docket?D=FDA-2021-N-0471.*

TABLE 2—LIST OF KEY **Federal Register** 2015 PRODUCE SAFETY FINAL RULE DOCUMENTS

Description	Publication
Notice of proposed rulemaking (2013 proposed produce safety rule)	78 FR 3504, January 16, 2013.
Notice of correction for the 2013 proposed produce safety rule	78 FR 17155, March 20, 2013.
Supplemental notice of proposed rulemaking (2014 supplemental proposed rule)	79 FR 58434, September 29, 2014.
Final rule (2015 produce safety final rule or final rule)	80 FR 74354, November 27, 2015.
Technical amendment to the 2015 produce safety final rule	81 FR 26466, May 3, 2016.
FSMA: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules; Final rule.	81 FR 57784, August 24, 2016.
Extension of Compliance Dates for Subpart E; Notice of proposed rulemaking (2017 proposed compliance date extension).	82 FR 42963, September 13, 2017.
Extension of Compliance Dates for Subpart E; Final rule (2019 compliance date extension)	84 FR 9706, March 18, 2019.
Standards Relating to Agricultural Water; Notice of proposed rulemaking (2021 agricultural water proposed rule).	86 FR 69120, December 6, 2021.
Extension of Compliance Dates for Subpart E; Supplemental notice of proposed rulemaking (2022 supplemental proposed rule).	87 FR 42973, July 18, 2022.

C. New Information Since Issuance of the 2015 Produce Safety Final Rule

In November 2015, FDA began to conduct outreach to educate stakeholders about the requirements of the 2015 produce safety final rule, including through public meetings, speaking engagements, and participation in conferences convened by stakeholders representing a broad range of interests. FDA subject matter experts also participated in educational farm visits with State partners to observe a range of growing conditions and practices in varying regions. Through these efforts we heard consistent feedback that the pre-harvest agricultural water microbial criteria and testing requirements for non-sprout covered produce in the 2015 produce safety final rule were ''one-size-fits-all'' and did not sufficiently allow for the diversity of farms, including a variety of water uses and availabilities. For example, we received feedback that the long-term MWQPs required in the 2015 produce safety final rule can be difficult, and even impossible, to establish for farms that grow rotational crops or crops on leased land, both of which are common throughout industry. 86 FR 69120 at 69123–69124. FDA also received information and feedback from other stakeholders, including water quality specialists and researchers, indicating that the 2015 pre-harvest microbial water quality criteria and testing requirements did not adequately capture variability that can occur within a surface water source, and that sanitary surveys may better help inform water management decisions compared to testing.

In the face of these concerns, including new concerns not previously expressed, in March 2017, FDA announced that we were considering how we might simplify the microbial quality and testing requirements for agricultural water while still protecting public health and that we intended to work with stakeholders as these efforts progressed (Ref. 2). As part of these efforts, we participated in numerous additional meetings, educational farm visits, and listening sessions with an array of stakeholders—including produce industry members, food industry trade associations, researchers, extension educators, consumer groups, and State and Federal partners—to reflect various perspectives on managing risks associated with pre-harvest agricultural water for non-sprout

covered produce. See 86 FR 69120 at 69123–69125.

For example, in October 2017, FDA participated in a collaborative forum, sponsored by The Pew Charitable Trusts and the Robert Wood Johnson Foundation, where participants representing farms, academia, food industry trade associations, consumer groups, and State and other Federal partners discussed ideas for how to amend the agricultural water requirements within the then-current framework of the rule, as well as, and potentially in combination with, ideas for frameworks that could improve public health outcomes long-term and allow for the incorporation of new scientific knowledge and learnings as they become available (Ref. 3). Forum participants identified several possible approaches, including: (1) retaining the 2015 pre-harvest microbial water quality criteria and testing requirements and issuing companion guidance; (2) replacing the 2015 quantitative requirements with a qualitative standard and issuing companion guidance; (3) adopting private industry standards as a short-term measure while additional research continues; and (4) performing a multiyear quantitative microbial risk assessment to help fill research gaps. Forum participants identified advantages and disadvantages of each approach and also identified other areas for further consideration by FDA, including qualitative standards, data sharing, and the need for additional guidance.

The pre-harvest agricultural water requirements were also the focus of a 2-day Agricultural Water Summit, convened by the Produce Safety Alliance at Cornell University, in February 2018 (Ref. 4). The summit was attended by academics, produce industry, growers/grower associations, State agencies, Federal agencies, and supporting industries. During the summit, participants had many questions and concerns about reliance on testing as a mechanism for determining pre-harvest agricultural water quality, including that the 2015 pre-harvest agricultural water microbial criteria and testing requirements were not supported by scientific evidence sufficient to demonstrate their relevance to public health outcomes. Among other things, participants questioned the role of water testing, what the information tells farms about risks, and how farms would use that information to make water use management decisions. Some participants emphasized farms' interest in preventing produce contamination while expressing concern that the resources that would be required to conduct testing might be better used for other approaches with relevance to public health outcomes.

Many of the discussions at the summit addressed hazards in the growing environment, including examples of how risk assessment has been conducted in other fields of study, such as for drinking water and wastewater management. During the summit, participants identified ''agricultural water assessments'' as a promising approach for managing water quality, suggesting that assessments may provide a more effective risk management strategy to farms than a numerical testing standard can provide (Ref. 4).

Moreover, scientific information has become available since the 2015 produce safety final rule issued that indicates potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements and that supports a shift in regulatory approach away from those requirements. For example, various studies since 2015 indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5–10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies since 2015 have underscored the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11–16).

Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources leads to highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Specifically, Havelaar et al. found that the 20-sample MWQP for untreated surface water was not sufficient to reliably characterize the quality of the irrigation water with higher variability in generic *E. coli* levels than was determined for the 2015 produce safety final rule (Refs. 1, 7). In simulation modeling, the rolling 20-sample MWQP responded ''very slowly'' to shifts in water quality. Increases in generic *E. coli* levels were detected only after one to six sample sets, thus delaying signals of changes in water quality and (and any needed measures) by 1 to 6 years depending on the nature and magnitude of the shift.

For surface water that had standard deviations up to three times higher than accounted for in the 2015 produce safety final rule, Havelaar et al. determined that an 180-sample MWQP would be required to obtain the same precision of the GM as required by the rule (Ref. 7). Havelaar et al. observed that the (nine-fold) increase in sampling might address the problem, but it would increase testing costs. We acknowledge their findings on the need for substantial testing for highly variable pre-harvest agricultural water. Such testing would be beyond what is required for pre-harvest surface water testing under the 2015 produce safety final rule, with an attendant increase in costs. Additionally, other recent studies demonstrate a high degree of variability in generic *E. coli* levels in surface waters for pre-harvest application (Refs. 5–10), suggesting similar questions about necessary additional testing and costs that were not accounted for in the 2015 produce safety final rule.

Havelaar et al. also suggested that additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements (Ref. 7). Additionally, for several years, FDA has conducted investigations of produce outbreaks to learn what factors may have contributed to the outbreaks of foodborne illness or food contamination events (Ref. 17). Findings from investigations of several outbreaks linked to consumption of produce since 2015—including: (1) the spring 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from the Yuma growing region (Refs. 18 and 19); (2) the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20); (3) the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21); (4) the fall 2020 *E. coli* O157:H7 outbreak linked to leafy greens (Ref. 22); and (5) the Summer 2020 *Salmonella* Newport outbreak linked to red onions (Ref. 23)—highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. These outbreak investigations reiterate decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. See 86 FR 69120 at 69125–69127. Findings such as these build upon our peer-reviewed ''FDA Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce'' (QAR) (Ref. 17), which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in

produce to inform FDA's implementation of section 419 of the FD&C Act, with a focus on public health risk associated with the on-farm contamination of produce, including from agricultural water.

D. 2021 Agricultural Water Proposed Rule

In light of recent studies and other new information gathered since issuance of the 2015 produce safety final rule, including findings from FDA produce outbreak investigations as well as feedback on the previous pre-harvest agricultural water requirements, on December 6, 2021, FDA issued a proposed rule, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,'' (86 FR 69120; hereafter referred to as the ''2021 agricultural water proposed rule'') that proposed to revise certain requirements relating to pre-harvest agricultural water for covered produce other than sprouts, while retaining the existing standards applicable to agricultural water for sprouts and for harvest and post-harvest activities. For pre-harvest agricultural water for non-sprout covered produce, we proposed to replace the microbial quality criteria and uniform testing requirements with provisions for: requiring systems-based pre-harvest agricultural water assessments to evaluate the key determinants of risk attributable to agricultural water use practices, including a requirement to test pre-harvest agricultural water when doing so would not delay action most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary; adding new options for mitigation measures; and adding a new requirement for expedited implementation of mitigation measures for hazards related to certain adjacent and nearby land uses. We also proposed to require management review of records related to agricultural water assessments and to add new definitions of ''agricultural water assessment'' and ''agricultural water system'' to the 2015 produce safety final rule.

We solicited comments on these proposed amendments. We also proposed additional amendments, such as reorganizing subpart E to group requirements of a similar nature and ensure that interested parties could readily view the proposed pre-harvest agricultural water revisions.

Additionally, in the preamble to the 2021 agricultural water proposed rule (86 FR 69120 at 69147) we explained that at that time, farms were required to comply with the subpart E pre-harvest, harvest, and post-harvest agricultural water requirements for covered produce (other than sprouts) beginning on January 26, 2024, for very small farms; January 26, 2023, for small farms; and January 26, 2022, for all other farms (see also 84 FR 9706). We also explained that we intended to exercise enforcement discretion for the subpart E pre-harvest, harvest, and post-harvest agricultural water requirements for covered produce (other than sprouts) while working to address compliance dates in a targeted manner through the rulemaking process, with the goal of completing the rulemaking as quickly as possible.

The public comment period for the 2021 agricultural water proposed rule closed on April 5, 2022.

In the 2021 agricultural water proposed rule, we indicated that we were developing an online tool related to the pre-harvest agricultural water assessments described in the proposed rule. In March 2022, FDA released v1.0 of an online ''Agricultural Water Assessment Builder'' to help farms understand the proposed requirements for an agricultural water assessment (Ref. 24). Since then, we have released paper-based versions of the Builder in both English and Spanish to make the content more accessible to a broader array of users (Ref. 25). We have also updated the online version of the Builder to v1.1 to make it more user-friendly in response to stakeholder feedback. We expect to update the Builder to reflect the requirements we are finalizing here.

E. 2022 Supplemental Proposed Rule

On July 19, 2022, we published a supplemental notice to the 2021 agricultural water proposed rule (87 FR 42973) (2022 supplemental proposed rule) in which we proposed dates for compliance with the pre-harvest agricultural water requirements for covered produce other than sprouts in the 2021 agricultural water proposed rule. In light of the revisions we proposed to certain pre-harvest agricultural water requirements for non-sprout covered produce, we proposed to establish dates for compliance with the pre-harvest agricultural water requirements for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses.

We also specified the duration of the period of enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts until January 26, 2025, for very small businesses; January 26, 2024, for small businesses; and January 26, 2023, for all other businesses. As discussed in the 2022 supplemental proposed rule, we specified the duration of our intended period of enforcement discretion to provide farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those requirements.

We explained in the 2022 supplemental proposed rule that the proposed compliance dates for pre-harvest agricultural water requirements and our intent to exercise of enforcement discretion were intended to facilitate successful implementation and optimize public health protections. We reopened the comment period only with respect to the extension of compliance dates for pre-harvest agricultural water for non-sprout covered produce. The comment period for the supplemental proposed rule closed on September 19, 2022.

In this document, we use the broad term ''agricultural water proposed rule'' to refer to the complete proposed rule, including both the 2021 agricultural water proposed rule and the 2022 supplemental proposed rule.

F. Public Comments

After issuing the agricultural water proposed rule, we conducted numerous outreach activities. We held two virtual public meetings on February 14, 2022, and February 25, 2022, to solicit public comments on the proposed rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the proposed rule. The public meetings were attended by domestic and foreign industry representatives, academia, State and Federal regulators, retailers, third-party certification bodies, laboratories, consumer groups and others, and included discussion panels consisting of representatives from industry, the States, consumer groups, and retailers. We also held a consultation with Federally recognized Indian tribes on February 4, 2022, to provide an overview of the proposed rule, answer questions, and receive feedback.

Additionally, FDA participated in a webinar hosted by the National Association of State Departments of Agriculture (NASDA) on December 15, 2021, as well as five regional meetings (Southern Region (March 14, 2022); Western Region (March 11, 2022); Northwestern Region (March 2, 2022);

North Central Region (March 2, 2022); and Northeast Region (March 11, 2022)) that were sponsored by State regulatory partners and attended by farms, irrigation districts, educators, environmental groups, and others. We also participated in numerous other meetings and speaking engagements to discuss the proposed rule, respond to questions, and receive feedback.

We received approximately 180 comment submissions on the agricultural water proposed rule by the close of both comment periods, each containing one or more comments on one or more issues. We received submissions from diverse members of the public, including produce farms; coalitions; trade organizations; academia; consumers; consumer groups; State and foreign government agencies; and other organizations. Some submissions included statements from multiple individuals.

In sections V and VI of this document we describe these comments, respond to them, and explain the changes we made to the agricultural water proposed rule, in addition to discussing our consideration of alternative approaches, such as requiring all farms to test their water as part of their pre-harvest agricultural water assessments. We also discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements. The remainder of this document establishes a final rule (''the final rule,'' ''this final rule,'' ''the rule,'' or ''this rule'') based on the agricultural water proposed rule.

G. General Overview of Changes in the Final Rule

In response to comments received and on our own initiative, we have made several changes to the proposed requirements for pre-harvest agricultural water assessments for non-sprout covered produce and for mitigation measures to reduce the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards associated with such agricultural water. We have provided clarification related to the timing of agricultural water assessments and exemptions from the requirement to prepare an agricultural water assessment. We have also revised the mitigation measures related to a time interval between last direct water application and harvest and a time interval between harvest and end of storage and/or use of other post-harvest activities to further emphasize the flexibility afforded to farms in ways to comply with those requirements and provide flexibility as science and post-harvest handling practices evolve. Consistent with the changes discussed above, we have revised the requirements for certain records that farms are required to establish and maintain. This final rule also includes a requirement to maintain scientific data or information in support of an alternative mitigation measure to align with the agricultural water records requirements in the 2015 produce safety final rule.

IV. Legal Authority

We are issuing this final rule under FDA's authorities in sections 402, 419, and 701(a) of the FD&C Act and sections 311, 361, and 368 of the PHS Act.

Section 419(a) of the FD&C Act, in relevant part, directs FDA to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of serious adverse health consequences or death. Section 419(a)(3) of the FD&C Act further requires that these minimum standards provide sufficient flexibility and are appropriate to the scale and diversity of the production and harvesting of raw agricultural commodities. Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Additionally, section 701(a) of the FD&C Act grants the authority to issue regulations for the efficient enforcement of the FD&C Act. This rule includes requirements that are necessary to prevent food from being adulterated, and a regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. The amendments we are finalizing to the 2015 produce safety final rule thus allow FDA to efficiently enforce sections 402 and 419 of the FD&C Act.

In addition to the FD&C Act, FDA's legal authority for the final rule derives from sections 311, 361, and 368 of the PHS Act, which provides authority for FDA to issue regulations to prevent the spread of communicable diseases from one State to another. Specifically, the PHS Act authorizes the Secretary of HHS to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see Staff Manual Guide 1410.10 at *https://www.fda.gov/about-fda/reports-manuals-forms/staff-manual-guides* for delegation from the Secretary to FDA.) The provisions in this final rule are necessary to prevent food from being contaminated with human pathogens such as *Salmonella, Listeria monocytogenes* (*L. monocytogenes*), and *E. coli* O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. These amendments to the 2015 produce safety final rule will help prevent the spread of communicable diseases associated with contaminated produce.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 180 comment submissions on the proposed rule by the close of both comment periods, each containing one or more comments on one or more issues. We received submissions from diverse members of the public, including produce farms; coalitions; trade organizations; academia; consumers; consumer groups; State and foreign government agencies; and other organizations. Some submissions included statements from multiple individuals.

In the remainder of this document, we describe the comments that are within the scope of this rulemaking, respond to them, and explain the revisions we made to the proposed rule. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received.

We received no comments regarding § 112.40 (''What requirements of this subpart apply to my covered farm?'') and are finalizing that provision as proposed. We received no comments regarding conforming changes in §§ 112.12, 112.151, or 112.161(b), or amendments to §§ 112.42, 112.44, and 112.46 through 112.49 related to providing additional clarity and reorganizing subpart E in its entirety to group provisions of a similar nature. We are finalizing these amendments without changes.

We received some comments on provisions we did not propose to revise and that are outside of the scope of this rulemaking. For example, we received comments on the definition of ''agricultural water'' (§ 112.3); the requirements for general agricultural water quality (§ 112.41); the requirements for inspections and maintenance of agricultural water systems (§ 112.42); the requirements for harvest and post-harvest agricultural water (§ 112.44); and the requirements for agricultural water treatment (§ 112.46). We do not address out of scope comments in this document.

We also received some comments that address FDA's plans for implementation activities that are outside the scope of this rulemaking. As such, we do not address those comments in this document. We nonetheless recognize the importance of having educational materials and technical assistance and are taking efforts to ensure that guidance, training, educational resources, and the FSMA Technical Assistance Network are available to help farms as they prepare to comply with the requirements in this rule.

Note that summaries of and responses to comments on the estimated costs and benefits of the proposed rule and other topics covered by the Preliminary Regulatory Impact Analysis (PRIA) may be found in the Final Regulatory Impact Analysis (FRIA) (Ref. 26).

B. General Comments on the Proposed Rule

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. Among comments that were supportive of the proposed rule, some provided general feedback suggesting that additional information would help clarify the rule. Several comments focused on other topics, such as alternative options to the regulatory approach for pre-harvest agricultural water and the shift from mandated agricultural water testing in the 2015 produce safety final rule to the proposed approach for pre-harvest agricultural water assessments. In the following paragraphs, we discuss and respond to such general comments.

1. General Comments

(Comment 1) Many comments support the proposed rule, suggesting that the proposed pre-harvest agricultural water assessments are more risk-based, flexible, and holistic than the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule, which commenters characterized variously as complex, prescriptive, and ''one-size-fits-all.'' Many comments suggest that the proposed approach better accommodates the diversity in industry, noting the variety of conditions that can exist on farms when it comes to different regions, crops, water sources, and water uses. Many of these comments suggest that the proposed requirements will help prevent foodborne illness outbreaks and lead to improved public health outcomes. Among comments supportive of the proposed approach, some suggest that additional information on agricultural water assessments would be beneficial to further clarify the proposed requirements.

In contrast, a few comments suggest that the proposed requirements for pre-harvest agricultural water assessments are too complicated. Some of these comments suggest that quantitative metrics (such as criteria derived from testing) would be easier for farms to understand and easier for regulators to enforce than agricultural water assessments, which are more qualitative in nature. Some of these comments suggest that the requirements for agricultural water assessments will not be more effective at preventing foodborne illness than mandated pre-harvest agricultural water testing.

(Response 1) We agree with comments received that support the proposed rule, including the systems-based assessments that are grounded in our QAR (Ref. 17), incorporate recent scientific data and other information available to FDA, and are designed to ensure that farms have robust and meaningful information about the quality of their pre-harvest water for use in risk management decision making. We developed this approach to pre-harvest agricultural water by considering the public health objectives we aim to achieve through pre-harvest agricultural water measures for covered produce other than sprouts while recognizing that each farm—whether foreign or domestic—has a unique combination of agricultural water source(s), growing practices, current and previous uses of the farmland, and adjacent and nearby land uses, among other factors, that may influence the safety of its agricultural water.

The rule establishes assessment factors with sufficient specificity to provide farms robust and meaningful information on the quality of pre-harvest agricultural water, while also offering adequate flexibility to account for the diversity of operations that we are required to consider in developing the regulations under 419(a)(3)(A) of the FD&C Act.

The requirements for comprehensive, systems-based pre-harvest agricultural water assessments and appropriate corrective and mitigation measures as needed will help farms identify potential sources of contamination and effectively manage their water. Specifically, farms must use the results of assessments to determine when, within the framework for risk-based outcomes, they are required to take measures to ensure that their pre-harvest agricultural water is safe and is of adequate sanitary quality for the intended use(s). The combination of assessments and risk-tiered outcomes require farms to identify and address sources of potential hazards through implementation of effective prevention-oriented mitigation measures within specified timeframes. Under the final rule, farms will assess hazards at the beginning of the growing season and implement mitigation measures for certain hazards earlier than under the 2015 produce safety final rule. Further, under the 2015 produce safety final rule, farms were required to test pre-harvest agricultural water as close in time as practicable to, but prior to harvest, and use those results to determine whether to implement mitigation measures without the benefit of the written systems-based evaluation of potential sources of contamination we are requiring in this final rule.

We recognize that agricultural water assessments, by their nature, will require farms to consider a broader set of factors as part of the systems-based approach we are finalizing here, compared to the microbial quality criteria and testing requirements for pre-harvest agricultural water in the 2015 produce safety final rule. In addition to providing the specific factors farms must consider in their pre-harvest agricultural water assessments in § 112.43(a), we provide additional information on the requirements for agricultural water assessments throughout the remainder of section V. We reiterate our commitment to providing farms education, outreach, and technical assistance to facilitate

compliance with the rule. We intend to pursue various mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including work with other stakeholders (such as State agencies, educators, and extension agents), to do so. See also the response to comment 29.

Further, the knowledge and experiences gained since 2015 will be helpful in supporting successful implementation of the rule, including compliance with the requirements for pre-harvest agricultural water assessments. For example, we developed the 2015 produce safety final rule after considering, in part, that at the time of rulemaking, some farms had significant expertise in the area of food safety, and other farms had minimal knowledge in the area. We also considered that the produce farming community did not have the history of regulatory interaction with FDA and the same experience with food safety regulations as did the food manufacturing industry. 78 FR 3504 at 3530. However, we recognize that since that time, knowledge and awareness of food safety, as well as the produce farming community's experience with food safety regulations, has evolved. For example, many farms, whether for the purposes of required training in accordance with § 112.22(c) (which we did not propose to change) or for other purposes, have since received food safety training, including on topics related to potential hazards in the growing environment.

Additionally, FDA has provided investigation reports for various produce-related outbreaks that have occurred since 2015 (*e.g.,* Refs. 18–23), many of which discuss factors potentially contributing to contamination and provide recommendations for farms to consider in light of those findings. Moreover, other provisions in the 2015 produce safety final rule for which compliance dates have passed, such as those in subpart I, ''Domesticated and Wild Animals'' (§§ 112.81–112.83), may provide farms with useful information when evaluating the degree of protection of a pre-harvest agricultural water system as part of an agricultural water assessment (see response to comment 55).

For these reasons we have concluded that sufficient support exists—including through identification of specific factors that farms must consider in § 112.43(a), information provided throughout this final rule, and knowledge and experiences gained since 2015 (including lessons learned from various produce-related outbreaks)—for farms to effectively implement the requirements for agricultural water assessments and risk-tiered outcomes that we are finalizing with this rule.

With respect to comments suggesting that the requirements for pre-harvest agricultural water assessments will be difficult to enforce, we disagree. The annual assessments employ a prevention-oriented quality-systems approach to food safety regulation that FDA has long used and successfully enforced across the highly diverse food industry that FDA regulates. For example, FDA issued the juice hazard analysis and critical control point (HACCP) regulation (that is, the Hazard Analysis and Critical Control Point Systems regulation in 21 CFR part 120) and the seafood HACCP regulation (that is, the Fish and Fishery Products regulation in 21 CFR part 123) more than 20 years ago, which establish mandatory frameworks through which industry assesses hazards that are reasonably likely to occur and designs tailored controls to prevent or eliminate them or reduce them to an acceptable level. More recently, in 2015, FDA issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117), under which food facilities conduct a qualitative assessment to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring a preventive control. These regulations all require the development of a food safety plan.

As discussed in comment 18, we have incorporated many of these principles—such as an assessment of risk and the development of a food safety plan based on that assessment—into the requirements for pre-harvest agricultural water assessments in § 112.43. For example, in § 112.43(a), we require farms to evaluate and document specific factors as part of an assessment, all of which are key determinants of contamination risks associated with pre-harvest agricultural water. Based on that evaluation, in § 112.43(c), we require farms to make written determinations on whether measures under § 112.43(d) are reasonably necessary. We further require farms to take necessary and timely action in accordance with those determinations. Thus, the requirements we are finalizing here share common principles with other FDA food safety regulations that have been enforced.

Thus, based on the specific criteria we have included in § 112.43 and our experience enforcing other regulations that rely on similar food safety principles and approaches to operation-specific assessments, we have concluded we can enforce the requirements we are finalizing here. For example, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation includes requirements for hazard identification (see 21 CFR 117.130), and FDA has enforced that regulation. Additional information on inspection, compliance, and enforcement-related information can be found on the ''FDA Data Dashboard'' at *https://www.fda.gov/about-fda/transparency/fda-data-dashboard*.

To the extent that comments voicing concerns with the proposed rule are suggesting that the requirements for pre-harvest agricultural water assessments are more than what is necessary for public health purposes, we disagree. While we believe that requiring operational assessments and food safety plans that address the entirety of a farm's operations (including potential sources and routes of contamination addressed in other subparts of the 2015 produce safety final rule) would be more than a minimum standard and more than what is reasonably necessary for us to require to achieve the statutory purposes (80 FR 74354 at 74380), given the scientific support for pre-harvest agricultural water assessments; the limited scope of the assessments (*i.e.,* the requirements only apply for pre-harvest agricultural water for non-sprout covered produce); and the knowledge and experiences gained since 2015, we continue to conclude that requiring farms to prepare a pre-harvest agricultural water assessment for non-sprout covered produce is a science-based minimum standard as described in section 419 of the FD&C Act. There is significant public health benefit in requiring farms to prepare a written assessment that considers various factors that affect the safety of their pre-harvest agricultural water and its appropriate use during pre-harvest activities for non-sprout covered produce. Such written assessments also require farms to identify the actions they will take to manage risks associated with their pre-harvest water. Further, in some instances, the written assessments will provide farms with a historical record that will allow them to more readily detect changes and react in a timely manner to protect public health.

With respect to comments suggesting that the requirements for agricultural water assessments will not be more effective at protecting public health than

the 2015 pre-harvest agricultural water testing requirements, we disagree. As discussed further in response to comment 3, there are various limitations associated with testing, including that: the presence of indicators does not always signal the presence of pathogens, and the absence of detection of indicators does not guarantee that pathogens are absent (Refs. 27–30) (80 FR 74354 at 74428). Moreover, since sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Refs. 31 and 32), non-detection of generic *E. coli* cannot be considered absolute confirmation that fecal contamination has not occurred (80 FR 74354 at 74428). In light of these challenges, testing may inadvertently provide farms with a false sense of security as to the quality of their water, potentially resulting in farms not taking action where necessary to protect public health. Moreover, as discussed in response to comment 11, rather than relying on results of a multi-year rolling profile that might not always reflect a need for mitigation or elicit a timely reaction from farms to address potential hazards (Ref. 7), the approach we are finalizing here establishes requirements for measures that are directly responsive to the conditions identified as part of an assessment and requires that farms implement those measures within specific timeframes based on risk.

As noted in comment 11, our FRIA (Ref. 26) indicates that the increase in costs associated with this rule compared to the 2015 pre-harvest agricultural water testing requirements is largely a result of more mitigation occurring in response to findings from pre-harvest agricultural water assessments than as a result of the previous testing requirements. As also discussed in the FRIA, we estimate likely greater benefits under the requirements we are finalizing here, with more mitigation occurring in response to assessment findings than in response to the testing approach in the 2015 produce safety final rule.

(Comment 2) Some comments support the proposed requirements for pre-harvest agricultural water assessments, and further suggest that agricultural water assessments should be required for all agricultural water, including treated water, water from public water sources, water used for harvest and post-harvest activities, and for sprout irrigation water.

(Response 2) In light of these comments, we considered removing the proposed exemptions from the requirement to prepare an agricultural water assessment, including for water meeting certain requirements applicable to harvest and post-harvest agricultural water (proposed § 112.43(b)(1)); water from public water systems or supplies meeting certain requirements (proposed § 112.43(b)(2)); and agricultural water treated in accordance with § 112.46 (proposed § 112.43(b)(3)). However, we ultimately determined that eliminating the exceptions was not necessary, for the reasons described below.

Section 419 of the FD&C Act directs FDA to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act. Subpart E of the 2015 produce safety final rule establishes requirements that are broadly applicable to all agricultural water—namely, the requirement in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use, and the requirements in § 112.42 related to inspections and maintenance of agricultural water systems to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. We consider applying these requirements to all agricultural water (including that used during pre-harvest, harvest, and post-harvest activities, even if an exemption from other provisions in subpart E applies) as commensurate with the risk associated with the use of agricultural water for the growing, harvesting, packing and holding of covered produce.

With respect to comments about water from public water supplies, in the U.S., Public Water Systems are required under U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Regulations (NPDWR) in 40 CFR part 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination (Ref. 17). Similarly, public water supplies that meet the microbial requirement in § 112.44(a) are included in the exemption under proposed § 112.43(b)(2) (final § 112.45(b)(1)(ii)) to accommodate other public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of § 112.44(a). See also 78 FR 3504 at 3571. Given the nature of Public Water Systems and public water supplies meeting these requirements and the low likelihood of pathogen contamination of such systems, we consider it appropriate to exempt farms using such water sources as pre-harvest agricultural water for non-sprout covered produce from the requirement to prepare an agricultural water assessment under § 112.43 provided all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). (See § 112.45(b)(1)(ii) and by reference, § 112.44(c).) In light of the nature of these water sources, we have concluded that to require farms to prepare an agricultural water assessment for such water sources would be more than a science-based minimum standard as described in section 419 of the FD&C Act. We also note that the exemption for public water systems or public water supplies meeting the requirements in § 112.45(b)(1)(ii) is consistent with the exemption from the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule as well as the exemption at § 112.44(c)(1) and (2) from the requirement to test agricultural water used for sprout irrigation and for harvest and post-harvest activities for covered produce.

In consideration of the risks associated with agricultural water uses outlined in § 112.44(a) (including harvest and post-harvest agricultural water), we have also established requirements in subpart E specific to those uses. This includes a stringent microbial quality criterion of no detectable generic *E. coli* per 100 mL of agricultural water and a prohibition on the use of untreated surface water (§ 112.44(a)). We established requirements applicable to the water uses specified in § 112.44(a) in the recognition that such water uses have high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. See 80 FR 74354 at 74440. Moreover, we have established requirements in subpart E that are specific to agricultural water treatment. Specifically, § 112.46 establishes requirements related to treatment efficacy, delivery, and monitoring to ensure that treated agricultural water is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criterion in

§ 112.44(a), as applicable. We also note that with respect to treated agricultural water, an exemption for water treated in accordance with § 112.46 is consistent with the exemption from the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule as well as the exemption at § 112.44(c)(3) from the requirement to test agricultural water used for sprout irrigation and for harvest and post-harvest activities for covered produce.

We consider the requirements in subpart E that apply for agricultural water treatment, agricultural water used for sprout irrigation and harvest and post-harvest activities on covered produce, and public water systems and public water supplies meeting the requirements in § 112.44(c) to be reasonable and appropriate based on the risk associated with such water sources and practices. We do not consider it necessary or appropriate to require farms to prepare an agricultural water assessment for such water sources and practices, as doing so would be more than a science-based minimum standard as described in section 419 of the FD&C Act. Thus, we decline the request in the comments to broaden the provisions for agricultural water assessments in § 112.43 to apply to all agricultural water.

(Comment 3) While supportive of the general proposed approach for pre-harvest agricultural water assessments, some comments suggest that all farms should be required to test their pre-harvest agricultural water as one part of their agricultural water assessments. Several of these comments suggest that mandatory testing with assessments for all farms would help with objectivity and provide more certainty for farms and regulators. Some comments suggest that if testing is not required for all farms as part of an agricultural water assessment, farms may avoid testing water, lest the results show a need for treatment or other mitigation. Some comments suggest that farms should only be exempt from testing as part of an agricultural water assessment if they can demonstrate that testing is not necessary for public health purposes.

Conversely, some comments express support for what they consider to be a flexible approach to testing in the proposed rule, noting that they found the testing requirements in the 2015 produce safety final rule to be inflexible, expensive, cumbersome, and not risk-based. Some of these comments suggest that testing should not be required for all situations, and that mandatory testing for all farms would create unnecessary economic hardship for farms.

(Response 3) In light of these comments, we considered adding a requirement for all farms to test their pre-harvest agricultural water as one part of their agricultural water assessments. We considered the additional burden that would be imposed on farms by such a requirement and the impacts on public health that might result. For the reasons discussed below, we have concluded that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would be more than a minimum standard and more than what is reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act. Thus, we are retaining the requirements for agricultural water assessments and risk-tiered outcomes as proposed, including a requirement in § 112.43(c)(4) to test pre-harvest agricultural water as part of an assessment in certain circumstances.

First, a requirement for all farms to test pre-harvest agricultural water as one part of an assessment is not necessary given the nature of the potential sources of hazards for which immediate action is most critical to protect public health. For example, if a farm's agricultural water system was impacted by the presence of dead sheep in a canal or discharge of untreated sewage into a river, the outcome in § 112.43(c)(1), which requires immediate discontinuation of the relevant use(s) of the water and corrective measures prior to resuming that use, would apply, and agricultural water test results would be unlikely to provide information suggesting that those steps would not be appropriate or necessary to protect public health.

Moreover, requiring all farms to test in such circumstances could undermine public health protections by inadvertently providing farms with a false sense of security as to the quality of their water, potentially resulting in farms not taking action where necessary to protect public health. For example, throughout rulemaking for the 2015 produce safety final rule, we discussed the role of water testing when it comes to understanding and managing water quality, including various challenges with using test results as a direct indicator of the safety agricultural water (78 FR 3504 at 3561–3563; 80 FR 74354 at 74427–74428). Of particular note, we discussed that the presence of indicators does not always signal the presence of pathogens, and the absence of detection of indicators does not guarantee that pathogens are absent (Refs. 27–30). We also discussed that since sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Refs. 31 and 32), non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. 80 FR 74354 at 74428. We emphasized that we viewed the 2015 requirement outlining the GM and STV criteria as a water management tool for use in understanding the microbial quality of water over time and determining how to appropriately use water from that source, rather than as a direct indicator of the safety or adequacy of the sanitary quality of water for its immediate purposes. 80 FR 74354 at 74430. Further, we acknowledged that while testing water for pathogens allows for direct targeting of microorganisms in water that are a risk to public health, it can also present significant challenges, including those associated with large sample sizes, high costs, and the wide array of potential target pathogens (*i.e.,* the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See response to comment 91 and 80 FR 74354 at 74427–74428.

Indeed, these challenges with using water test results as a direct indicator of water safety, particularly when it comes to surface water sources, have long been recognized, even before FDA initiated rulemaking to establish the 2015 produce safety final rule (see 78 FR 3504 at 3561–64 and 3567–71 and references cited therein, for example). However, despite the historical record of these challenges, comments received for the current rulemaking indicate that some farms continue to believe that, even under the assessment framework, agricultural water test results should alone dictate the level of risk associated with a water system and whether action related to the farm's pre-harvest agricultural water is warranted (see comment 96). As such, we are concerned that—particularly in circumstances where quick action is most critical to protect public health (*i.e.,* those situations that would lead to the outcomes in § 112.43(c)(1) or (2))—a requirement for all farms to test their water as part of an assessment would result in some farms using test results inappropriately to justify not taking action, to the detriment of public health. Further, a requirement for all farms to test pre-harvest agricultural water as part of an assessment could undermine public health protections by 1) delaying discontinuance and necessary corrective action for water that is not safe or of

adequate sanitary quality for the intended use(s) (per § 112.43(c)(1)), and 2) delaying prompt implementation of mitigation measures to address conditions related to animal activity, BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands (per § 112.43(c)(2)).

Of particular note, when testing agricultural water, it can take time to develop a plan, collect samples, test the samples, and analyze the results in the context of the other information evaluated as part of an assessment—particularly when a farm is collecting samples over time to better understand the effects of certain conditions on water quality. As a result, if a farm initially identified a potential source of hazards as part of its assessment and were then to test the farm's agricultural water to better understand that condition, it could delay steps the farm takes to protect public health. This would be particularly problematic when it comes to conditions for which the outcomes in § 112.43(c)(1) and (2) are appropriate. While we considered whether to require farms to immediately discontinue the relevant use of the water until they have agricultural water test results demonstrating safety of the water, we determined that this, too, would not be in the best interest of public health due to the challenges discussed above with using testing results as a direct indicator of the safety of the water and that doing so may result in farms inappropriately using test results to justify not implementing necessary measures.

Moreover, we emphasize that for some farms, a requirement to test their pre-harvest agricultural water as one part of an assessment would impose significant burden without necessarily leading to additional public health benefits. For example, in preparing an agricultural water assessment, a farm that uses water from a pond as pre-harvest agricultural water might find that the pond is at a higher elevation than the surrounding land, and that conditions, such as large numbers of animals, are not present that would be reasonably likely to introduce known or reasonably foreseeable hazards. Depending on the circumstances, the farm might determine, along with the other factors evaluated under § 112.43(a), that the outcome in § 112.43(c)(3) is appropriate and that measures under § 112.45 are not reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces. Because test results would be unlikely to change the farm's determination in this (and similar) situations, and because the farm would not be implementing measures as a result of its assessment findings, requiring the farm to test would impose significant burden on the farm without providing added public health benefit.

In light of the concerns discussed above that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would provide farms with a false sense of security as to the quality of their pre-harvest agricultural water; delay or preclude action most critical to protect public health; and impose significant burden on farms without commensurate public health benefits, we have concluded that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would be more than a minimum standard and more than what is reasonably necessary to prevent introduction of hazards and provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act.

(Comment 4) Some comments suggest that farms should be subject to different requirements depending on the risk associated with their crop, water source, or water use practices (such as the method and timing of water application). For example, several comments suggest that farms that grow certain low-risk crops or that use low-risk irrigation methods should be exempt from preparing an agricultural water assessment and/or from testing their agricultural water. Some comments suggest that farms growing low-risk crops and using low-risk water sources should be allowed to choose whether to conduct agricultural water testing, agricultural water systems inspections under § 112.42(a), or a combination of the two, while those growing higher-risk covered produce or using higher-risk water should be required to conduct both.

(Response 4) This rule, and the produce safety rule of which it is a part, acknowledges and differentiates requirements as appropriate based on the varying risks presented by different crops, water sources, and water use practices. For example, the requirements for agricultural water in subpart E do not apply to water that is not intended to, or not likely to, contact covered produce or food-contact surfaces because we previously concluded that applying the requirements in subpart E to such water is more than what is reasonably necessary for us to require to achieve statutory purposes set forth in section 419 of the FD&C Act (that is, it is not reasonably necessary to apply the requirements to such water to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated). 80 FR 74254 at 74429.

However, we decline to establish differing requirements for pre-harvest agricultural water based on crop, water source, and/or agricultural water use practices alone.[5] The QAR (Ref. 17) concluded that using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne illness outbreak. Rather, the specific conditions and practices associated with a produce commodity also influence the potential routes of contamination and the likelihood that a given route could lead to contamination and illness. Additionally, with respect to water sources, the QAR (Ref. 17) concluded that the microbial quality of source water is one of the key determinants in assessing the relative likelihood of contamination attributable to agricultural water. While noting that surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources, the QAR also concluded that though less likely to be contaminated than surface water, ground water continues to pose a public health risk, despite the regulation of many U.S. public wells under the Ground Water Regulation. Moreover, ground water sources (such as some wells) may contain deficiencies which, if left uncorrected, can result in hazards being introduced to the water source (Ref. 17).

While we continue to include agricultural water systems, water use practices, and crop characteristics as factors that farms must consider as part of their pre-harvest agricultural water assessments under § 112.43, we emphasize that this information must be considered in concert with the other factors of the systems-based assessment identified in § 112.43(a)(1) through (5). While we have incorporated testing agricultural water as part of a pre-harvest agricultural water assessment under § 112.43(c)(4), farms must not rely on test results alone in making decisions around the safe use of their agricultural

[5] We note that because sprouts present a unique safety risk, the final 2015 produce safety final rule established sprout-specific requirements on multiple topics, including agricultural water. The agricultural water requirements for sprouts are different from the agricultural water requirements for other produce commodities (for example, sprout irrigation water is subject to the microbial criterion and testing requirements in § 112.44(a) and (b)).

water. Rather, results from pre-harvest agricultural water testing serve as an additional source of information for farms to consider alongside the other factors evaluated in § 112.43(a)(1) through (5) in making a determination as to whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with biological hazards associated with agricultural water. See also response to comment 83.

(Comment 5) Several comments request that FDA modify various requirements (such as the requirements for mitigation measures in § 112.45(b), and the definition of ''agricultural water assessment'' in § 112.3) so that farms may consider strategies or other practices already being implemented to control hazards with respect to agricultural water.

(Response 5) We agree that strategies or practices a farm is already implementing to control potential hazards may affect whether a condition is reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. Further, farms must consider such strategies or practices in complying with various agricultural water requirements. For example, farms must consider the degree of protection of their agricultural water system under § 112.43(a)(1); this includes a situation in which a farm has a berm established that prevents runoff (which may contain hazards) from being introduced to an agricultural water system. As another example, farms must consider their agricultural water practices under § 112.43(a)(2); this includes a situation in which a farm only applies agricultural water from a certain water source to non-sprout covered produce early in the growing season. Farms must consider the relevant strategy or practice, along with the other information evaluated under § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. As farms must consider such strategies or practices they are currently implementing in complying with the requirements for pre-harvest agricultural water assessments, we do not consider it necessary to revise the requirements related to agricultural water to further emphasize the point.

(Comment 6) Several comments seek clarity on what is expected of farms in terms of assessing water that is outside the scope of ''agricultural water.'' A few comments express concern that in some of the outbreaks cited in the 2021 agricultural water proposed rule, the water used to grow the produce would not have been subject to the requirements in the proposed rule.

(Response 6) We define agricultural water in § 112.3, in part, as ''water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces.'' If a specific use of water does not fit within the definition of agricultural water, then the requirements in subpart E, including those for pre-harvest agricultural water assessments for non-sprout covered produce, do not apply to that specific use of water. See 80 FR 74354 at 74429.

With respect to comments related to the outbreaks referenced in the 2021 agricultural water proposed rule (86 FR 69120 at 69125–69127) (Refs. 18–23), we acknowledge that a definitive source or route of contamination of the implicated produce could not always be determined. Nevertheless, findings from these outbreaks underscore the potential impacts of adjacent and nearby land uses on agricultural water, which we designed the requirements for pre-harvest agricultural water assessments, in part, to address. See 86 FR 69120 at 69125–69127 and responses to comment 16 and comment 56.

(Comment 7) A few comments state that produce contamination can be attributed to more than agricultural water (*e.g.,* airborne transmission or long-term persistence in soil) and request that FDA include these other methods of pathogen transmission in the proposed rule.

(Response 7) We agree that produce can become contaminated through various routes, including those other than water (Ref. 17). As such, the 2015 produce safety final rule focuses on major routes of microbial contamination—including agricultural water; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools. This rulemaking, however, focuses specifically on certain requirements in Subpart E of that regulation relating to agricultural water.

(Comment 8) A few comments argue that the scope of the proposed rule is too narrow and FDA should include chemicals and biological toxins in the requirements for agricultural water assessments, since, the comments suggest, these agents pose a potential toxic disease risk to humans. Some comments seek clarity regarding what testing, if any, is expected for non-microbial contaminants, such as heavy metals and chemicals.

(Response 8) We disagree with suggestions to expand the scope of hazards covered by the rule. Section 419(c)(1)(A) of the FD&C Act requires that the 2015 produce safety final rule set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act. This language provides FDA with discretion to determine what procedures, processes, and practices are ''reasonably necessary'' for the purposes identified in the statute with respect to the identified types of hazards.

As discussed in the 2015 produce safety final rule, FDA carefully considered different types of hazards and determined that the available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. On that basis we concluded that it was appropriate to establish the 2015 produce safety final rule to cover biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (80 FR 74354 at 74377). Foodborne illness attribution data reported by the Interagency Food Safety Analytics Collaboration (IFSAC) (Refs. 33–35), a tri-agency group created by the Centers for Disease Control and Prevention (CDC), FDA, and U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service, reinforce the significance of biological hazards in produce. See also comment 13.

As further explained in the 2015 final rule, although the potential exists for physical or chemical (including radiological) hazards to contaminate produce, our analysis led us to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. Chemical and physical hazards in produce: (1) occur only rarely at levels that can pose a risk of serious adverse health consequences

or death (*e.g.,* radiological contamination as a result of a nuclear power plant accident); (2) occur with greater frequency, but rarely at levels that can pose a risk of serious adverse health consequences or death (*e.g.,* pesticide or mycotoxin residues); or (3) occur infrequently and usually do not pose a risk of serious adverse health consequences or death (*e.g.,* physical hazards). Moreover, there are other programs in place for monitoring and/or controlling physical and chemical hazards that may contaminate produce. These programs include FDA's routine monitoring of chemical and pesticide residues, other FDA efforts (such as Closer to Zero to address environmental contaminants in food [6]), EPA's registration of pesticides, and various State and industry initiatives. In light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards, we concluded that it was not reasonably necessary to establish controls for physical or chemical hazards in the 2015 produce safety final rule. See 80 FR 74354 at 74376–74379.

We note that comments on the 2021 agricultural water proposed rule did not include data or other information demonstrating a need to expand the scope of the pre-harvest agricultural water requirements for covered produce other than sprouts to include chemical and physical hazards, nor is FDA aware of any such data or information. Therefore, we conclude that expanding the scope of the pre-harvest agricultural water requirements for covered produce other than sprouts is not reasonably necessary.

(Comment 9) Some comments seek clarity on which requirements of Subpart E the proposed rule supersedes or replaces.

(Response 9) As finalized with this rule, we are reorganizing subpart E in its entirety to group similar requirements. We note in particular that with this final rule, we are replacing §§ 112.44(b) and 112.46(b) in the 2015 produce safety final rule (microbial criteria and testing requirements, respectively, for pre-harvest agricultural water for covered produce other than sprouts) with requirements for written pre-harvest agricultural water assessments. While the requirement numbers may have changed for agricultural water used for sprouts; agricultural water used during harvesting, packing, and holding activities; and for treatment of agricultural water, this final rule does not substantively alter those standards as established in part 112, subpart E.

Table 3 summarizes the major changes made to the agricultural water provisions in subpart E between the 2015 produce safety final rule and this final rule, including the location of the relevant requirements. The second column does not reflect technical edits made to provisions that were designed to provide added clarity (for example, edits to add descriptive headings). While not reflected in the table below, conforming changes are also being made to §§ 112.12, 112.151, and 112.161(b) in light of our revisions to the microbial water quality criteria in § 112.44(b), the microbial die-off (calculated log reduction) rate in § 112.45(b), and the testing requirements in § 112.46(b) as set forth in the 2015 produce safety final rule. As discussed in sections V.A., we received no comments on these conforming changes and are finalizing them without changes.

TABLE 3—SUMMARY OF CHANGES MADE TO SUBPART E REQUIREMENTS SINCE THE 2015 PRODUCE SAFETY FINAL RULE

Subpart E provisions in the 2015 produce safety final rule	Changes made with this final rule	Location of relevant provision as established with this final rule
§ 112.41: All agricultural water must be safe and of adequate sanitary quality for its intended use.	None	§ 112.41.
§ 112.42: Regularly inspect and maintain all agricultural water systems and implement measures to reduce potential for contact between covered produce and pooled water.	None	§ 112.42.
§ 112.43: If treating agricultural water, ensure that the treatment is effective and that treatment is delivered and monitored appropriately.	None	§ 112.46.
§ 112.44(a): Ensure that water used for certain purposes (for example, for sprouts and for harvest and post-harvest uses) contains no detectable generic *E. coli* per 100 mL and not use untreated surface water for such purposes.	None	§ 112.44(a).
§ 112.44(b): Ensure that water used during pre-harvest activities for covered produce (other than sprouts) meets a GM of 126 generic *E. coli* per 100 mL and a STV of 410 generic *E. coli* per 100 mL.	Replaced with provisions for pre-harvest agricultural water assessments and risk management determinations, with a requirement to test in certain circumstances.	§ 112.43.
§ 112.45(a): Immediately discontinue use (and take corrective measures prior to resuming use) if water is not safe or is not of adequate sanitary quality or if the microbial criterion of no detectable generic *E. coli* per 100 mL is not met for certain uses of water.	None	§ 112.45(a).
§ 112.45(b): Implement risk-reduction measures as soon as practicable but no later than the following year if the GM and STV microbial criteria in § 112.44(b) are not met for pre-harvest water uses for non-sprout covered produce.	Removed pre-harvest microbial criteria and revised to account for pre-harvest agricultural water assessments; expanded measures to include the flexibility to change the water application method to reduce the likelihood of contamination of covered produce or to use an alternative mitigation measure; added expedited timing for mitigation related to certain uses of adjacent and nearby lands.	§ 112.45(b).
§ 112.46(a): There is no requirement to test if farms can demonstrate that water: comes from a Public Water System that meets Safe Drinking Water Act regulations; comes from a public water supply that meets the microbial criterion in § 112.44(a); or is treated in accordance with § 112.43.	Added similar exemptions from the requirements for a written pre-harvest agricultural water assessment.	§ 112.44(c) for exemptions from testing water for uses specified in § 112.44(a); § 112.43(b) for exemptions from requirements for pre-harvest agricultural water assessments.

[6] See ''Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods'' at *https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods.*

TABLE 3—SUMMARY OF CHANGES MADE TO SUBPART E REQUIREMENTS SINCE THE 2015 PRODUCE SAFETY FINAL RULE—Continued

Subpart E provisions in the 2015 produce safety final rule	Changes made with this final rule	Location of relevant provision as established with this final rule
§ 112.46(b): For untreated surface water sources used for pre-harvest applications for non-sprout covered produce, establish an initial MWQP with ≥20 samples collected over 2–4 years and update with ≥5 samples per year thereafter; for untreated ground water sources, establish an initial MWQP with ≥4 samples collected over 1 year and update with ≥1 sample per year thereafter.	Replaced with provisions for pre-harvest agricultural water assessments, with a requirement to test in certain circumstances.	§ 112.43.
§ 112.46(c): For untreated ground water used for certain uses in § 112.44(a), initially test ≥4 samples over the course of 1 year and ≥1 sample per year thereafter.	None	§ 112.44(b).
§ 112.47: Ensure that testing is done by the farm or other entity or third-party acting on its behalf, and that water samples be aseptically collected and tested using a method set forth in § 112.151.	None	§ 112.47.
§ 112.48: For water used during harvest, packing, and holding activities, ensure that: water is managed as necessary (such as by establishing and following water change schedules); water is visually monitored for buildup of organic material; and an appropriate temperature differential between the commodity and the water is maintained and monitored.	None	§ 112.44(d).
§ 112.49: For pre-harvest water for non-sprout covered produce, farms may establish alternative microbial criteria, sampling frequencies for untreated surface water sources, or die-off rates between last direct water application and harvest so long as certain requirements are met.	Replaced with provision allowing for alternative mitigation measures to those listed in § 112.45(b)(1)(i) through (v).	§ 112.45(b)(1)(vi).
§ 112.50: Maintain certain records related to the farm's agricultural water, including test results.	Added recordkeeping requirements related to pre-harvest agricultural water assessments; conforming changes to remove records related to microbial criteria and testing for pre-harvest agricultural water.	§ 112.50.

2. Scientific and Public Health Support

(Comment 10) Some comments express concern that FDA lacks scientific support for the proposed rule. Of these, some comments raise general concerns about the state of the science on pre-harvest agricultural water quality as a basis for rulemaking. Other comments focus on the science relating to specific requirements, such as the assessment of crop characteristics, environmental conditions, and potential impacts of cattle operations on adjacent and nearby land, as well as the application of a pre-harvest time interval as a mitigation measure. These include comments focused on how farms will implement the rule with an emphasis on the need for scientific research reflecting real-world conditions for farms in various circumstances.

(Response 10) We disagree with the suggestion that the requirements for pre-harvest agricultural water assessments and risk-tiered outcomes lack scientific support. We address comments on the scientific support for specific provisions in relevant sections of this document. See, for example, comment 16 for discussion of comments of the scientific evidence on potential risks posed by cattle operations and other animal activities on adjacent and nearby lands. We address comments on the scientific support for crop characteristics and environmental conditions as assessment factors in comment 63 and comment 68, respectively. Comment 114 discusses comments on the scientific basis for the 4-day pre-harvest time interval as a mitigation measure.

FDA outlined the history of contamination associated with produce, predominantly during growing, harvesting, packing, and holding, during the rulemaking to establish the 2015 produce safety final rule in part 112. See, for example, 78 FR 3504 at 3507 and 80 FR 74354 at 74731. As part of that rulemaking, we also developed a peer-reviewed QAR, which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). With respect to water used during growing, harvesting, and post-harvesting activities, the QAR concludes in part that agricultural water can be a source of contamination of produce and that the microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices. The QAR also concludes that while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. See also 86 FR 69120 at 69128.

Scientific information has also become available since FDA issued the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5–10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Additionally, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Specifically, Havelaar et al. found that the 20-sample MWQP for untreated surface water was not sufficient to reliably characterize the quality of the irrigation water with higher variability in generic *E. coli* levels than assumed in the 2015 produce safety final rule. In simulation modeling, the rolling 20-sample MWQP responded ''very slowly'' to shifts in water quality. Increases in generic *E. coli* levels were detected only after one to six sample sets, thus delaying signals of changes in water quality and (and any needed measures) by one to six years depending on the nature and magnitude of the shift. Havelaar et al. suggested that additional understanding of the processes that drive variability in the

quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements.

Moreover, we have extensively discussed other information that has become available since 2015, such as findings from several produce-related outbreak investigations, that support this rulemaking. In particular, in the 2021 agricultural water proposed rule, we discussed: (1) the spring 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from the Yuma growing region (Refs. 18 and 19); (2) the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20); (3) the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21); (4) the fall 2020 *E. coli* O157:H7 outbreak linked to leafy greens (Ref. 22); and (5) the summer 2020 *Salmonella* Newport outbreak linked to red onions (Ref. 23); that highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water. These outbreak investigations underscore decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. 86 FR 69120 at 69125–69127. We also discussed foodborne illness attribution data reported by IFSAC (Ref. 33), a triagency group created by the CDC, FDA, and the USDA Food Safety and Inspection Service, that reinforce the significance of biological hazards in produce. 86 FR 69120 at 69127. See also comment 13.

Comments did not indicate what data or information they considered to be lacking or provide information that alters FDA's conclusions made in light of the information referenced above. As such, we have concluded that the scientific information available supports this rulemaking and are finalizing the requirements for pre-harvest agricultural water assessments for non-sprout covered produce. However, we recognize that additional information on the requirements for agricultural water in subpart E will help support farms as they work to come into compliance. We provide information on the agricultural water requirements throughout this final rule, and, to the extent that certain requirements are not substantively changing with this rulemaking (such as the requirements in § 112.42 for agricultural water system inspection and maintenance), in the preamble to the 2015 produce safety final rule. Additionally, we recognize the need to provide farms with education, outreach and technical assistance to facilitate compliance with the rule, and we intend to pursue various mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including work with other stakeholders (such as State agencies, educators, and extension agents), to do so.

(Comment 11) Some comments express concern that FDA changed the pre-harvest microbial quality and testing requirements in the 2015 produce safety final rule in response to industry concerns, rather than in an effort to improve public health.

(Response 11) We are issuing this final rule having determined that it will enhance public health protections by setting forth requirements for comprehensive, systems-based agricultural water assessments evaluating a broad range of factors that may impact the quality of pre-harvest agricultural water to assist farms in identifying and managing risks using appropriate corrective and mitigation measures, including expedited mitigation in certain circumstances. As discussed in the proposed rule, this comment response, and elsewhere in this rule, these revisions to the 2015 produce safety final rule reflect findings of our QAR (Ref. 17), new information we have gathered since publication of the 2015 produce safety final rule (including findings from several produce-related outbreaks), as well as information and feedback from an array of stakeholders, including the produce industry, educators, researchers, and regulators. As discussed in response to comment 1, we continue to conclude that the requirements for systems-based agricultural water assessments and risk-management determinations are consistent with our mandate to establish science-based minimum standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death. As such, we disagree with comments suggesting that we are making these revisions to the 2015 produce safety final rule in response to industry concerns alone, and not in an effort to improve public health.

As part of rulemaking for the 2015 produce safety final rule, we developed a peer-reviewed QAR (Ref. 17), which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). In part, the QAR discusses that public drinking water is generally considered the least likely to serve as a source of contamination, followed by ground water, surface water protected from runoff, and surface water unprotected from runoff. The QAR also notes that where contamination in a water source is known to exist, the likelihood of contamination is a function of contact with the commodity (example, whether contact is indirect or direct); commodity effects (characteristics) (for example, whether the surface is conducive to adhesion); and application timing (for example, early or late in crop growth). These factors—the water source, method and timing of water application, and commodity characteristics—are all reflected in the requirements for comprehensive agricultural water assessments under § 112.43(a) due to the impact they can have on risk associated with pre-harvest agricultural water use.

Further, findings from investigations of several outbreaks linked to consumption of produce that have occurred since 2015 (Refs. 18–23) highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water. These outbreak investigations underscore decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. 86 FR 69120 at 69125–69127. Findings from our investigations into these outbreaks also informed the requirements that we are finalizing here—in particular, the requirement in § 112.43(c)(2) for expedited mitigation for conditions related to animal activity, BSAAOs, and untreated or partially treated human waste associated with adjacent and nearby lands.

With respect to feedback from stakeholders in the regulated community, as described further in response to comment 14, we designed the requirements for pre-harvest agricultural water assessments, in part, by taking into account the realities of many agricultural operations that resulted in the 2015 pre-harvest agricultural water testing requirements being challenging, and in some cases, impossible, for farms to implement. For example, while the long-term MWQPs required in the 2015 produce safety final rule can be difficult, and even impossible, to establish for farms that grow rotational crops or on leased land, we have incorporated flexibility in the requirements for the once-annual assessments we are finalizing with this rule to allow farms to account for these realities, which will assist farms in better evaluating and making decisions

regarding the use of pre-harvest agricultural water as appropriate to their unique operations and circumstances.

However, we emphasize that this rule is reflective of information and insights from stakeholders beyond just the regulated industry. For example, the pre-harvest agricultural water requirements were the focus of a 2-day Agricultural Water Summit, convened by the Produce Safety Alliance, in February 2018 (Ref. 4). The summit was attended by academics, produce industry, growers/grower associations, State agencies, Federal agencies, and supporting industries. During the summit, participants had many questions and concerns about water testing, what the information tells them about risks, and how to use that information to make water use management decisions. Participants also had questions about the generic *E. coli*-based standards in the 2015 produce safety final rule and suggested that the testing frequency required to establish a MWQP for surface or ground water sources lacked the necessary science to support its relevance to public health outcomes. Many of the discussions at the summit addressed hazards in the growing environment, including examples of how risk assessment has been conducted in other fields of study, such as for drinking water and wastewater management. During the summit, participants identified ''agricultural water assessments'' as a promising approach for managing water quality, suggesting that assessments may provide a more effective risk management strategy to farms than a numerical testing standard can provide.

Additionally, information has become available since issuing the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5–10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies have further contributed to our knowledge about the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11–16). Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Havelaar et al. suggested that while increasing the number of samples might address these issues, doing so would increase costs and would not be an effective or efficient way to control the microbial quality of agricultural water sources. Rather, they suggested, additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements (Ref. 7).

While we established the 2015 pre-harvest agricultural water testing requirements as a long-term strategy to ensure that farms understand the quality of their water, pay attention to changes that may affect water quality, and make appropriate decisions about use of that water (80 FR 74354 at 74458), we recognize that if farms focus too heavily on results of microbial testing and whether quantitative metrics are met, they may be left with a false sense of security as to the quality of their water, and as a result, not investigate for conditions that may warrant further action to protect public health. Indeed, rather than relying on results of a multi-year rolling profile that might not always reflect a need for mitigation or elicit a timely reaction from farms to address potential hazards (Ref. 7), the approach we are finalizing here establishes requirements for measures that are directly responsive to the conditions identified as part of an assessment and requires that farms implement those measures within specific timeframes based on risk. Further, as our FRIA indicates (Ref. 26), the increase in costs associated with this rule compared to the 2015 pre-harvest agricultural water testing requirements is largely a result of more mitigation occurring in response to findings from pre-harvest agricultural water assessments than as a result of the previous testing requirements. As also discussed in the FRIA, we estimate likely greater benefits under the requirements we are finalizing here, with more mitigation occurring in response to assessment findings than in response to the testing approach in the 2015 produce safety final rule.

In light of the foregoing, we disagree with comments suggesting that we are replacing the previous pre-harvest agricultural water testing requirements with requirements for agricultural water assessments and risk-management determinations in response to industry concerns alone, and not in an effort to improve public health. We continue to consider it appropriate to pursue an alternative approach to the 2015 pre-harvest agricultural water testing requirements that protects public health and is adaptable for use in diverse circumstances. As such, with this rule, we are replacing the pre-harvest agricultural water testing requirements in the 2015 produce safety rule for covered produce other than sprouts with requirements for systems-based agricultural water assessments that are designed to achieve improved public health protections, while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science.

3. Options for Regulatory Approach

(Comment 12) A few comments suggest that issuing guidance would be a more appropriate approach to addressing pre-harvest agricultural water than rulemaking.

(Response 12) As discussed in the 2021 agricultural water proposed rule, FDA considered various options to address stakeholder concerns about complexity and practical implementation challenges with the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule, one of which entailed developing additional guidance to support the requirements that were outlined in the 2015 produce safety final rule. We concluded that issuing additional guidance alone would not adequately address the practical implementation issues associated with the pre-harvest agricultural testing requirements in the 2015 produce safety final rule. For example, we contemplated issuing additional guidance to describe circumstances in which farms might satisfy the pre-harvest sampling and testing requirements through shared data with other farms. However, there are several limitations with this option, including challenges related to establishing data-sharing arrangements and difficulties in establishing such programs given the diversity of agricultural water systems and the 2015 requirements related to sample collection timing. Moreover, guidance alone could not overcome difficulties related to rotational crops or growing non-sprout covered produce on leased land, in which a farm may not be using (or have access to) the same water source over multiple years. See also response to comment 14. Further, while subpart P of the 2015 produce safety final rule allows requests for variances from one or more requirements of part 112, under § 112.171, only States, Federally recognized tribes, or countries from which food is imported into the

United States are able to make such a request. See 86 FR 69120 at 69129.

Comments received on the 2021 agricultural water proposed rule do not provide new information on overcoming these practical implementation challenges through the issuance of guidance alone. As such, we have concluded that guidance alone would not adequately address the practical implementation issues associated with the pre-harvest agricultural testing requirements in the 2015 produce safety final rule.

(Comment 13) Some comments state that FDA did not directly address why the option to conduct a risk assessment and research followed by rulemaking was not chosen, suggesting that the Agency moved forward with the proposed rule despite lacking sufficient information.

(Response 13) As discussed in the 2021 agricultural water proposed rule, FDA considered whether to conduct another risk assessment, followed by a rulemaking to revise the pre-harvest agricultural water testing requirements. We also considered whether to issue guidance on pre-harvest agricultural water based on industry standards while additional research is conducted, followed by rulemaking to revise the pre-harvest agricultural water testing requirements. For the reasons discussed below, we continue to conclude that it is not necessary for additional risk assessment or research to take place before conducting or finalizing this rulemaking.

As part of the rulemaking to establish the 2015 produce safety final rule in part 112, we developed a peer-reviewed QAR, which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). In considering the option to conduct a risk assessment or additional research followed by a rulemaking to revise the pre-harvest agricultural water testing requirements, FDA reviewed the conclusions of the QAR. With respect to water used during growing, harvesting, and post-harvesting activities, the QAR concludes as follows:

- Agricultural water can be a source of contamination of produce.
- Public drinking water systems (domestically regulated by the EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.
- Though less likely to be contaminated than surface water, ground water continues to pose a public health risk, despite the regulation of many U.S. public wells under the Ground Water Regulation.
- There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.
- Susceptibility to runoff significantly increases the variability of surface water quality.
- Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.
- Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.
- Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.
- Commodity type (growth characteristics, *e.g.,* near to ground) and surface properties (*e.g.,* porosity) affect the probability and degree of contamination.
- Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

The QAR (Ref. 17) discusses that potential contributing factors cited in produce-associated outbreaks where water was identified as the likely source of contamination include runoff from nearby animal pastures and feed lots, raw sewage, and surface waters contaminated with feces (Ref. 36).

We have also considered scientific information that has become available since issuing the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5–10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies have contributed to our knowledge about the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11–16). Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Havelaar et al. suggested that additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements.

In addition to the findings from the QAR and scientific information on the previous pre-harvest agricultural water testing requirements that has become available since 2015, we considered conclusions from the 2019 IFSAC report (Ref. 33), and more recently, the 2020 and 2021 IFSAC report (Refs. 34 and 35, respectively), which reinforce the significance of biological hazards in produce. We also considered FDA's experience with investigations of produce-related outbreaks that occurred since we issued the 2015 produce safety final rule (Refs. 18–23), which underscore the importance of pre-harvest agricultural water quality and highlight the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. 86 FR 69120 at 69125–69127. These sources of information helped to inform the requirements we are finalizing here—in particular, the requirement for expedited mitigation for known or reasonably foreseeable hazards related to certain activities associated with adjacent or nearby lands in light of findings from several produce outbreak investigations—and further support the conclusions of our QAR (Ref. 17). See also response to comment 10.

Commenters did not indicate what data or information they felt was lacking regarding the option to conduct an additional risk assessment, nor did they provide information demonstrating that our conclusions in the proposed rule regarding that option were inappropriate. Therefore, we continue to conclude that it is not necessary for FDA to conduct an additional risk assessment or research before conducting rulemaking to establish new pre-harvest agricultural water standards. Further, given that the requirements for assessments are well-grounded in science, we do not consider it necessary to establish interim guidance based on industry standards in lieu of the requirements we are finalizing here.

While we do not consider it necessary to conduct additional risk assessment or research in order to establish standards for pre-harvest agricultural water, we note that the requirements for agricultural water assessments are designed, in part, to be adaptable to scientific advancements. To the extent

that risk assessment and/or additional research related to pre-harvest agricultural water may continue to develop in the future, farms may use such information as an additional resource to further inform their agricultural water assessments under the approach we are finalizing here.

(Comment 14) A few comments express a preference for pre-harvest agricultural water testing requirements in the 2015 produce safety final rule compared to the proposed pre-harvest agricultural water assessments because, the comments suggest, many farms have already worked towards compliance with the 2015 testing requirements.

(Response 14) We understand that not all farms may have faced challenges with the pre-harvest microbial quality and testing requirements in the 2015 produce safety final rule. However, in light of frequent, consistent feedback from industry stakeholders regarding challenges associated with the pre-harvest microbial quality and testing requirements, as well as information and insights from other relevant stakeholders (such as academic researchers), findings of our QAR (Ref. 17), and new information gathered since publication of the 2015 produce safety final rule, we concluded that the most appropriate regulatory approach is to undertake rulemaking. See 86 FR 69120 at 69129–69130. As discussed further in response to comment 10, we continue to consider it appropriate to pursue and finalize an alternative approach that is adaptable for use in diverse circumstances. Thus, we are finalizing requirements for pre-harvest agricultural water assessments that are designed to achieve improved public health protections, while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science. We designed the requirements for pre-harvest agricultural water assessments to be flexible to account for the diversity of water systems, commodities, and operations that exist across industry, which included, as discussed below, taking into account the realities of many agricultural operations that resulted in the 2015 pre-harvest agricultural water testing requirements being challenging, and in some cases, impossible, for farms to implement.

For example, feedback on the 2015 pre-harvest agricultural water testing requirements indicated that long-term MWQPs can be difficult, and even impossible, to establish for farms that grow rotational crops or on leased land, both of which are widespread throughout the produce industry (Refs. 3 and 4). It has further been suggested that the financial investment needed to develop a long-term profile for a water source that is only used every few years may not result in commensurate food safety benefits (Ref. 4). Conversely, the requirements for once-annual assessments that we are finalizing here incorporate flexibility to allow farms to account for these realities. Such flexibility will assist farms in better evaluating and making decisions regarding the use of pre-harvest agricultural water as appropriate to their unique operations and circumstances, allowing risk-management decisions to be made even in the absence of historical knowledge of a water system. See also comment 35.

Farms with multiple water sources, for example, would face significant logistical challenges in complying with the 2015 testing requirements, since separate MWQPs would be required for each source (Ref. 4). These challenges would be particularly difficult to navigate for farms that grow multiple types of covered produce using different water application timings, given the 2015 requirements for samples to be representative of use and collected as close in time as practicable to, but prior to, harvest. As discussed further in response to comment 34, while we acknowledge that farms using multiple agricultural water systems during pre-harvest activities for covered produce (other than sprouts) will need to conduct an assessment for each system, several of the factors evaluated in the assessment might be similar across agricultural water systems, thus limiting the amount of information a farm needs to collect and consider. Further, the pre-harvest agricultural water assessments enable farms to focus on the key determinants of contamination risks, without doing so in a way that will add significant burden to stakeholders.

Additionally, while data-sharing is one way that implementation challenges associated with 2015 pre-harvest agricultural water testing requirements may have been reduced, such data-sharing programs among multiple parties could be difficult (or impossible) to establish due to the aforementioned 2015 requirements for samples to be representative of use and collected close to harvest (Refs. 3 and 4). Conversely, the requirements for pre-harvest agricultural water assessments were built to be flexible enough for farms to consider and adjust for their unique circumstances without having to rely on others' actions in order to make use of the inherent flexibility. Moreover, because farms that test their water in accordance with § 112.43(c)(4)(ii) will be testing to better understand a narrow set of circumstances using an approach that incorporates greater flexibility related to sample collection requirements, concerns about testing burden associated with the 2015 pre-harvest agricultural water testing requirements are largely addressed with this rule.

Thus, although we recognize that some farms may not have faced practical implementation challenges with the 2015 pre-harvest agricultural water testing requirements, we continue to conclude that the requirements for pre-harvest agricultural water assessments achieve public health protections, while also being more feasible to implement across the diversity of farms and their agricultural water systems, uses, and practices. To the extent that some farms may be testing their pre-harvest agricultural water using the 2015 (or other) approach, we emphasize that nothing in this rule precludes them from continuing to do so, as long as they also comply with the requirements we are finalizing here, as applicable.

4. Responsibility

(Comment 15) Some comments, while generally supportive of the proposed pre-harvest agricultural water assessments, voice concern that farms will be required to account for and manage hazards that are outside the farm's control (for example, hazards that may be introduced by other water users or adjacent and nearby land uses). Some comments indicate that the Clean Water Act (CWA) requires State and/or Federal governments to hold polluters accountable, suggesting that it is therefore unjust to place that responsibility on farms. One comment suggests that irrigation districts should not allow livestock to graze in open drains, as doing so will introduce risk for downstream users who do not have control over that activity.

(Response 15) We recognize that farms may have little or no control over factors such as weather events, other water users, and adjacent and nearby lands. However, considering factors such as these, which may affect the quality of water source(s) even though they are not necessarily under a farm's control, is an important part of evaluating whether a farm's water source(s) meets the requirement in § 112.41 that agricultural water must be safe and of adequate sanitary quality for its intended use. Considering these factors under § 112.43(a), will help farms determine the appropriate and safe use of the agricultural water from their water source(s).

Further, we recognize that the CWA (33 U.S.C. 1251 *et seq.*) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters (Ref. 37). Under the CWA, the EPA has implemented pollution control programs and developed national water quality criteria recommendations for pollutants in surface waters. We recognize that hazards may be introduced into an agricultural water system under conditions that may or may not be covered by the CWA and that in many instances, this may occur before an agricultural water system comes under a farm's control. We emphasize that farms are not required to mitigate such hazards at the location where they originate, nor are farms expected to take action against other entities that may be introducing contaminants into a water system. Rather, farms are required to assess potential impacts from activities on nearby and adjacent lands and/or other water users on the quality of their agricultural water and, as appropriate, implement measures that are under the farm's control to reduce the risk associated with that water source or system to protect public health. For example, depending on the circumstances, this might entail the use of earthen berms on land that is under the farm's control to divert runoff from a nearby land use from entering the farm's surface water source. See also response to comment 105.

Additionally, we recognize the need to provide farms with outreach and education to facilitate compliance with the rule, including in those situations where hazards may originate outside of a farm's control. We are also aware of efforts underway to bring together members of agricultural communities on a large scale to further conversations and encourage discussions between land users in agricultural areas. For example, the California Agricultural Neighbors (CAN) Initiative is designed to provide an opportunity to foster collaboration and discuss enhanced neighborly food safety practices when various agricultural operations such as leafy green fields, cattle ranches, vineyards and compost sites are adjacent to one another (Ref. 38). Various action items have been identified as part of CAN, one of which entails steps that can be taken to foster neighbor-to-neighbor interactions and conversations (Ref. 39). See also response to comment 33. As efforts such as these progress, farms may consider participating as an additional means to help address crosscutting food safety issues.

(Comment 16) Some comments suggest that cattle producers will be negatively impacted by the requirement that farms assess the use of nearby and adjacent land. These comments suggest that the proposed rule implies that adjacent or nearby cattle operations increase food safety risks for produce farms without sufficient scientific justification. Comments also request clarification that cattle operations are not required to change practices in order to assist produce farms in complying with the rule.

(Response 16) As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69135–69136), it is well established in the literature that animal activities on adjacent and nearby lands—including grazing, livestock operations, and wildlife intrusion—may introduce contamination to surface and ground water through runoff and through direct access by animals to waterways (Refs. 40–43). Moreover, we discussed in the proposed rule various produce related outbreaks (Refs. 18–22) in which investigators noted presence of concentrated animal feeding operations (CAFOs) or cattle grazing operations as potential sources of contamination to agricultural water systems and covered produce. See 86 FR 69120 at 69125–69127. In light of this information and findings from several produce related outbreaks, we consider it important for farms to evaluate animal impacts and activities in identifying conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces as part of their agricultural water assessments.

We acknowledge the longstanding colocation of animals and plant food production systems in agriculture and note that this rule does not prohibit the presence of animals on or near a farm, nor does it establish requirements or responsibilities for entities other than farms covered by the rule. Rather, the rule requires a farm to conduct an agricultural water assessment for hazard identification purposes and take any measures that are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with its pre-harvest agricultural water. This may involve, for example, the farm implementing measures that are within its control, such as changing the method of water application under § 112.45(b) to reduce the likelihood of contamination of the covered produce.

5. Other Food Safety Standards

(Comment 17) Several comments note that many farms are already subject to third-party water quality standards that some produce farms follow. Comments seek clarity on whether the proposed rule aligns with these standards and, if some third-party standards are more stringent than FDA's regulation, whether an audit to those standards could be used to meet the rule's requirements.

(Response 17) We acknowledge the important role third-party standards may play in ensuring food safety and questions about alignment of FDA's produce safety rule requirements and third-party standards. For example, in 2018, FDA and USDA announced the alignment of the USDA Harmonized Good Agricultural Practices Audit Program (USDA H–GAP) with the requirements in the 2015 produce safety final rule (Ref. 44), which preceded both the 2021 agricultural water proposed rule and this final rule. In the announcement, we explained that while the requirements of both programs are not identical, the relevant technical components in the 2015 produce safety final rule are covered in the USDA H–GAP Audit Program. We also explained that the alignment will help farms by enabling them to assess their food safety practices as they prepare to comply with the produce safety rule. However, we also noted that USDA audits are not a substitute for FDA or state regulatory inspections.

In October 2023, FDA announced the final results of a voluntary pilot program on alignment of private third-party food safety audit standards with applicable FDA regulations (Ref. 45). It included a third-party primary production standard for non-sprout produce that we found to be in alignment with applicable provisions of the produce safety regulation—except for the subpart E agricultural water requirements that were excluded from the review as they were under reconsideration through this rulemaking. Our conclusion from the pilot is that FDA currently does not have adequate resources to review and evaluate the alignment of third-party food safety standards beyond the pilot—notwithstanding the value that such standards may have in facilitating industry's implementation of FSMA and the potential of these audits to inform risk prioritization. FDA will continue to assess future opportunities but is unable to undertake any additional alignment reviews at this time, including review of third-party standards for pre-harvest

agricultural water for non-sprout produce.

Finally, as a general matter, a determination of alignment alone does not indicate that a farm audited to that standard is necessarily in compliance with the 2015 produce safety final rule. While a determination of alignment may help farms as they prepare to comply with requirements in the 2015 produce safety final rule, as discussed above, audits conducted under third-party standards found to be in alignment are not a substitute for FDA or State regulatory inspections.

(Comment 18) Some comments seek clarity on whether the proposed approach for pre-harvest agricultural water assessments is intended to be similar to a HACCP approach.

(Response 18) As discussed in response to comment 1, the annual pre-harvest agricultural water assessments employ a prevention-oriented quality-systems approach to food safety regulation that FDA has long used for the highly diverse food industry that FDA regulates. For example, FDA's juice HACCP regulation (21 CFR part 120), seafood HACCP regulation (21 CFR part 123), and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117), establish frameworks under which industry qualitatively assesses, and as necessary, controls, potential hazards as appropriate to their operations. While we believe that a HACCP approach—particularly at the level required in parts 120, 123, and 117—would not necessarily be appropriate at the farm level (80 FR 74354 at 74379), many of the principles of HACCP can still be applied, such as an assessment of risk and the development of a food safety plan based on that assessment, and we have incorporated elements such as these within the requirements for pre-harvest agricultural water assessments in § 112.43.

6. Other Comments

(Comment 19) A few comments note the phrasing in the proposed rule that assessments are designed to be ''adaptable to future advancements in agricultural water quality science'' and express concerns that this language implies that FDA will make significant implementation decisions in the future without public discussion and input. A few comments seek clarity on whether and how emerging science or additional information relevant to agricultural water assessments will be incorporated into trainings.

(Response 19) We acknowledge that water quality science is expected to evolve over time, and we have designed the rule to achieve improved public health protections, while also being feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future scientific advancements. For example, we discuss in response to comment 115 that as more studies are conducted that examine in-field die-off for various circumstances (for example, different regions, environmental conditions, commodities, pathogens, and crop growth characteristics) (Refs. 46–49), farms may use that information to inform a time interval between last direct water application and harvest under § 112.45(b)(1)(ii). We anticipate that as new information becomes available, it will be shared with farms and other interested stakeholders through various mechanisms, including guidance in accordance with our good guidance practices regulation, 21 CFR 10.115, which generally provides an opportunity for public comment before a guidance document is finalized.

Additionally, new information and scientific advancements will likely be incorporated into training programs and other education and outreach materials in order to increase awareness by farms. For example, we are aware that food safety trainings intended to be specific to certain commodities (or commodity groups) have been held, which could be a mechanism in the future by which information relevant to specific commodities will be shared. We are also aware of research organizations and universities that prioritize sharing their findings with the produce industry and related stakeholders. We also expect that as new science relates to region-specific considerations, local extension agents will play an important role in disseminating that information to interested parties.

(Comment 20) A few comments express concerns that the rule will result in farms increasing their reliance on ground water sources, which could be in conflict with the goals of certain state laws designed to help protect ground water resources. For example, some comments suggest that the exemption from the requirements to prepare an agricultural water assessment in proposed § 112.43(b)(1) related to untreated ground water will incentivize farms to make greater use of already-stressed resources. Several comments suggest that changing from surface water to ground water as a way to reduce risk associated with agricultural water may be difficult for some farms due to existing conservation laws.

(Response 20) We are not requiring farms to change their water sources, either for the purposes of an exemption from the requirements to prepare a pre-harvest agricultural water assessment or as a mitigation measure. Rather, we have incorporated flexibility to provide farms viable options to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water without needing to alter the source of agricultural water. See also response to comment 124.

In the Environmental Impact Statement (EIS) that was prepared during rulemaking for the 2015 produce safety final rule (Ref. 50), we discussed that, based on our qualitative analysis, we did not consider impacts to water resources to be significant, with the potential exception related to ground water withdrawal, where existing significant adverse long-term impacts (*i.e.,* water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated as a result of excessive ground water use.

We also noted that we did not anticipate that the approach taken for pre-harvest agricultural water in the 2015 produce safety final rule (*i.e.,* microbial criteria consisting of a GM and STV, with various actions a farm may take if the GM and/or STV are exceeded) would result in farms on a regional or national scale switching to ground water sources. For example, stakeholder feedback indicated that allowing for microbial die-off between last irrigation and harvest and/or microbial reduction or removal resulting from post-harvest practices provides farms viable options to meet the microbial quality criteria without needing to, for example, treat water or switch to a ground water source (Ref. 50).

Under this rule, those mitigation measures remain available as options. Further, with this rule we are incorporating additional mitigation measures beyond those in the 2015 produce safety final rule to provide farms with even more flexibility in ways to manage risks associated with pre-harvest agricultural water. (Specifically, this rule adds mitigation measures for changing the method of water application or taking an alternative mitigation measure in accordance with § 112.45(b)(1)(iv) and (vi), respectively.). We have provided various options for mitigation measures encompassing a range of possible costs (see the FRIA (Ref. 26)) to provide farms with

flexibility in managing risks associated with their agricultural water as appropriate to their agricultural water systems, water use practices, and unique circumstances. Given the various options farms have under this rule, including options that involve more targeted changes (such as making necessary repairs to agricultural water systems), we do not expect farms to preferentially alter the source of their agricultural water as a mitigation measure or for the purposes of an exemption from the requirements to prepare a pre-harvest agricultural water assessment.

As discussed in the Agency's finding of no significant impact for the current rulemaking and the evidence supporting that finding (Refs. 51–53), the potential number of farms that could switch to ground water, potentially exacerbating drawdown, would be reduced compared with the 2015 produce safety final rule with the revisions to the subpart E provisions we are finalizing here (Ref. 50). No significant adverse environmental impacts have been identified with this rule. See also section VIII.

(Comment 21) FDA received several comments related to conservation practices and environmental protection programs, which generally appear to be out of scope. Specifically, commenters urge FDA to encourage the co-management of food safety, conservation, and environmental protection. A few comments request that guidance and training on the rule for covered farms and inspectors acknowledge that animals and covered farms can co-exist, noting that this is especially important when it comes to conservation practices and/or diversified farms. In addition, one comment discusses state programs providing incentives for farmers to implement climate and environmentally friendly agricultural practices, such as use of energy-efficient irrigation systems, healthy soil practices (such as compost application), and establishment of seasonal and/or permanent vegetation for pollinators and wildlife. The comment expresses concern that farms may not participate in such environmental stewardship programs if doing so might be in conflict with the proposed requirements for pre-harvest agricultural water assessments. Further, comments recommend that FDA work with stakeholders to develop solutions that will help farmers co-manage such environmental sustainability goals with food safety.

(Response 21) As indicated, FDA considers these comments to generally be outside the scope of this rulemaking. However, to the extent they are in scope, FDA acknowledges the longstanding co-location of animals and plant food production systems in agriculture. 80 FR 74354 at 74482. As discussed in the 2021 agricultural water proposed rule, this rule does not prohibit the presence of animals (such as grazing animals or working animals) on a farm, nor does it require the destruction of wildlife habitat or the clearing of farm borders. Rather, the rule requires farms to evaluate and take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto non-sprout covered produce or food contact surfaces by pre-harvest agricultural water. 86 FR 69120 at 69135.

Additionally, as discussed in the 2015 produce safety final rule, we continue to encourage the co-management of food safety, conservation, and environmental protection. We consider it important to take into account the environmental practice standards and policies of other agencies in the context of food safety. 80 FR 74354 at 74365. We believe that the provisions of part 112 are consistent with existing conservation and environmental practice standards and policies and are not in conflict with Federal or State programs. In addition, § 112.84, which we did not propose to change, codifies a statement that the requirements of part 112 do not require or permit the use of practices in violation of the Endangered Species Act (16 U.S.C. 1531–1544), and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields. 80 FR 74354 at 74365.

C. Definitions (§ 112.3)

We proposed to add two new definitions for ''agricultural water assessment'' and ''agricultural water system'' in § 112.3 to provide clarity for terminology used in the proposed requirements for pre-harvest agricultural water assessments. We received several comments on those proposed definitions and respond to comments about these definitions in the following paragraphs. We are finalizing the definitions for ''agricultural water assessment'' and ''agricultural water system'' as proposed, without changes.

1. Agricultural Water Assessment

(Comment 22) Several comments express support for the definition of ''agricultural water assessment,'' noting that the assessment, as defined, provides broad, science-based flexibility so as to be applicable to a wide variety of growing scenarios. One comment suggests the definition be revised to include an assessment of the severity of illness and injury from the hazard and the probability that the hazard will occur. Another comment recommends that FDA clarify in its definition of ''Agricultural Water Assessment'' that the assessment must be in written form.

(Response 22) We considered these comments, and as discussed below, are finalizing the definition of ''agricultural water assessment'' as proposed, without changes. An ''agricultural water assessment'' means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to: (1) identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and (2) determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards (§ 112.3).

With respect to comments suggesting the definition be revised to capture the severity of illness and injury from the hazard and the probability that the hazard will occur, we note that as discussed in response to comment 27 and comment 76, the requirements for agricultural water assessments provide a mechanism through which farms evaluate the risk associated with their pre-harvest agricultural water and use that information to determine whether measures are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. See also comment 18, where we discuss comments related to HACCP. As such, we do not consider this a necessary change to make. In response to comments suggesting that the definition of ''agricultural water assessment'' be revised to clarify that the assessment must be in written form, we note that § 112.43(a) already specifies that farms ''must prepare a written agricultural water assessment'' and that § 112.50(b)(2) requires farms to maintain a record of that agricultural water assessment. Therefore, we also do not consider this a necessary change to make. As such, we are finalizing the definition of ''agricultural water assessment'' as proposed, without changes.

2. Agricultural Water System

(Comment 23) Several comments support the proposed definition of ''agricultural water system,'' suggesting that the proposed definition helps provide clarity. In reference to farms that draw agricultural water from systems that span long distances (such as canals), a few comments suggest that the definition of ''agricultural water system'' be revised to better account for the point at which the water comes under the farm's control.

(Response 23) We reviewed comments for the proposed definition of ''agricultural water system'' and agree that it will provide stakeholders with additional clarity that will be helpful, for example, to farms in determining the scope of where and what to inspect and maintain under § 112.42 and for those farms required to conduct a pre-harvest agricultural water assessment pursuant to § 112.43.

With respect to the comment requesting we revise the definition of ''agricultural water system'' to provide limitations regarding the point at which the water comes under a farm's control, we note that certain factors over which a farm may have little or no control (such as water users upstream of a farm), will likely influence the identification or characterization of potential hazards associated with the farm's agricultural water system(s). See also comment 15. As such factors are important to consider in meeting relevant requirements that apply for agricultural water systems (such as those in § 112.42 for inspections and maintenance of agricultural water systems and § 112.43 for pre-harvest agricultural water assessments), we decline to revise the definition of ''agricultural water system'' as requested by the comment. We also note that § 112.42 requires farms, in part, to inspect and maintain agricultural water systems *to the extent they are under the farm's control* (emphasis added) to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. As such, we are finalizing the definition for ''agricultural water system'' as proposed, without changes, to mean a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities (§ 112.3).

We also anticipate that the configuration of agricultural water systems will vary from operation to operation, depending on individual water sources, the type of distribution system (including whether a building or structure is a component), and the type of equipment used to apply agricultural water. Related to our definition of ''agricultural water system'' is our definition of ''water distribution system,'' which means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings (§ 112.3).

D. General Comments Regarding Pre-Harvest Agricultural Water Assessments (§ 112.43)

In the 2021 agricultural water proposed rule, we proposed to require farms to prepare systems-based agricultural water assessments for pre-harvest agricultural water for non-sprout covered produce (proposed § 112.43). We proposed that the assessments would be conducted annually (and more frequently as needed), documented in writing, and used for hazard identification and risk management decision-making purposes. We respond to comments of a general nature regarding the requirement for farms to prepare an agricultural water assessment in the following paragraphs. As discussed below, in response to comments received, we are revising § 112.43(a) to clarify that agricultural water assessments must be prepared at the beginning of the growing season, as appropriate, but at least once annually. Comments on exemptions from the requirement to prepare an agricultural water assessment, the factors that farms must evaluate as part of an agricultural water assessment, and outcomes of an agricultural water assessment are discussed in sections V.E., V.F., and V.G., respectively.

(Comment 24) Several comments request greater specificity on when farms should conduct their annual agricultural water assessment (for example, prior to planting, prior to harvest, between planting and harvest, or prior to water use). Some comments request clarity on how frequently FDA expects farms to determine the likelihood of any given hazard (for example, at least annually). Other comments suggest that farms should be required to prepare an agricultural water assessment at least annually, with an additional assessment within a week prior to harvest.

(Response 24) We anticipate that preparing an annual agricultural water assessment towards the beginning of the growing season may be of benefit for farms, as doing so may allow for early identification of conditions for which measures under § 112.45 may be reasonably necessary. (See, for example, § 112.43(c)(2), which outlines circumstances in which mitigation measures must be implemented promptly, and not later than the same growing season as the assessment.) However, we recognize that flexibility is needed to account for certain situations, such as for crops that have year-round growing seasons, and for farms that may have multiple crops with year-round or staggered growing seasons throughout the year. As such, to provide additional clarity, we are revising § 112.43(a) to require farms to prepare an agricultural water assessment ''at the beginning of the growing season, as appropriate, but at least once annually.'' We note that this change aligns with the requirement in § 112.42(a) for timing of agricultural water system inspections, which we did not propose to revise. See 80 FR 74354 at 74433.

Recognizing that farms may be more likely to prepare their agricultural water assessments towards the beginning of their growing season in light of this clarification, we also considered whether it would be warranted to require farms to conduct a reassessment close to harvest to reflect different practices and operations than might exist earlier in the growing season (such as during planting). However, we do not consider it necessary for farms to prepare an additional assessment close to harvest, as farms are already required to account for harvest conditions within their initial agricultural water assessments. (For example, the requirement in § 112.43(a)(2) for farms to evaluate the time interval between the last direct application of agricultural water and harvest of the covered produce indicates that farms must consider conditions that are close to harvest as part of their assessments.) However, we emphasize that a farm must conduct a reassessment whenever a significant change occurs in the farm's agricultural water system, water use practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces. A reassessment conducted under § 112.43(e) due to a significant change

must evaluate any factors and conditions affected by the change.

(Comment 25) Some comments seek clarity on the relationship between inspections, maintenance, and pre-harvest agricultural water assessments in proposed §§ 112.42(a), 112.42(b), and 112.43, respectively. A few comments ask whether conducting an agricultural water system inspection would eliminate the need for an agricultural water assessment and vice versa. One comment requests clarification as to whether the intent is for inspections to inform assessments, which in turn, inform maintenance activities such as monitoring—and if so, requests that FDA clarify as such by reordering the sequence of those requirements to reflect that intent. Another comment suggests that FDA limit the scope of the inspection and maintenance requirements to water system components that are under the ownership, management, or contractual oversight of the operator to help clarify the differences in expectations between inspections and maintenance under § 112.42 and agricultural water assessments under § 112.43, the latter of which are intended to be more comprehensive in nature.

(Response 25) We agree that there are differences between the requirements in § 112.42 for inspection and maintenance of agricultural water systems used for all covered activities and the requirements we are finalizing in § 112.43 for pre-harvest agricultural water assessments for covered produce other than sprouts.

As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69133–69134), the requirements for pre-harvest agricultural water assessments in § 112.43 supplement the requirements for inspection and maintenance of agricultural water systems in § 112.42, the latter of which requires a farm to regularly inspect and routinely maintain the components of its agricultural water systems, to the extent that such components or systems are under its control. While § 112.42 entails inspecting and maintaining components of an agricultural water system to the extent that they are under the farm's control, and applies for all uses of agricultural water (not just water used for pre-harvest activities), § 112.43(a) requires farms to conduct a more comprehensive assessment of possible sources and routes by which known or reasonably foreseeable hazards are reasonably likely to be introduced into its pre-harvest agricultural water for non-sprout covered produce. Additionally, farms are required to establish records of the findings of their inspections under § 112.42 (§ 112.50(b)(1)), whereas they are required to establish more comprehensive records of their written agricultural water assessments, including the descriptions of factors evaluated and written determinations, in accordance with § 112.43 (§ 112.50(b)(2)). Moreover, unlike the inspection and maintenance requirements in § 112.42, findings from a farm's agricultural water assessment are directly tied to implementation of corrective or mitigation measures, as described in § 112.43(c).

While results of inspections and maintenance under § 112.42 can be used to inform an agricultural water assessment under § 112.43(a) (or the need for a reassessment under § 112.43(e)), meeting the requirements in § 112.42 does not eliminate the need for a farm to prepare an agricultural water assessment in accordance with § 112.43. For discussion related to records of agricultural water system inspections and assessments, see response to comment 133.

With respect to comments requesting that we reorder the provisions to clarify that inspections inform assessments, which in turn inform maintenance, we decline to make this change. Not only do the requirements for inspections and maintenance under § 112.42 have different applicability than the requirements for agricultural water assessments under § 112.43 as discussed above, but farms are required to base their agricultural water assessments, in part, on the results of any inspections and maintenance conducted under § 112.42. We expect that reordering the provisions may result in confusion as to their applicability and relationship, and as such, are finalizing the order of §§ 112.42 and 112.43 without change.

(Comment 26) A few comments ask FDA to clarify in the final rule that the assessment is intended to identify known or reasonably foreseeable *microbial* hazards, specifically.

(Response 26) As discussed in the 2015 produce safety final rule, the regulation focuses on biological hazards related to produce growing, harvesting, packing, and holding. We conducted a QAR (Ref. 17) and considered the findings of that assessment in finalizing the 2015 produce safety final rule. While we acknowledged the potential for nonbiological (physical or chemical (including radiological)) hazards in produce, we explained that we do not address such hazards in the produce safety rule. See 80 FR 74354 at 74355 and 74377 and response to comment 8. Further, the 2015 produce safety final rule defines ''known or reasonably foreseeable hazard'' to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food (§ 112.3). We did not propose to change this definition from the 2015 final produce safety final rule. As the scope of the regulation and definition of ''known or reasonably foreseeable hazards'' are specific to biological hazards, we do not consider it necessary to revise the requirements for pre-harvest agricultural water assessments as suggested by the comments.

(Comment 27) One comment seeks clarity on how to assess known or reasonably foreseeable hazards that are inherent in the environment, such as *Listeria,* for purposes of an agricultural water assessment under § 112.43.

(Response 27) The information considered as part of an agricultural water assessment in § 112.43(a) will assist farms in determining whether measures under § 112.45 are reasonably necessary in light of concerns for the potential presence of environmental pathogens. For example, if a farm suspects that adjacent or nearby land that had historically been used for a grazing operation may contain pathogens, the farm might consider the topography of the land and likelihood of whether those hazards may be introduced to the water system. In combination with the other factors considered as part of its agricultural water assessment (for example, the farm's water use practices, crop characteristics, and environmental conditions (such as air temperature and UV))—the farm must then consider whether measures are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces.

We also note that the requirements for systems-based agricultural water assessments are designed, in part, to be adaptable to future advancements in agricultural water quality science. We anticipate that this is an area where science will continue to evolve and provide stakeholders with an enhanced understanding of the ecology of human pathogens in the environment that may cause foodborne illness outbreaks. For example, FDA sometimes conducts multiyear environmental studies that are designed to elucidate environmental conditions that can impact food safety (Ref. 54). Factors that are studied may include, but are not limited to, pre-harvest water sources and uses, soil and soil amendments, topography of the growing region, areas where animals are present (such as wildlife and livestock), wind speed and direction, airborne particulates, water runoff, and

environmental factors (such as temperature, rainfall, fog, and dew). Within recent years, FDA, with support from State and local partners, has initiated two longitudinal multiyear studies that examine how pathogens survive, move through the environment of two different regions, and possibly contaminate produce (Refs. 55 and 56). As these and similar efforts progress, farms will be able to use similar information learned about regions as an additional resource to further inform their agricultural water assessments.

(Comment 28) Many comments suggest that the proposed requirements for pre-harvest agricultural water assessments do not sufficiently acknowledge that the presence of a hazard does not necessarily represent a risk to water or produce that needs to be managed. Some of these comments express concerns that, as written, the proposed rule would require farms to implement mitigation measures if a hazard is present, even if the overall risk associated with the water (for example, in light of the other information evaluated as part of an assessment) is low.

(Response 28) We consider that the identification of potential sources of known or reasonably foreseeable hazards and consideration of the likelihood of those hazards being introduced to an agricultural water is an appropriate approach, within a risk-based framework, to implement the requirements of section 419 of the FD&C Act to set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The systems-based framework in § 112.43 of evaluating conditions that are reasonably likely to introduce known or reasonably foreseeable hazards will help a farm determine, alongside the results of inspections and maintenance under § 112.42, whether corrective or mitigation measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.

In particular, we note that agricultural water assessments must identify conditions that are *reasonably likely* (emphasis added) to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces based on an evaluation of all factors identified in § 112.43(a)(1) through (5). These factors include: the agricultural water system (including the source, water distribution system, and degree of protection from possible sources of contamination); agricultural water use practices; crop characteristics; environmental conditions; and other relevant factors, including test results, where appropriate. (See also comment 29, where we respond to comments regarding the terms ''reasonably likely'' and ''reasonably necessary.'')

Thus, if a farm identifies a potential source of contamination under § 112.43(a)(1), it is not a foregone conclusion that measures under § 112.45 are reasonably necessary. Rather, in consideration of all of the information evaluated under § 112.43(a)(1) through (5), the farm might ultimately determine, for example, that measures under § 112.45 are not reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with its agricultural water used in growing covered produce (other than sprouts).

Similarly, while two different farms might identify similar potential sources of contamination under § 112.43(a)(1), depending on the other information they evaluate in § 112.43(a)(1) through (5), their determinations under § 112.43(c) might differ. For example, one farm with a surface water source that is regularly subject to runoff from lands where animal grazing occurs may determine that mitigation measures are reasonably necessary under § 112.45, since the farm applies agricultural water from that source to covered produce close to harvest, and environmental conditions and crop characteristics are not conducive to microbial die-off. However, another farm with different crop characteristics, environmental conditions and water use practices may determine that mitigation measures are not reasonably necessary, even if it uses pre-harvest agricultural water from a surface water source with similar runoff conditions.

As discussed further in comment 29, we have provided various examples throughout the proposed rule and this final rule that farms should consider in determining whether (and what kind of) measures are reasonably necessary. We remain committed to providing education, outreach, and training, and intend to pursue various mechanisms for disseminating information about the requirements of this rule to farms.

(Comment 29) Many comments request clarity related to the terms ''reasonably likely'' and ''reasonably necessary'' as they relate to the requirements for agricultural water assessments These comments suggest that the terms are subjective and that without a more objective benchmark it will be difficult to consistently determine what is ''reasonably likely'' for a farm.

(Response 29) Given the diversity that exists across the operations of foreign and domestic farms and their agricultural water systems, uses, and practices, phrases such as ''reasonably likely to introduce known or reasonably foreseeable hazards'' and ''determine whether measures are reasonably necessary'' provide flexibility for farms to make decisions around the use of agricultural water as appropriate to their unique circumstances and operations, taking into account the requirement in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. We note that similar language appears in section 419(c)(1)(A) of the FD&C Act,[7] in the agricultural water requirements for harvest-, post-harvest, and sprout uses (which we did not propose to change) (*e.g.,* § 112.44(d)), and in FDA's HACCP regulations (21 CFR part 120 and 21 CFR part 123) and FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117). This language is designed to be flexible given the diversity of commodities and operations to which these requirements apply, and in keeping with the principle that the farm bears the responsibility and accountability for establishing and implementing food safety systems tailored to its circumstances. We also note that such language is flexible to account for future scientific advancements, consistent with the requirements for pre-harvest agricultural water assessments we are finalizing with this rule.

What is considered a known or reasonably foreseeable hazard for one farm, in light of the conditions and potential impacts to its agricultural water system, may not be known or

[7] Section 419(c)(1)(A) of the FD&C Act requires that the 2015 produce safety final rule set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

reasonably foreseeable hazard in the light of the conditions and potential impacts to the agricultural water system of another farm. For example, while a farm in one region might identify wild pigs as a potential source of known or reasonably foreseeable hazards to agricultural fields and surface waterways (Refs. 57 and 58), wild pigs might not be considered a likely source of known or reasonably foreseeable hazards in regions where pigs are not prevalent. As another example, if runoff is likely to serve as a source of hazards, but the farm's agricultural water system is sufficiently protected (*e.g.,* water from a well is conveyed through a piped distribution system, and both the well and distribution system are properly constructed and maintained), then the farm might determine that runoff is not a condition that is reasonably likely to introduce known or reasonably foreseeable hazards to covered produce (other than sprouts) or food contact surfaces.

Further, farms must use information on the various factors evaluated as part of an agricultural water assessment under § 112.43(a)(1) through (5)—including information related to their agricultural water systems; agricultural water use practices; crop characteristics; environmental conditions; and other relevant factors, such as the results of pre-harvest agricultural water testing, where appropriate—to determine whether, given their unique conditions, measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water used in growing covered produce (other than sprouts). Given the diversity that exists across industry in these factors, situations in which measures under § 112.45 are reasonably necessary for one farm will not necessarily be the same for another. Rather, the unique factors that are relevant to a farm and its agricultural water systems will together assist the farm in decision-making related to its pre-harvest agricultural water as appropriate for its relevant conditions, practices, and circumstances. See also response to comment 28.

We have provided various examples throughout the proposed rule and this final rule that farms should consider in identifying potential sources of hazards, evaluating the likelihood of hazards being introduced to covered produce (other than sprouts) or food contact surfaces, and determining whether (and what kind of) measures are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. See 86 FR 69120 at 69133 and sections V.F., V.G., and V.J. Such examples, and consideration for the principles presented in the context of each farm's unique conditions, will assist farms in conducting their pre-harvest agricultural water assessments under § 112.43. However, we also recognize that guidance, educational materials, as well as trainings, will help farms understand the requirements of this final rule. We remain committed to providing education, outreach and training and intend to pursue various mechanisms for disseminating information to farms.

(Comment 30) A few comments suggest that under the proposed rule, any surface water source that a farm is preparing an agricultural water assessment for will be considered ''hazardous,'' and therefore require that the farm conduct mitigation measures.

(Response 30) The risk associated with agricultural water will vary from source to source. For example, ground water obtained from deep underground aquifers, with properly designed, located, and constructed wells, generally yields higher quality water with little variability due to the natural filtering capacity of soils, the depth pathogens would have to travel to compromise the source, and because it is not expected to be subject to environmental factors such as runoff (Refs. 17 and 59). By contrast, surface waters, which are exposed to the environment, pose a higher potential for becoming contaminated with human pathogens due to runoff and greater variability in quality because of the potential for external influences (Ref. 17). However, we recognize that even within a single type of water source (*e.g.,* surface water), the associated risk may vary depending, in part, on the nature and likelihood of hazards being introduced. For example, if a farm has two different holding ponds—one that is at a higher elevation than surrounding lands, and the other that is at a lower elevation—both are considered surface water sources. However, the holding pond at the higher elevation may be more well-protected from the introduction of hazards via runoff than the other holding pond and may therefore present less risk when used as pre-harvest agricultural water.

Additionally, we recognize that the risk associated with agricultural water also depends on how and when agricultural water is applied to covered produce, characteristics of the covered produce, and environmental conditions. As such, we require farms to evaluate these various factors under § 112.43(a) as part of their agricultural water assessments to assist them in determining whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. See also response to comment 28. Given the variability that exists across industry in water systems, operations, and conditions, not every surface water source will require that corrective or mitigation measures be implemented under § 112.45.

(Comment 31) Several comments seek clarity on how to weigh ''low risk'' and ''high risk'' elements within an assessment. For instance, comments seek clarity on how farmers should weigh a ''low risk'' crop irrigated with water from a ''high risk'' source. One comment seeks clarity on whether farms can continue using ''low'' or ''medium-risk'' practices until ''specific science determines there is a real, attributable risk.''

(Response 31) Throughout the 2021 agricultural water proposed rule, this final rule, and supporting materials (such as the QAR (Ref. 17)), we have provided principles related to general risk associated with conditions and practices related to pre-harvest agricultural water sources and uses. For example, table 7 of the QAR (Ref. 17) demonstrates that public drinking water is generally considered the least likely to serve as a source of contamination, followed by ground water, surface water protected from runoff, and surface water unprotected from runoff. Further, that table notes that where contamination in a water source is known to exist, the likelihood of contamination is a function of:

- Contact with the commodity (example, whether contact is indirect or direct);
- Commodity effects (for example, whether the surface is conducive to adhesion); and
- Application timing (for example, early or late in crop growth).

Given the diversity that exists across the operations of foreign and domestic farms and their agricultural water systems, uses, and practices, what might be considered ''low'' or ''high'' risk for one farm will not necessarily be the same for another.

As such, in establishing the requirements for pre-harvest agricultural water assessments, we have provided flexibility for farms to make decisions

around the use of agricultural water as appropriate to their unique circumstances and operations. See also response to comment 29.

To the extent that comments are voicing concern over the scientific basis for the requirements for pre-harvest agricultural water assessments in § 112.43, comment 10 addresses those comments.

(Comment 32) One comment asserts that quantitative microbial risk assessment and risk modeling tools may help establish when certain ''safe harbors,'' such as the use of four days or more between last direct water application and harvest as a mitigation measure, may be appropriate for farms to use. Specifically, this comment suggests that the proposed approach for mitigation measures provides options for farms to choose from without caveats or limitations.

(Response 32) Given the diversity of operations, agricultural water sources, and agricultural water uses of domestic and foreign farms, the requirements for comprehensive, systems-based pre-harvest agricultural water assessments, which require farms to evaluate a broad range of factors that may impact the quality of the water they use during pre-harvest activities, will assist farms in identifying, and managing, risks associated with pre-harvest agricultural water as appropriate for their relevant agricultural water systems, conditions, and practices. While we do not believe that quantitative risk benchmarks are necessary in order to establish science-based minimum standards within the framework of the comprehensive, systems-based agricultural water assessment we are finalizing here, we have included a requirement to test pre-harvest agricultural water as part of an assessment when doing so would not delay action most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary. See § 112.43(c)(4).

We also recognize that additional clarification, such as related to the circumstances under which certain mitigations may be appropriate, is appropriate. As such, we provide various examples throughout the proposed rule and this final rule that farms should consider in preparing their agricultural water assessments and taking actions based on their assessments. See 86 FR 69120 at 69133 and sections V.F., V.G., and V.J. For example, in comment 115, we explain that the use of microbial die-off between last direct water application and harvest as a mitigation measure under § 112.45(b) can be impacted by a broad range of conditions specific to a farm, such as the timing of water its water applications and relevant environmental conditions, crop characteristics, and pathogen characteristics.

Further, the QAR (Ref. 17) explains that where contamination of a water source is known to exist, the likelihood of contamination is a function of various factors, including contact with the commodity, commodity effects (characteristics), and application timing. Moreover, we discuss in our memos supporting the pre-harvest microbial die-off requirements in the 2015 produce safety final rule (Refs. 60 and 61) that the reduction of pathogen populations on produce surfaces to the point of non-detection is not guaranteed. As such, we disagree that use of a time interval between last direct water application and harvest alone can serve as a ''safe harbor.''

We also note that the requirements for agricultural water assessments are designed, in part, to be adaptable to scientific advancements. To the extent that risk modeling and predictive analytics related to pre-harvest agricultural water may continue to develop in the future, farms will be able to use such information as an additional resource to further inform their agricultural water assessments under the approach we are finalizing here.

(Comment 33) A few comments suggest that evaluating various factors (such as the agricultural water source's degree of protection under proposed § 112.43(a)(1)) will present a significant challenge to many farms and argues that broader collaborations across the agricultural sector will need to occur to achieve compliance with this requirement. The comment suggests that FDA foster relationships with irrigation water districts and engage in conversations with animal operations and livestock associations, or other Federal partners such as the EPA and USDA's Natural Resources Conservation Service to achieve compliance.

(Response 33) We are aware of efforts underway to bring together members of agricultural communities on a large scale, such as through the CAN (Ref. 38), which provides a roundtable opportunity to foster collaboration and discuss enhanced neighborly food safety practices when various agriculture operations such as leafy green fields, cattle ranches, vineyards, and compost sites are adjacent to one another. Various action items have been identified as part of the CAN initiative, including fostering neighbor-to-neighbor interactions and conversations, and building a research roadmap to understand key landscape processes to guide decision-making both now and into the future (Ref. 39).

Additionally, FDA sometimes conducts multiyear environmental studies in collaboration with State and local public health officials, academia, and members of the produce industry, that are designed to shed light on environmental conditions that can impact food safety (Ref. 32). Within recent years, FDA, with support from State and local partners such as extension specialists, academic researchers, irrigation districts, industry groups, and farms, has initiated two longitudinal multiyear studies that examine how pathogens survive, move through the environment of two different regions, and possibly contaminate produce (Refs. 55 and 56). Information learned through such efforts may help inform agricultural water assessments.

Further, as discussed in section V.K., FDA has collaborated with EPA to develop a testing protocol for evaluating the efficacy of antimicrobial chemical treatments against certain foodborne pathogens in agricultural water sources. We recognize the value of collaborating with Federal partners in related disciplines, and will consider additional collaborative efforts related to the requirements we are finalizing here.

(Comment 34) Some comments voice concern that it will be difficult to prepare agricultural water assessments for farms that use multiple sources of water for pre-harvest activities.

(Response 34) We acknowledge that farms using multiple agricultural water systems during pre-harvest activities for covered produce (other than sprouts) will need to conduct an assessment for each system unless an exemption under § 112.43(b) applies. However, several of the factors evaluated in the assessment (for example, agricultural water use practices, commodity characteristics, and environmental conditions) might be similar across agricultural water systems, thus limiting the amount of information a farm needs to collect and consider. We emphasize that under Subpart O, ''Records'' of the 2015 produce safety final rule, it is not necessary for farms to keep all of the required information in only one set of records, nor do farms need to duplicate existing records, provided that, taken together, the records satisfy all of the applicable requirements. See § 112.163. Therefore, farms have flexibility in maintaining records for agricultural water assessments as long as all relevant requirements are met.

(Comment 35) Some comments voice concern that farms who lease land for short-term use (for example, one

growing season) may face challenges in implementing the requirements for agricultural water assessments as they lack historical knowledge on adjacent lands and water systems available to them. One comment suggests that having multiple years of experience using surface water to cool strawberries in the field without any history of problems makes it difficult to identify risks.

(Response 35) We recognize that not all farms (including, for example, new farms and those growing covered produce on land under short-term lease), will have a historic understanding of their agricultural water systems, including uses of adjacent and nearby lands. While we understand that historical knowledge may be useful in preparing an agricultural water assessment, the absence of it does not preclude a farm from evaluating the factors in § 112.43(a)(1) through (5).

Moreover, we do not consider a lack of reported issues in the past as necessarily being indicative of the risks associated with a farm's agricultural water systems and pre-harvest water use. For example, between June and October 2020, Federal and State agencies investigated a *Salmonella* Newport foodborne illness outbreak associated with consumption of red onions (Ref. 23). We noted that the food vehicle in this outbreak, whole red onions, is a raw agricultural commodity that had not previously been documented as associated with a foodborne illness outbreak. Although a conclusive root cause could not be identified, several potential contributing factors were identified, including a leading hypothesis that contaminated irrigation water used in a growing field may have led to contamination of the onions.

The QAR (Ref. 17) concluded that, although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of the potential routes of contamination, including water. Use of poor agricultural practices can lead to contamination and illness, even where the potential for contamination is relatively low. As such, it is important for all farms to consider the various factors under § 112.43(a) as part of their agricultural water assessments, even in the absence of any reported history of safety problems associated with their covered produce.

E. Exemptions From Agricultural Water Assessments (§ 112.43(b))

In § 112.43(b), we proposed various exemptions from the requirement to prepare a pre-harvest agricultural water assessment. We tentatively concluded that an agricultural water assessment would not be necessary when a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce:

- Meets the requirements in § 112.44(a), including the microbial quality criterion, and, if untreated ground water, also meets the testing requirements in §§ 112.44(b), 112.47, and 112.151 (proposed § 112.43(b)(1));
- Meets the requirements in § 112.44(c) for water from a Public Water System or public water supply (proposed § 112.43(b)(2)); or
- Is treated in accordance with § 112.46 (proposed § 112.43(b)(3)).

We received numerous comments on the exemptions in proposed § 112.43(b) and respond to those comments below. As discussed below, we are finalizing the exemptions from the requirement to prepare a pre-harvest agricultural water assessment and clarifying that an exemption only applies if it is reasonably likely that the relevant quality of water will not change prior to the water being used as agricultural water.

(Comment 36) Some comments voice concern with the proposed exemptions in § 112.43(b), noting that while farms may be exempt from preparing an agricultural water assessment for water from a municipal source or treated water, depending on how the water is used, the water quality may change. These comments suggest that exempting water in these situations could be a gap in assessing the safety of the water.

(Response 36) We recognize that where the quality of water meeting the requirements in proposed § 112.43(b) may change before a farm uses it as pre-harvest agricultural water, it would be inappropriate for the farm to be eligible for an exemption from the requirement to prepare an agricultural water assessment for that water. As such, we are revising proposed § 112.43(b) to clarify that a farm is only exempt from preparing a written agricultural water assessment if the farm can demonstrate that the water meets the requirements in § 112.43(b)(1)(i), (ii), or (iii) and it is reasonably likely that the relevant quality of water will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed) (§ 112.43(b)(2)).

For example, if a farm receives water that meets the requirements in § 112.44(c) for water from a Public Water System that furnishes water meeting the microbial requirements in 40 CFR part 141 and conveys that water through a closed distribution system that allows for water quality to be maintained, the farm may be eligible for an exemption under § 112.43(b), provided all requirements are met (including the requirement that the farm have results or certificates of compliance demonstrating that relevant requirements are met). However, if a farm conveys that water through an open canal system prior to using it as pre-harvest agricultural water for non-sprout covered produce and it is reasonably likely that the quality of water will change prior to use of the water, the farm is not eligible for an exemption from the requirement to prepare an agricultural water assessment. The farm must consider the nature of the water source as part of their evaluation of the agricultural water system under § 112.43(a)(1).

(Comment 37) Several comments support the exemption in proposed § 112.43(b)(1) for water that meets the requirements of proposed § 112.44(a), noting that, in some cases, it may make sense for some farms to rely on test results rather than conducting annual (or more frequent, as appropriate) assessments. Some comments seek clarity about whether FDA intends for water tests to be performed each growing season for the sole purpose of demonstrating one's exemption from performing an agricultural water assessment. Comments also seek clarity as to when FDA would expect the testing to be completed (for example, before the season starts). Further, some comments question whether historical water testing data could be used for the purposes of an exemption from preparing an agricultural water assessment. Comments also request clarification on whether this exemption could be used for a farm that only uses pre-harvest water, but tests to the same standard as post-harvest water and meets all other relevant requirements.

(Response 37) We reviewed comments related to the exemption in proposed § 112.43(b)(1) and conclude that an agricultural water assessment is not necessary when a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets the requirements in § 112.44(a) (including the stringent microbial quality criterion of no detectable generic *E. coli*) and the testing requirements in §§ 112.44(b), 112.47, and 112.151 that are applicable to agricultural water for sprout irrigation and harvest and post-harvest uses. While the provisions referred to in

§ 112.43(b)(1)(i) apply to water that is used for purposes outlined in § 112.44(a) (such as water used for harvest and post-harvest purposes), we note that a farm that only uses agricultural water for pre-harvest activities may still be eligible for this exemption, provided all applicable requirements are met.

For the exemption from the requirement to prepare an agricultural water assessment in § 112.43(b)(1)(i), if the water is untreated ground water, § 112.44(b) requires that a farm initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected aseptically and representative of the intended use(s). If the four initial sample results meet the microbial quality criterion under § 112.44(a), the farm may test once annually thereafter. As such, in order to be eligible for the exemption in § 112.43(b)(1)(i), the farm must test the source of untreated ground water each growing season or year.

Recognizing the diversity that exists in industry as to when and how agricultural water is used, the requirement that samples be ''representative of the intended use(s) of the water'' provides farms with flexibility for sample collections under § 112.44(b). While one farm may, for example, collect a sample that is representative of use at the beginning of the growing season, another farm may, for example, collect a sample that is representative of use later in the year, or at some other time such as when production occurs year-round.

Regarding the use of historical data, we note that if a farm already possesses sufficient data (consisting of the minimum required number of samples) collected in the manner required under § 112.44(b), the farm is permitted to use that data in support of the exemption in § 112.43(b)(1)(i).

(Comment 38) Several comments address the exemption in proposed § 112.43(b)(2) for water that meets the requirements in § 112.44(c) for water from a Public Water System or public water supply that furnishes water that meets the microbial water quality criterion on § 112.44(a). Some comments suggest that other water sources, such as water from public wastewater treatment systems, should be similarly exempt from preparing an agricultural water assessment, even if they do not meet the microbial criterion in § 112.44(a). A few comments specifically ask that the exemption be revised to apply to water from publicly owned systems (including from drinking water systems and wastewater treatment systems) that has been treated to meet a GM of 126 or less and an STV of 410 or less CFU generic *E. coli* per 100 mL, as opposed to expecting such water to meet the microbial criterion of no detectable generic *E. coli* per 100 mL. Some comments suggest that use of the GM and STV criteria for such purposes would shift the burden of proof to the water supplier, as compared to under the 2015 produce safety final rule requirements in which farms would be responsible for demonstrating that water meets such criteria.

(Response 38) In the U.S., Public Water Systems are required under NPDWR in 40 CFR part 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination (Ref. 17). Similarly, public water supplies that meet the microbial requirement in § 112.44(a) are included in the exemption under proposed § 112.43(b)(2) to accommodate other public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of § 112.44(a). See 78 FR 3504 at 3571. Where a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets microbial EPA drinking water standards or other comparable public water supply standards, we have concluded that it is not necessary to require farms to prepare a pre-harvest agricultural water assessment under § 112.43(a) provided all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). See also response to comment 2.

We do not consider it appropriate to broaden the exemption in proposed § 112.43(b)(1) to include water from other public water supplies, such as wastewater treatment systems, since, as the comments note, water from these systems is often not treated to meet or be comparable to EPA's drinking water standards and may not similarly be at the lowest likelihood for pathogen contamination.

We also decline to provide an exemption from the requirements to prepare an agricultural water assessment for water supplied by a public water system that meets a GM of 126 and STV of 410 CFU generic *E. coli* per 100 mL of water, as we do not consider water meeting those criteria to provide the same level of confidence in the quality of water compared to water from a Public Water System or public water supply that meets or is comparable to microbial EPA drinking water standards. As such, we are finalizing the exemption in final § 112.43(b)(1)(ii) to refer to agricultural water that meets the requirements in § 112.44(c) for water from a public water system or public water supply.

(Comment 39) One comment notes that the exemption for water from a municipal source does not provide guidance on what farms should do in the case of potential water main breaks or other failures of the system. The comment suggests that FDA account for such circumstances and establish requirements for what farms should do when there are microbiological risks associated with a municipal source.

(Response 39) We recognize that water main breaks or other issues may occur on occasion that have the potential to affect the quality of water coming from public water systems. We emphasize that it is the farm's responsibility to ensure that the water the farm uses meets all applicable requirements in subpart E, including that all agricultural water be safe and of adequate sanitary quality for its intended use (§ 112.41), even if the farm is eligible for an exemption from the requirement to prepare a pre-harvest agricultural water assessment under § 112.43(b).

Nonetheless, as discussed in comments 3 and 37, where a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets microbial EPA drinking water standards or other comparable public water supply standards, we have concluded that it is not necessary to require farms to prepare a pre-harvest agricultural water assessment under § 112.43(a) provided all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). See § 112.43(b)(1)(ii) and, by reference, § 112.44(c). In the case of issues such as water main breaks or other failures occurring in a public water system or public water supply meeting the requirements in § 112.44(c), the system authority will oftentimes communicate the issue, along with recommendations for whether and how to use the impacted water, in an advisory to their affected constituents. Farms may find it helpful to consider such information in ensuring that the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use is met.

(Comment 40) Several comments voice concern over how the exemptions in proposed § 112.43(b) relate to controlled environment agriculture

(CEA) farms (for example, indoor farms), including hydroponic or aquaponic operations. For example, one comment suggests that recirculated water used in such operations would be considered untreated surface water, and therefore, the exemption in proposed § 112.43(b)(1) would not apply. Some comments note that while hydroponic and aquaponic operations may source their water from a public water supply, water in these operations can be recirculated and/or held for extended periods of time prior to its use for produce. A few comments note that if farms recirculate that water without treatment or other controls, they could end up irrigating produce using contaminated water. Other comments suggest that chemical treatment for the purposes of an exemption in proposed § 112.43(b)(3) may not be applicable in hydroponic and aquaponic operations due to concerns over a lack of treatment efficacy and that chemical treatment is not currently an option for aquaponic operations. For example, one comment notes that chlorine and chloramine are toxic to fish at certain concentrations and not labeled for use in aquaculture.

(Response 40) As discussed in comment 36, we are revising proposed § 112.43(b) to clarify that a farm is only exempt from preparing a written agricultural water assessment if the farm can demonstrate that the water meets the requirements in § 112.43(b)(1)(i), (ii), or (iii) and it is reasonably likely that the relevant quality of water will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed) (§ 112.43(b)(2)). As such, it is important that each farm, including those involved in CEA, consider its unique operations in determining whether it is eligible for an exemption from the requirement to prepare an agricultural water assessment under § 112.43(b), including how the farm conveys and/or holds the water; how the farm manages the water prior to its point of intended use; and how the farm uses pre-harvest agricultural water for non-sprout covered produce.

For example, we are aware that in some CEA operations, such as those that employ deep water culture methods, pre-harvest agricultural water can be used for extended periods of time to grow multiple batches of covered produce in continuous production. For example, some operations introduce a new production raft to a growing pond when another raft is removed for harvest. Unless there are measures that will allow for the quality of water in § 112.43(b)(1)(i), (ii), or (iii) to be maintained as new batches of covered produce are added to the system, a farm that implements such water use practices is unlikely to satisfy the requirements for an exemption in § 112.43(b). Examples of measures that may allow for the quality for water to be maintained prior to use as agricultural water for sequential batches of covered produce include, but are not limited to, ensuring that distribution system components and equipment surfaces do not serve as a source of contamination to the water and/or using other measures, such as adequate treatment, to maintain the quality of water.

Regardless of whether an exemption from the requirement to prepare an agricultural water assessment under § 112.43(b) applies, farms remain responsible for meeting all other applicable requirements of subpart E, including those related to inspection and maintenance of agricultural water systems (§ 112.42) and the requirement that all agricultural water be safe and of adequate sanitary quality for its intended use (§ 112.41).

(Comment 41) A few comments assert that in the 2021 outbreak of *Salmonella* Typhimurium associated with product from a hydroponic leafy green facility, the water would have been exempt from the requirement to prepare an agricultural water assessment under the proposed rule, as the water was from a municipal water source and was treated.

(Response 41) In response to comment 40, we discuss information that CEA farms should consider in determining whether they are eligible for an exemption under § 112.43(b). We also explain that regardless of whether a farm is eligible for an exemption under § 112.43(b), the farm remains responsible for ensuring the safe and adequate sanitary quality of the water used to grow covered produce (§ 112.41).

Regarding the outbreak of *Salmonella* Typhimurium associated with packaged leafy greens produced in a CEA indoor hydroponic operation specifically, we note that our investigation did not result in the identification of the specific source or route of contamination of the leafy greens (Ref. 62). However, we explained in our investigation report (Ref. 62) that recovery of *Salmonella* Liverpool, a strain not associated with the outbreak, from a water sample of an indoor production pond highlights the importance of minimizing sources of microbial contamination as well as operating and maintaining production ponds in a manner that does not result in the spread of pathogens to produce. For example, while the growing ponds in the operation were filled with water sourced from a public water supply that was further treated on-site using a sand filtration and ultraviolet (UV) system, as our investigation report notes, once water was in the growing ponds, it was not routinely disinfected or otherwise treated. Moreover, while the operation indicated to investigators that ponds get treated in response to sample results revealing the presence of generic *E. coli,* the operation did not have a procedure or systematic approach to ensure adequate water treatment. We also noted that a water sample collected from a stormwater retention basin located outside of the CEA operations' property but approximately 25 feet from the CEA structure tested positive for the outbreak strain.

Although investigators did not observe specific routes of contamination to or from areas surrounding the CEA operation, we note that the report findings provide further evidence supporting the requirements that farms, including those involved in CEA, assess and mitigate risks associated with adjacent and nearby land uses that may impact operations in both rural and more urbanized settings. While we recognize that CEA may provide an additional degree of control compared to more traditional outdoor farming operations, we emphasize that it is still important for farms that participate in CEA to consider a range of potential sources of hazards in ensuring that subpart E requirements are met, including those above.

(Comment 42) A few comments request clarification on the documentation farms need to support an exemption from the requirement to prepare an agricultural water assessment. For example, one comment asks if all farms need to prepare an agricultural water assessment, but that for farms eligible for an exemption, doing so would only entail maintaining information relevant to the exemption.

(Response 42) If a farm satisfies the criteria for an exemption under § 112.43(b), the farm is not required to prepare a written agricultural water assessment. However, the farm is required to maintain records applicable to the exemption, such as:

- In support of the exemption in § 112.43(b)(1)(i), documentation of test results (§ 112.50(b)(5)) and analytical methods (if applicable) (§ 112.50(b)(12));
- In support of the exemption in § 112.43(b)(1)(ii), annual documentation of the results or certificates of compliance from a public water system or public water supply demonstrating that the water meets the relevant requirements in § 112.44(c) (§ 112.50(b)(6)); and

• In support of the exemption in § 112.43(b)(1)(iii), documentation of scientific data or information the farm relies on to support the adequacy of a treatment method (§ 112.50(b)(10)) and documentation of the results of water treatment monitoring (§ 112.50(b)(11)).

(Comment 43) Some comments seek clarity on whether the exemptions in proposed § 112.43(b) are permanent or temporary.

(Response 43) Farms are eligible for an exemption from the requirement to prepare a written agricultural water assessment under § 112.43(b) for as long as the relevant requirements are met. This includes maintaining records applicable to the exemption, as discussed in response to comment 42.

F. Elements of an Agricultural Water Assessment (§ 112.43(a))

We proposed to require farms that use pre-harvest agricultural water for non-sprout covered produce to prepare a written agricultural water assessment that would identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, based on an evaluation of the farm's agricultural water system; agricultural water practices; crop characteristics; environmental conditions; and other relevant factors, including, if applicable, results of any testing conducted (proposed § 112.43(a)). We respond to the comments on proposed § 112.43(a) in the following paragraphs. We note that comments on testing conducted under § 112.43(d) are discussed in section V.H. As discussed in our response to comments, we are finalizing § 112.43(a) as proposed, with minor edits for clarification.

1. Agricultural Water Systems

(Comment 44) Several comments contend that the proposed rule does not adequately address various types of agricultural water, since only ground water and surface water are identified in proposed § 112.43(a)(1), which would require farms to evaluate each agricultural water system (*i.e.,* source and distribution system) used for growing activities for covered produce. These comments request that FDA clearly define various agricultural water types (including surface water, ground water, municipal water, and recycled water) and provide examples of when classification may change. For example, one comment requests clarity on what requirements in the proposed rule would apply for shallow ground water influenced by surface water.

(Response 44) We recognize that farms may use a variety of water sources and distribution systems for their pre-harvest agricultural water. As such, we are revising the requirement to clarify that considering whether a water source is ground water or surface water is just one example of the information farms might consider in evaluating the location and nature of the water source (see § 112.43(a)(1)(i)).

We do not consider it necessary or practical for us to define types of water sources other than ''ground water'' and ''surface water'' in § 112.3, as the conditions associated with such other sources are expected to vary widely and contain elements addressed within the definitions for ground water and surface water, which may result in confusion. For example, the term ''recycled water'' in common usage can refer to many different things—such as use of water from a canal system that is subject to return flows, or use of treated, recycled wastewater—such that it would be difficult to define ''recycled water'' in a way that is meaningful for hazard identification purposes across categories of recycled water. Rather, we intend farms to describe the specific conditions and characteristics associated with a water source that may affect the likelihood of known or reasonably foreseeable hazards being introduced when evaluating the location and nature of the source under § 112.43(a)(1)(i), including for recycled water. We provide examples of such considerations, including situations in which classification of a water source may change, in response to comment 30.

With respect to comments requesting clarity on whether different requirements apply based on water source, we note that the requirements for agricultural water quality in §§ 112.41 and 112.43 apply regardless of the source or type of water used as agricultural water. Farms must determine the appropriate use of their water sources by assessment as required under § 112.43, taking into account the standard in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. As such, we are not establishing different requirements for pre-harvest agricultural water based on the nature of a farm's water source.

(Comment 45) A few comments seek clarity on how to classify municipal water stored in jugs, enclosed cisterns, food-grade tanker trucks, or barrels, and rainwater that is collected prior to use.

(Response 45) In evaluating each agricultural water system a farm uses for pre-harvest agricultural water in § 112.43(a)(1), farms are required to evaluate the location and nature of the water source; the type of water distribution system; and the degree of protection from possible sources of contamination. Considering such information will assist farms in evaluating the likelihood of known or reasonably foreseeable hazards being introduced to their pre-harvest agricultural water, the latter of which may then serve as a source of contamination to covered produce or food contact surfaces. For example, if farms hold pre-harvest agricultural water in storage vessels such as jugs, cisterns, or barrels, the following factors are relevant to consider as part of their agricultural water assessment under § 112.43(a)(1):

• Where they sourced the water from (and what they know about its quality at that point);

• Whether the storage vessels are structured to protect that quality of water (such as whether they are kept closed to prevent entry of contaminants, such as from birds or other pests); and

• Whether the storage vessels undergo any regular maintenance, cleaning and/or sanitizing to prevent them from serving as a source of contamination for the water.

Such storage vessels are part of the farm's agricultural water system as defined in § 112.3, and as such, under § 112.42 the farm must inspect and maintain the vessels, to the extent that they are under the farm's control, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. In accordance with § 112.43(a), farms must also consider the results of any inspections and maintenance conducted under § 112.42 in preparing an agricultural water assessment.

(Comment 46) One comment requests that FDA provide information on the scope of water sources that would be considered adjacent and how those would be incorporated into agricultural water assessments.

(Response 46) We recognize that in some instances, known or reasonably foreseeable hazards may be introduced into an agricultural water system (defined at § 112.3) from a body of water that is not otherwise a part of that system. For example, a canal that a farm uses for pre-harvest agricultural water may be subject to known or reasonably foreseeable hazards from a nearby pond if, when it rains, runoff from the pond is introduced into the canal. If there are other bodies of water that may introduce

known or reasonably foreseeable hazards to an agricultural water system (as in the above example), farms must consider that information in evaluating the degree of protection of the agricultural water system from possible sources of contamination under § 112.43(a)(1)(iii). For example, a farm might consider the nature of the other body of water, the proximity of the other body of water to the farm's agricultural water system, and local topography, as these factors might affect the likelihood of known or reasonably foreseeable hazards being introduced to the agricultural water system from the other body of water.

(Comment 47) Some comments seek clarity as to how the requirements to consider the location and nature of the water source in proposed § 112.43(a) applies in CEA farms, such as some hydroponic and aquaponic operations. Additionally, one comment suggests that indoor farms should consider whether the surrounding building and/or other infrastructure may impact the quality of pre-harvest agricultural water.

(Response 47) Section § 112.43(a)(1) requires farms to evaluate each agricultural water system that they use for growing activities for covered produce, including, in part, the location and nature of the water source (for example, whether it is ground water or surface water) and the degree of protection from possible sources of contamination. Although CEA operations may provide an additional degree of control over some types of hazards compared to other operations, we emphasize that it is still important to consider a range of potential sources of hazards that might affect agricultural water used in CEA. For example, in our investigation report for the 2021 outbreak of *Salmonella* Typhimurium associated with packaged leafy greens produced in a CEA indoor hydroponic facility, we discussed various findings related to water use and highlighted the importance of assessing and mitigating risks associated with adjacent and nearby land uses that may impact CEA operations, in both rural and more urbanized settings (Ref. 62). See response to comment 41.

We also agree that it is important for farms in general (not just those participating in CEA) to consider buildings and/or other infrastructure that might affect the quality of their pre-harvest agricultural water. We note in particular that the definition of ''agricultural water system'' includes, in part, ''any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities'' (§ 112.3). As such, to the extent that any building, structure, or equipment is a component of a farm's agricultural water system, the farm must inspect and maintain those components to the extent that they are under the farm's control in accordance with § 112.42 and consider those components in conducting an agricultural water assessment pursuant to § 112.43. For example, in evaluating the degree of protection of an agricultural water system from possible sources of contamination under § 112.43(a)(1)(iii), farms should consider whether buildings or structures that are part of its agricultural water system protect other components of the agricultural water system from possible sources of contamination (such as where a well house or storage shed might protect wells and/or water application equipment from debris, trash, domesticated animals, or other possible sources of contamination).

1. Degree of Protection of Each Agricultural Water System

a. General

(Comment 48) A few comments request examples of types of hazards beyond animals, biological soil amendments of animal origin (BSAAOs), and human waste that should be considered as part of an agricultural water assessment. One comment suggests that farms might also consider maintenance activities in an irrigation district and whether a farm is near an airport subject to nearby chemical intrusion as part of an agricultural water assessment.

(Response 48) Section 112.43(a)(1)(iii) requires that as part of an agricultural water assessment, farms evaluate the degree of protection of the agricultural water system from possible sources of contamination. While other water users, animal impacts, and adjacent and nearby land uses related to animal activity, BSAAOs, or presence of untreated or improperly treated human waste are provided as examples of possible sources of contamination, we note that the list of examples in § 112.43(a)(1)(iii) is not exhaustive. For example, if applicable to the circumstances, the farm must consider the following potential sources of contamination as part of its agricultural water assessment: upstream maintenance activity (such as dredging) within a canal system that may affect the microbial quality of the water; urban development activities from which runoff may introduce hazards to the agricultural water system; and human activities (such as recreational vehicle parks) that may introduce hazards to the agricultural water system. We note, however, that the 2015 produce safety final rule applies to biological hazards and not, for example, chemical hazards. See response to comment 8.

(Comment 49) Some comments suggest that farms with agricultural water systems that span long distances from source to point of delivery (such as some irrigation canals) will face challenges when preparing agricultural water assessments, as certain portions of the water system, such as those that relate to adjacent and nearby lands and/or other water users, may not be under the farm's control. A few comments suggest that additional clarity on how far upstream farms are required to consider impacts on their water systems would help, and request more information on what distance upstream farms are responsible for considering.

(Response 49) We recognize that some farms have pre-harvest agricultural water systems with water sources and/or distribution systems, such as irrigation canals or rivers, that span long distances or are impacted by land uses covering a wide area. We further recognize that factors that can affect water sources, including those related to adjacent and nearby lands and/or other water users, may be outside of a farm's control.

More broadly, due to the variability that exists in agricultural water systems and across different growing regions, including in the characteristics of water sources and the nature of potential sources of hazards, farms' consideration of other agricultural water users and/or adjacent or nearby lands will vary widely, include factors that may be outside of a farm's control, and will likely depend on each farm's unique agricultural water systems and growing operations. For example, the QAR (Ref. 17) found that the composition and chemistry of flowing waters can be expected to be largely influenced by their course through land used for purposes that may lead to their contamination and, potentially, to the contamination of produce exposed to those waters. As such, we do not consider it appropriate to prescribe a distance for which farms must consider factors that have the potential to impact their water quality.

While we are not requiring farms to physically visit areas of an agricultural water system that are outside of their control, farms must include in their assessments information on sources of hazards (such as adjacent and nearby

land uses and other water users) that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water. We note that there are a variety of resources available to farms that may provide information as to the presence and nature of impacts that might affect the quality of their agricultural water. See response to comment 51.

(Comment 50) One comment requests that FDA revise the requirements for agricultural water assessments in proposed § 112.43(a) to clarify that farms are only required to consider the degree of protection and/or adjacent and nearby land uses for surface water sources, and that only possible sources of contamination within the surface water's drainage basin need to be considered.

(Response 50) We do not consider it appropriate to limit consideration for the degree of protection of an agricultural water system and/or adjacent and nearby land uses to surface water sources only, as doing so would not sufficiently capture the variety of water sources and potential sources of hazards that exist in industry. While surface water sources are generally more vulnerable to contamination, the potential for contaminants to be introduced to agricultural water is not limited to surface water (Ref. 17). For example, if a well is not sufficiently protected (for example, due to unprotected cross-connections or from having an impaired well cap, seals, and/or casing), it may increase the likelihood of hazards being introduced to the water. Similarly, if the well is situated at a lower elevation than adjacent and nearby lands and is subject to runoff from those lands, it may be subject to the introduction of hazards. As occurrences such as these are important for farms to consider in complying with the requirements for pre-harvest agricultural water assessments, we decline to make the change suggested by the comment.

(Comment 51) Some comments state that farms will face difficulties in getting information on factors that are outside of their control (for example, other users of water and adjacent and nearby lands), such as when those areas are not available for farms to access due to ownership or geographic barriers. A few comments indicate comfort speaking with neighbors about their land use(s), whereas other comments state that some farms may face challenges in obtaining information on adjacent and nearby lands due to land users either being unwilling to share information or providing incomplete or inaccurate information. Some of these comments request that farms should be able to assume that, in the absence of obvious evidence to the contrary, neighbors are following the law. One comment expresses a concern that situations could arise in which a neighbor informs a farm that they are appropriately controlling hazards but are not doing so, and seeks clarity as to whether the farm would be held responsible in this situation. While some comments acknowledge that there may be other sources of information on adjacent and nearby lands, a few suggest that some of these resources (such as visual observation and mapping tools) are inadequate because they cannot reveal all specific hazards.

(Response 51) Farms are responsible for ensuring that all applicable requirements of subpart E are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use. While farms are not required to physically visit areas of an agricultural water system that are outside of their control, in preparing an agricultural water assessment under § 112.43, farms must include in their assessments information on sources of hazards (such as adjacent and nearby land uses and other water users) that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water.

Although farms may consider working with adjacent and nearby land users in evaluating adjacent and nearby land uses under § 112.43(a), there are a variety of resources available that may provide insight as to the presence and nature of impacts that can affect the quality of agricultural water. For example, information can be acquired through visual observation, from local extension agents and/or industry associations, or from online resources such as mapping tools, which may provide helpful information on topography and proximity to potential sources of hazards. Depending on the water source being used, there may also be organizations or water management authorities, such as irrigation district managers, that can serve as a source of information. We are also aware of efforts underway to bring together members of agricultural communities on a large scale, such as through the CAN Initiative (Ref. 38), to further conversations and encourage discussions between land users in agricultural areas. Various action items have been identified as part of CAN, one of which entails steps that can be taken to foster neighbor-to-neighbor interactions and conversations (Ref. 39). See also response to comment 33. As efforts such as these progress, they too may serve as an additional source of information for meeting the requirements in § 112.43. In some instances, farms may benefit from looking to a variety of resources to assist in their understanding of other water users and adjacent and nearby land uses to further inform their determinations under § 112.43(c) as to whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.

We recognize that even with the variety of resources available to farms, farms may still face uncertainty with respect to other water users and adjacent and nearby lands that are outside of their control, such as if upstream users are not willing to share information. As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69137–69138), due to the nature of the risks associated with animal activity, BSAAOs, and untreated or partially treated human waste on adjacent and nearby lands, in the event of uncertainty, farms should consider accounting for the increased likelihood of hazard introduction to the water systems. Farms should use that information, particularly for surface water unprotected from runoff and in light of other factors evaluated under § 112.43(a), in determining whether measures under § 112.45 are reasonably necessary. See also response to comment 53.

(Comment 52) Some comments suggest that when evaluating the degree of protection of each agricultural water system, farms may recognize riparian buffers and filtrating vegetation for their role in protection water from sources of contamination.

(Response 52) We agree that buffers and filtrating vegetation, in addition to walls, earthen berms, ditches, or other barriers, may help minimize the influence of runoff on water sources and distribution systems. (See 86 FR 69120 at 69134 and 69136.) The comments did not request, nor are we requiring, farms to use any of these barriers in managing their identified risks. We further agree that there may be other mechanisms by which agricultural water systems are protected from possible sources of contamination via runoff, the impact of which farms may consider when

conducting their agricultural water assessments.

b. Adjacent and Nearby Land Uses

(Comment 53) Several comments support the proposed rule's requirement for farms to assess adjacent and nearby land uses. Conversely, some comments assert that the proposed requirement that covered entities must evaluate adjacent and nearby land uses represents an unreasonable burden on farms. A few of these comments claim that if farms are not able to prove that adjacent or nearby land use does not pose a risk, they would be forced to assume risks are present and undertake potentially overly conservative or unnecessary mitigations. One comment requests that FDA include in the final rule an alternative option for achieving the requirement to evaluate adjacent and nearby land use, suggesting that a provision for a written explanation for why the adjacent and nearby lands cannot be assessed, combined with water testing, would suffice. Another comment suggests that adjacent and nearby lands should only be evaluated for certain high-risk activities, although, the comment notes, what is considered ''high risk'' is also dependent on the water source and crop being grown.

(Response 53) As discussed in the 2021 agricultural water proposed rule (80 FR 74354 at 69126–69127), adjacent and nearby land uses have been identified as possible contributing factors in several produce outbreaks (Refs. 18–23, 58, 63 and 64). FDA's investigations of such outbreaks underscore the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. The requirements we are finalizing with this rule are designed to address these concerns by requiring farms to evaluate adjacent and nearby land uses in preparing an agricultural water assessment under § 112.43(a) and manage use of their pre-harvest agricultural water accordingly. As such, we decline to provide an alternative to the requirement that adjacent and nearby lands be evaluated under § 112.43(a) as part of an agricultural water assessment.

Moreover, we are providing for expedited implementation of mitigation measures under § 112.45(b) for known or reasonably foreseeable hazards related to certain adjacent and nearby land uses. We recognize that activities associated with adjacent or nearby lands that introduce known or reasonably foreseeable hazards into a water source or distribution system are often not under a farm's control. While the farm may not have control over those potential hazards at their point of introduction into a water source or system, the potential hazards are important for the farm to consider in making decisions about the use of agricultural water on covered produce. Therefore, for animal activities, BSAAOs, or untreated or partially treated human waste associated with adjacent and nearby lands, it is important that the farm not only implement mitigation measures that are under its control to reduce the risk associated with that water source or system, but that it do so on an expedited basis to protect public health.

Many activities on adjacent or nearby lands may create or pose conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, which farms must consider under § 112.43(a) as part of an agricultural water assessment if applicable to their operations. Examples include other agricultural operations (such as land used for growing operations, animal grazing, dairy production, poultry production, barnyards, commercial animal feeding operations, and farms with working animals); composting sites; lands used for recreational activities (such as campgrounds); wastewater treatment facilities (or other potential sources of human waste like toilet facilities and sewage disposal systems); urban/suburban development activities; and lands with significant wildlife intrusion or habitat.

We recognize that farms may face uncertainty around evaluating information related to adjacent and nearby land uses such as these, such as if upstream users are not willing to share information. As discussed in the 2021 proposed rule (86 FR 69120 at 69137–69138), in the event of uncertainty, due to the nature of the risks associated with animal activity, BSAAOs, and untreated or partially treated human waste on adjacent and nearby lands, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from adjacent or nearby lands when making decisions around the use of their water. However, we disagree that this will ''force'' farms to assume risks are present and implement mitigation measures that might otherwise not be necessary. Rather, farms should consider the increased likelihood of hazard introduction from such adjacent and nearby land uses, in addition to other information evaluated in § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary. As a result, farms may find, for example, that in light of the information evaluated under § 112.43(a)(1) through (5), mitigation may not be reasonably necessary to address potential hazards from an adjacent or nearby land use.

(Comment 54) Many comments request that FDA clarify the definition of and/or narrowly define ''adjacent and nearby lands'' in terms of distance, arguing that absent such a definition, it will be unclear what lands farms are responsible for considering. One comment notes that other food safety schemes define adjacent land as no CAFOs closer than 0.25 miles or 400 feet buffer from hobby farms. Another comment expresses concerns that in the Fall 2019 *E. coli* O157:H7 outbreak linked to romaine lettuce referenced in the proposed rule, the outbreak strain was found at a point nearly two miles upslope from the impacted farms, a distance the comment deems unreasonable for a farm to consider in its assessment.

(Response 54) In the 2021 agricultural water proposed rule (86 FR 69120 at 69135), we discussed ''adjacent and nearby lands'' with respect to agricultural water systems specifically, as adjacent and nearby lands may affect the safety of covered produce in ways not related to agricultural water, such as through movement of animals, equipment and tools, run-off into growing fields, and wind. We recognize that this may have led to uncertainty as to the lands that farms are required to consider for assessment purposes, and are clarifying that for the purposes of subpart E, by ''adjacent'' land we are referring to land sharing a common border with the farm's land. By ''nearby'' land we are referring to a broader category of land, including land that does not adjoin the farm's land but has the potential to affect the farm's agricultural water systems(s) based on the land's location. For example, agricultural water may be affected by agricultural practices and runoff from those operations into surface water sources or open distribution systems that are used for agricultural water even if the operations' lands are not adjacent to a farm's land. See also 80 FR 74354 at 74433. Due to the diversity that exists in agricultural water systems and across different growing regions, what constitutes ''adjacent'' and ''nearby'' land will vary between farms and likely depend on each farm's unique agricultural water systems. As such, we do not consider it appropriate to prescribe an upstream distance for

which farms must consider uses of adjacent and nearby lands. See also response to comment 49.

c. Animal Impacts and Activities

(Comment 55) Several comments seek clarity on how a farm should translate evidence of animal activity (*e.g.,* scat from unidentified animals, tracks without scat, or damaged irrigation pipes from an unidentified animal) into risk, noting that different animals and animal activities represent different levels of risk to water safety. One comment expressed a concern that the requirement for farms to consider animal activity may lead to the outcome that a farm with any animal activity nearby will be expected to implement significant safety measures.

(Response 55) Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with animals under § 112.43(a)(1)(iii) include, but are not limited to, the following:

- The presence and location of any animal activities, such as whether there are areas in which animals might be in close proximity and/or have direct access to pre-harvest agricultural water systems (such as for loafing or drinking). Included in this is consideration for any fencing, containment, or other measures that may affect animal access to agricultural water systems;
- The presence and location of potential attractants and habitats (such as heavy vegetation, wooded areas, water sources, or standing water) that may draw animals to agricultural water systems;
- Whether runoff into agricultural water systems from lands currently or historically associated with animals is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- Whether animals have access to areas relevant to agricultural water systems at times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- Whether any systems or structures are in place to handle, convey, or store animal waste (such as animal stalls, composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to agricultural water systems. Included in this, for example, is whether vehicles carrying animal waste follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the animal waste to agricultural water systems.

As discussed in the 2021 proposed rule, visual observations by a farm for purposes of §§ 112.81–112.83 in subpart I, ''Domesticated and Wild Animals'' of the 2015 produce safety final rule may provide useful information for evaluating the degree of protection of a pre-harvest agricultural water system under § 112.43(a)(1)(iii) (86 FR 69120 at 69135). Additionally, a farm may be aware of potential animal impacts on agricultural water systems through inspections and maintenance performed on agricultural water sources and agricultural water systems it controls under § 112.42, which we did not propose to change. For example, pooled water in close proximity to the crop may serve as an attractant for pests and other animals which may in turn introduce hazards into pooled water that may contaminate produce. (See 80 FR 74354 at 74434.)

Given the diversity that exists across industry in water systems, operations, and conditions, we do not expect that every animal impact or activity will require that corrective or mitigation measures be implemented under § 112.45. While farms are required to evaluate the degree of protection of an agricultural water system from possible sources of contamination including animal impacts and adjacent and nearby land uses related to animal activity, they are required to consider that information, along with the other factors evaluated under § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary.

(Comment 56) One comment suggests that farms should take the type of animal activity into account when evaluating risks as part of an agricultural water assessment. For example, the comment asserts that management techniques such as prescribed grazing can result in less opportunity for contamination of water via runoff compared to CAFOs, since fecal matter is dispersed across a larger area of land where prescribed grazing occurs. The comment also states that dispersed feces in areas used for prescribed grazing are more likely to be inactivated by the sun's UV rays versus feces at a CAFO.

(Response 56) The risk posed by animal activities to a farm's agricultural water systems may depend on various factors and are not limited only to animal activities with high densities of animals, such as CAFOs. Animal activities have the potential to serve as a source of human pathogens, and depending on the circumstances, may introduce hazards to agricultural water systems (Ref. 17). Animal activities can include those related to wildlife (*e.g.,* birds or deer); animal intrusion, domesticated companion animals (*e.g.,* dogs, cats); animals for protection (*e.g.,* guard dogs); working animals (*e.g.,* horses, mules); grazing animals; livestock (including CAFOs); poultry production; dairy production; and barnyards.

For example, as discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69125–69127), in the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20), investigators noted that extensive wild animal activity in the area and animal grazing on nearby land by cattle and horses, among other things, may have served as potential sources of hazards. Similarly, in the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21), investigators observed cattle grazing land in the hills above leafy greens fields, with numbers of cattle far lower than the volume of what is considered a large CAFO. As discussed in the QAR (Ref. 17), exposure of produce to hazards from animals may occur, among other means, through runoff that enters the growing area and contaminated agricultural water. As such, we consider it important for farms to consider various animal impacts and activities, not just those related to CAFOs, for the potential to serve as sources of known or reasonably foreseeable hazards that may be introduced into an agricultural water system and contaminate covered produce.

d. BSAAOs

(Comment 57) One comment requests more information on what FDA would consider to be ''high risk'' regarding agricultural water and the use of BSAAOs.

(Response 57) As discussed in response to comment 31, given the diversity across farms, ''risk'' related to BSAAOs will vary. For example, the QAR (Ref. 17) concluded that composting is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste; incompletely treated, or re-contaminated, BSAAOs may contain human pathogens; and biological soil amendments can transmit human pathogens to surface water or ground water when stockpiled or applied to fields. The use of BSAAOs both by the farm and by users of adjacent and nearby lands are factors to consider for purposes of an agricultural water assessment under § 112.43(a), and in making a risk management determination under § 112.43. We intend farms to consider information relevant to their specific circumstances

in evaluating the various factors under § 112.43(a).

Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with BSAAOs include, but are not limited to, the following:

- The location and proximity of areas where BSAAOs are held or applied to land in relation to agricultural water systems;
- Whether runoff or tailwater returns into agricultural water systems from areas where BSAAOs are held or applied to land is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- Whether the BSAAOs are treated and to what extent;
- Whether BSAAOs are applied to the land during times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- Whether any systems or structures are in place to handle, convey, and store BSAAOs (such as composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to agricultural water systems. Included in this, for example, is whether vehicles carrying BSAAOs follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the BSAAOs to agricultural water systems.

For farms subject to the 2015 produce safety final rule, we note that requirements in subpart F of part 112 (§§ 112.51–112.60) may apply, including § 112.52(a), which requires that farms handle, convey, and store any BSAAO in a manner and location such that it does not become a potential source of contamination to water sources and water distribution systems.

(Comment 58) One comment seeks clarity as to whether there are ''specifications'' for the use of BSAAOs and different types of irrigation methods under the proposed rule.

(Response 58) It is unclear to us what type of ''specification'' the commenter is referring to. However, we note that this rule does not establish requirements for allowable pre-harvest agricultural water application methods based on the source of known or reasonably foreseeable hazards to an agricultural water system. Farms remain responsible for ensuring that all applicable requirements are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use.

e. Untreated and Improperly Treated Human Waste

(Comment 59) Some comments address the requirement in § 112.43(a)(1) to consider the degree of protection from possible sources of contamination, including untreated or partially treated human waste. One comment pertains to the regulations laid out in 40 CFR part 503 related to land applied biosolids, and suggest that the applications of treated municipal biosolids to land can be safely done. Conversely, other comments suggest that application of biosolids from municipal or industrial sources requires further evaluation and/or research as it relates to impacts on agricultural water and produce safety. One comment opposes the land application of municipal wastewater sludge and industrial waste (for example, slaughterhouse sludge), suggesting that there should be restrictions for the use of such materials on crops and that land applications of those materials may serve as a source of contamination to water sources.

(Response 59) As described in the QAR (Ref. 17), human waste may contain pathogens in relatively high concentrations. Runoff associated with human waste from adjacent and nearby lands may contaminate sources or distribution systems for pre-harvest agricultural water for non-sprout covered produce. As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69137), an evaluation of hazards associated with untreated or improperly treated human waste can include consideration of potential sources of contamination such as toilet facilities (portable and fixed), sewage systems, sewer overflows, septic tanks, and drain fields. 86 FR 69120 at 69137.

With respect to comments relating to land applications of treated sewage sludge (biosolids) and/or industrial waste (such as from slaughterhouses), we note that such comments are outside the scope of this rulemaking. Rather, as part of a pre-harvest agricultural water assessment under § 112.43(a), farms are required to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces based on an evaluation of various factors, including the degree of protection of each agricultural water system from possible sources of contamination (§ 112.43(a)(1)(iii)). As part of this evaluation, farms consider the presence of potential sources of hazards (such as land applications of such materials); the likelihood of those hazards being introduced to their water systems (such as through runoff or seepage); and together with the other information evaluated in § 112.43(a)(1) through (5), make a determination as to whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces from hazards associated with pre-harvest agricultural water.

We emphasize that other provisions of the 2015 produce safety final rule that we did not propose to change, including the prohibition on the use of human waste for growing covered produce (except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements) (§ 112.53), continue to apply.

It is important for farms to consider the increased likelihood of hazard introduction to their agricultural water systems for any land applications of materials such as treated sewage sludge (biosolids) and industrial wastes, because those materials may serve as a source of known or reasonably foreseeable hazards that can be introduced into an agricultural water system (such as through runoff). Farms should consider the increased likelihood of hazard introduction to their agricultural water systems, particularly for surface water unprotected from runoff and in light of other factors evaluated under § 112.43(a), in determining whether measures are reasonably necessary under § 112.45.

f. Other Water Users

(Comment 60) Several comments address FDA's request for comment on water reuse for pre-harvest agricultural water. Some comments state that reused water can be used as safely as other types of water and may help farms faced with dwindling water supplies from other sources. A few of these comments specifically suggest that wastewater can be treated to be ''fit for purpose,'' in which it is treated to a level that is safe for a specific use on irrigated food crops. Some comments also note that the requirements related to quality and use of pre-harvest agricultural water in §§ 112.41, 112.42, and 112.43 are appropriate to apply for all types of water. However, a few comments suggest that reused water should be subject to testing before being used as pre-harvest water. Another comment requests that FDA clarify in the final rule and in subsequent guidance that untreated or improperly treated human waste is not present in treated recycled wastewater because water recycling includes proper treatment of human

waste. The comment suggests that without additional guidance from FDA, a farm may interpret using a recycled water source as inherently risky even when it is not.

(Response 60) As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69134–69135), the requirements for agricultural water quality in §§ 112.41 and 112.43 apply regardless of the source or type of water used as agricultural water. Thus, a farm must determine the appropriate use of the recycled water in light of the conditions and practices on the farm by assessment as required under § 112.43, taking into account the standard in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. As comments suggest, farms also need to ensure that all other applicable requirements in subpart E are met, including those in § 112.42 for inspection and maintenance of agricultural water systems to the extent they are under a farm's control, the results of which farms will consider in preparing an agricultural water assessment under § 112.43(a).

We are not aware of, and comments did not provide, data or information suggesting the need to require that all recycled or reused water be tested to adequately complete an agricultural water assessment. Therefore, consistent with our mandate to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act, we are not establishing separate requirements related to testing or quantitative thresholds for water reuse. Users of such water, if appropriate, may test that water as one part of an assessment under § 112.43(d). While we provide examples of scientifically valid microbial criteria and sampling frequencies in our responses to comment 95 and comment 93, respectively, we expect that as the science evolves and more information is learned about unique considerations relevant to certain sources of water (such as water reuse), such information may be incorporated in future guidance.

We also recognize that some suppliers of recycled water (for example, a public utility), may furnish information on the water's microbial quality which can be considered while preparing agricultural water assessments and determining whether measures are reasonably necessary under § 112.45.

2. Agricultural Water Practices

(Comment 61) Some comments address the requirement in proposed § 112.43(a)(2) that farms assess the time interval between the last direct application of agricultural water and harvest of the covered produce. These comments suggest that agricultural water used early in the production cycle is less risky than water used closer to harvest and request that FDA recognize this variation in risk when evaluating farms' assessments and records. Other comments note the variability in application-to-harvest intervals that exist across industry. For example, some comments note that for certain crops, agricultural water needs to be applied right up until harvest, whereas for other crops, there may be more flexibility as to the timing of the last water application. Others cite challenges associated with assessing the interval between the last direct application of agricultural water and harvest. These comments note that in some instances, the harvest date and/or the last water application is established by the shipper, and that such decisions may not be made until right before harvest.

(Response 61) As explained in the QAR (Ref. 17), the timing of water application is an important factor in determining the likelihood of contamination of produce, because many pathogens die off over time on the surface of produce. Generally, bacteria or pathogens in water that is applied early in the growing cycle are subject to die-off from several environmental forces, such as UV exposure, temperature, humidity, and the presence of competitive organisms (Ref. 65). In contrast, pathogens present in agricultural water that is applied shortly before harvest may not be exposed to the same environmental conditions for sufficient time to provide a similar magnitude of die-off (Ref. 17). We recognize that the time interval between last direct application of agricultural water and harvest is likely to vary widely across industry, and as such, each farm must capture the practices unique to its operation within its agricultural water assessments and use that information, alongside the other factors evaluated under § 112.43(a), in determining whether measures are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the farm's pre-harvest agricultural water.

Further, we recognize that there may be some instances in which there is uncertainty as to what the time interval between last application of agricultural water and harvest will be. In such instances, farms may use their previous experience and knowledge of agronomic practices to provide an estimate in their agricultural water assessment as to what the expected interval might be. For example, if a farm knows that the last water application generally occurs 1 to 2 weeks before harvest, even though the precise interval may vary and not be known until right before harvest, the farm may note that in its agricultural water assessment and use that information alongside other factors evaluated in § 112.43(a) in making decisions regarding use of its pre-harvest agricultural water.

3. Crop Characteristics

(Comment 62) Many comments address the proposed requirement in § 112.43(a)(3) that farms evaluate crop characteristics as part of their agricultural water assessments. Several comments seek clarification from FDA that characteristics of the crop include aspects beyond what is explicitly listed in the preamble of the proposed rule, such as whether the crop is grown in a manner that is exposed to pooled water or wet soil, whether it supports the growth of foodborne pathogens, and whether it has historically been linked to outbreaks where pre-harvest water use was a known or suspected route to contamination.

(Response 62) Section § 112.43(a)(3) requires farms to evaluate crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards, as part of their agricultural water assessments. Crop characteristics that a farm considers may extend beyond those provided as examples in § 112.43(a)(3), which we are finalizing as proposed, without changes. For example, a farm may have information suggesting that characteristics of its covered produce support the attachment, survival and/or growth of pathogens that may be introduced via agricultural water. We also note that contact between covered produce and pooled water is addressed in § 112.42(b)(4), which we did not propose to substantively revise. Section 112.42(b)(4) requires that farms, as necessary and appropriate, implement measures reasonably necessary to reduce the potential for contamination of covered produce resulting from contact of covered produce with pooled water.

We emphasize that absence of a history of outbreaks associated with a particular commodity should not be

relied upon as being indicative of that commodity having characteristics that inherently make it ''safe''. For example, in our investigation of the summer 2020 outbreak of *Salmonella* Newport linked to red onions, we noted that the outbreak was remarkable because the food vehicle, whole red onions, is a raw agricultural commodity that had not been previously associated with a foodborne illness outbreak (Ref. 23). Although a conclusive root cause could not be identified, several potential contributing factors were identified, including a leading hypothesis that contaminated irrigation water used in a growing field may have led to contamination of the onions.

(Comment 63) Several comments oppose the proposed requirement in § 112.43(a)(3) that farms identify and assess crop characteristics in their agricultural water assessments and recommend that assessment of crop characteristics be included in guidance and/or training programs instead, rather than as enforceable requirements in the final rule. Some comments request that FDA provide research support and scientific information on characteristics that do, or do not, make a crop more susceptible to contamination. A few comments note that crop characteristics are not a factor in other produce safety programs, such as the Leafy Greens Marketing Agreement (LGMA) metrics, noting that under the assessment that LGMA requires, leafy greens are treated equal, and water should be of adequate quality for its intended use no matter what covered produce crop is being grown.

(Response 63) All agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41), and we consider that evaluating crop characteristics, alongside other factors identified in § 112.43(a), as part of a farm's agricultural water assessment will assist farms in determining whether this standard is met.

While the QAR concluded that using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne outbreak, it also explains that where contamination of a water source is known to exist, the likelihood of contamination is a function of various factors, including contact with the commodity, commodity effects (characteristics), and application timing (Ref. 17). Moreover, in the 1998 Good Agricultural Practices (GAPs) Guide (Ref. 59), we explain that produce that has a large surface area (such as leafy vegetables) and produce with topographical features (such as rough surfaces) that foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact with agricultural water occurs close to harvest or during post-harvest handling. Studies have also shown that the contamination of produce by contact with irrigation water is dependent, in part, on the physical properties of the plant, such as surface texture (Ref. 66). Moreover, survival of pathogens on produce is known to be enhanced if the epidermal barrier has been broken by physical damage, such as punctures or bruising, or by degradation by plant pathogens or spoilage organisms (Refs. 67 and 68).

In light of the foregoing, we have concluded that there is sufficient evidence of the effect of crop characteristics on the safety of covered produce to which agricultural water is applied; therefore, and we are not removing crop characteristics as one of the factors farms are required to evaluate under § 112.43(a). Peer-reviewed literature, cooperative extension, and academic or trade organization research may serve as additional sources of information on the effect of crop characteristics on pre-harvest agricultural water.

(Comment 64) Several comments assert that the crop characteristics listed in the preamble of FDA's proposed rule are not specific to water and therefore are outside the scope of the proposed rule. For instance, one comment asserts that crop characteristics contribute to risks related to cultivation, harvesting, packing, and holding practices as a whole and not to agricultural water in particular. The comment recommends that if FDA intends to retain crop characteristics as a factor in the final rule related to agricultural water, the Agency should explicitly state that consideration of crop characteristics is limited to how the characteristics relate to potential contamination from direct application of agricultural water.

(Response 64) We disagree that including consideration of crop characteristics as part of a farm's agricultural water assessment under § 112.43(a) is outside the scope of this rulemaking, as crop characteristics have long been identified as a factor influencing the potential for water to contaminate produce (see response to comment 63). However, we recognize that not all crop characteristics may be relevant to potential contamination of covered produce by agricultural water, and we emphasize that farms are only required to evaluate those characteristics that might influence the safety of covered produce in light of a farm's pre-harvest agricultural water.

(Comment 65) Several comments suggest that the inclusion of crop characteristics in agricultural water assessments will result in confusion, because, the comments claim, crop characteristics are only relevant to consider if an agricultural water source is already contaminated. For example, comments suggest that crop characteristics are only relevant to agricultural water use if the agricultural water is not of adequate sanitary quality and, therefore, the farm would already need to undertake mitigation measures independent of crop characteristics.

(Response 65) We disagree that crop characteristics are only relevant to consider if a farm has already determined that water is not safe or not of adequate sanitary quality for its intended use. As discussed in the 2013 proposed rule, the principle of ''safe and of adequate sanitary quality for its intended use'' contains elements related both to the attributes of the source water used and the activity, practice, or use of the water. The way in which water is used for different commodities and agricultural practices can affect the risk of contamination of the produce. 78 FR 3504 at 3563. While the QAR concluded that crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne outbreak (Ref. 17), consideration of various factors that play a role in the safety and quality of pre-harvest agricultural water on covered produce, of which crop characteristics is only one, will assist farms in making decisions around the use of their pre-harvest agricultural water. As such, farms are required to consider crop characteristics, in conjunction with each other factor in § 112.43(a)(1) through (5), in determining whether measures are reasonably necessary under § 112.45.

(Comment 66) A number of comments note that many farms grow a wide variety of crops and suggest that it would be burdensome and time-intensive for a farm to assess susceptibility for all crops, particularly for crops for which limited scientific data on susceptibility exists. Some question whether farms need to conduct separate assessments for each commodity they grow. One comment notes that some farms change what commodities they grow frequently, suggesting that requiring the farm to prepare an assessment with each change in commodity will be burdensome.

(Response 66) Farms have the flexibility to evaluate crop characteristics in § 112.43(a)(3) as appropriate given their pre-harvest

agricultural water uses and growing operations. For example, while we recognize that some farms may be growing multiple types of crops using the same agricultural water system, in some instances, crops may have similar characteristics such that the farm may group them based on broad similarities. For example, a farm that grows multiple types of leafy greens may assess the characteristics of all types at once, noting, for example, the large, rough surface area that may increase the likelihood of contaminants being trapped and surviving for extended periods of time. Similarly, a farm that grows oranges, mandarins, and lemons may assess the characteristics of citrus fruit in general. To the extent that a single commodity may have a unique factor that sets them apart from the others, the farm may choose to note that unique characteristic within its agricultural water assessment, rather than establishing a separate evaluation for that one crop. For example, a farm might explain whether one type of leafy green is particularly susceptible to physical damage that has the potential to result in survival and/or growth of pathogens, if introduced.

Farms that change crops frequently are likely aware of what commodities (or types of commodities) it is reasonably likely they may grow. This knowledge, along with practices such as grouping crops based on similarities in characteristics as discussed above, will assist farms in efficiently evaluating crop characteristics as part of their assessments. Further, in the instance where a farm does begin growing a commodity whose characteristics were not already evaluated as part of its agricultural water assessment, we note that reassessments under § 112.43€ must evaluate any factors and conditions affected by the change. As such, a farm's reassessment in light of a new crop may be more limited in scope than if a farm were to prepare a completely new assessment under § 112.43(a).

(Comment 67) One comment suggests that for some covered produce grown in hydroponic systems (such as green onions and lettuce), human pathogens may be internalized via plant roots and translocated throughout the plant. The comment also suggests that surface characteristics of some crops grown in hydroponic systems, such a lettuce, are also applicable to consider as part of an agricultural water assessment, as hydroponic lettuce leaves have been shown to be suitable for attachment of *Listeria.*

(Response 67) We recognize that CEA operations have unique considerations compared to more traditional outdoor growing operations. We agree that in a CEA operation, crop characteristics may affect the safety of the covered produce if contaminants are introduced via agricultural water. As such, farms must consider crop characteristics as part of their agricultural water assessments under § 112.43(a). In response to comment 63, we provide general information on crop characteristics relevant to agricultural water assessments for non-sprout covered produce. We agree that if a farm has information reflective of its unique conditions regarding the effect of crop characteristics on the safety of covered produce to which agricultural water is applied—for example, in the case of hydroponic operations, studies demonstrating crop characteristics that are particularly relevant to practices used in such operations—then that too is relevant to the farm's agricultural water assessment.

4. Environmental Conditions

(Comment 68) Many comments address the requirement in § 112.43(a)(4) that an evaluation of environmental conditions be included in a farm's agricultural water assessment. A few comments suggest that weather conditions can be relatively easily evaluated as part of the agricultural water assessment and that basic information regarding controlling hazards from weather events is already included in grower training courses. In contrast, some comments express concerns, suggesting that such a requirement is an unreasonable burden on farms that, the comments state, would have to obtain information on years of weather history, travel great distances to obtain information from U.S. Weather Service-approved stations, or access scientific journals for relevant data. Some comments suggest that scientific information on environmental impacts on produce safety is limited or nonexistent and it is unreasonable, therefore, to expect farms to evaluate it. Several comments seek clarity on how FDA will evaluate whether environmental factors have been sufficiently considered in the agricultural water assessment.

(Response 68) We considered the comments and are finalizing § 112.43(a)(4) as proposed, without changes. As described in the QAR (Ref. 17), survival of pathogens in the environment is influenced by complex physical, chemical, and biological interactions. Generally, bacteria or pathogens in water that is applied early in the growing cycle are subject to die-off from several environmental forces, such as UV exposure, temperature, and humidity (Ref. 65). Changes in temperature and seasonality are expected to impact persistence of foodborne pathogens in the environment (Ref. 68). Seasonal changes in rainfall—particularly heavy rainfall and flooding events—can greatly affect surface water quality (Refs. 69 and 70) and may result in sediments, which can serve as reservoirs for pathogens, being dispersed within the water column (Ref. 71). Airborne transmission may also result in contamination of the environment—such as agricultural water and growing areas—particularly when dry, windy conditions are present (Ref. 72). Moreover, weather events, such as freezing or hail, can result in physical damage to the epidermal barrier or produce (*e.g.,* punctures or bruising), that may allow for survival of pathogens on produce (Refs. 67 and 68). See the 2021 agricultural water proposed rule at 86 FR 69120 at 69138–69139.

In many instances, farms will be able to use their previous experience and knowledge of their growing region to assess the environmental conditions for their agricultural water assessment. For example, many farms already take weather and climatic conditions into account when making management decisions for the crops they grow, and when and how those plants are planted and harvested. We do not expect farms to obtain detailed reports of local conditions, conduct complex scientific analyses of weather events, or travel to weather stations in order to obtain such information. Rather, knowledge of general trends, such as the identification of wet seasons, average monthly temperatures, and seasonal trends in sun exposure, will likely provide farms with adequate information for their agricultural water assessment. If a farm is new to the growing region, the farm can obtain relevant information on environmental conditions from internet resources (such as average monthly temperatures and rainfall), cooperative extension, and other local resources.

(Comment 69) One comment notes that the weather in their area varies significantly by season (*e.g.,* a rainy season and a dry season) and seeks clarity on whether FDA expects farms to take different measures depending on the season. Several comments suggest that weather is unpredictable, for example, due to effects of climate change, and request clarity on how this should be accounted for in an agricultural water assessment. One comment seeks clarity about whether 1 year of historical weather data is enough, and why historical data can be

used to inform a current plan if weather can be variable year to year. Several comments assert that the proposed rule fails to adequately define environmental conditions (*e.g.,* ''regular weather'', ''extreme weather events'', and ''heavy rain''), making it difficult for farms to assess actual risk and for inspectors to consistently evaluate compliance. Several comments seek clarity on how a farm should assess rare weather events versus routine weather events, and seek guidance on what constitutes an unusual weather event and successful strategies for managing risks associated with different weather patterns that can occur by region.

(Response 69) We recognize that weather is likely to vary both seasonally and year-to-year and expect that farms will take this variability into account for their agricultural water assessment and determinations under § 112.45. For example, if a farm identifies February through May as a rainy season, the farm may determine, alongside the other factors evaluated under § 112.43(a), that measures are reasonably necessary under § 112.45 during that time due to concern over rainfall introducing hazards to its agricultural water system via runoff and/or by stirring up sediments. However, the farm may determine that measures are not reasonably necessary during other times of the year, when rainfall is not as likely to impact its agricultural water system(s). Conversely, a farm may determine that its rainy season occurs early enough in the growing season that, considered alongside the other factors evaluated under § 112.43(a), measures may not be reasonably necessary. In the event a farm determines that corrective or mitigation measures are reasonably necessary in relation to an environmental condition, what measures are appropriate will largely depend on the nature of the other factors evaluated under § 112.43(a). For example, depending on a farm's water use practices and crop characteristics, the farm may find it appropriate to change the water application method under § 112.43(b)(1)(iv) in response to hazards that may be introduced as a result of an environmental condition. See response to comment 113 for discussion regarding mitigation measures following environmental events.

In most instances, farms will be able to use their previous experience and historical knowledge of their growing region to assess not only general ''routine'' trends in environmental conditions (*e.g.,* yearly seasonal patterns in sun exposure), but also those conditions that might happen on a less frequent basis, but that nonetheless have the potential to impact their agricultural water systems or covered produce (*e.g.,* hurricanes, heavy winds, or rains that otherwise may occur on occasion). By recognizing these events within their agricultural water assessments, farms will be able to develop a plan to ensure the safety and quality of their pre-harvest agricultural water in the instance that such events do occur. However, we recognize that farms will not be able to anticipate every environmental condition that occurs. If an unanticipated environmental event occurs that is not already addressed within a farm's agricultural water assessment, the farm must consider whether it results in a significant change that necessitates a reassessment under § 112.43(e). For example, an earthquake that impairs a farm's piped distribution system, or series of atmospheric river events that repeatedly impact a farm's agricultural water system over a period of time, may necessitate a reassessment under § 112.43(e), depending on the circumstances. See also response to comment 100.

(Comment 70) Some comments suggest that by including the phrase ''or covered produce'' in proposed § 112.43(a)(4), FDA is requiring a farm to evaluate how environmental conditions affect each crop, independent of how the environmental conditions impact an agricultural water system. These comments contend that any requirement to evaluate how environmental conditions affects crops is outside the scope of Subpart E. Several comments suggest that environmental considerations are better addressed through guidance, training, or education.

(Response 70) We disagree that an evaluation of environmental conditions that may impact covered produce is outside the scope of this rulemaking, because some environmental conditions may have a direct effect on the susceptibility of the covered produce to surface adhesion or internalization of hazards from agricultural water. (See also the requirement in § 112.43(a)(3) to consider crop characteristics as part of an agricultural water assessment.) For example, if a weather event results in physical damage to a crop (such as if hail results in punctures or bruising), it may increase the susceptibility to survival of pathogens on the produce, if introduced by agricultural water (Ref. 68). As such, we continue to find it appropriate to require farms to consider environmental conditions that impact covered produce as part of their agricultural water assessments. However, we recognize that not all environmental conditions that affect covered produce may be relevant to potential contamination of covered produce by agricultural water, and we emphasize that farms are only required to evaluate those environmental conditions that may be relevant in light of a farm's pre-harvest agricultural water use.

(Comment 71) One comment asserts that weather and climate conditions vary by region, and it is unreasonable to expect farmers in one area of the country be required to account for potential weather events that do not apply to their region.

(Response 71) We do not expect farms to evaluate environmental conditions not relevant to their agricultural water systems and pre-harvest agricultural water use. As such, a farm in one region is not required to consider weather events that occur in another region, if the other region's weather is not relevant to the farm.

(Comment 72) One question seeks clarity on what FDA is looking for in terms of air temperatures and sun exposure. Specifically, the comment seeks clarity on whether a farm will need to provide separate assessments for each field depending on its sun exposure.

(Response 72) The requirements in § 112.43(a) to prepare an agricultural water assessment are specific to each agricultural water system that a farm uses for pre-harvest agricultural water. As such, farms are not necessarily required to prepare a separate agricultural water assessment for each field they use to grow covered produce. (However, if, for example, a farm uses different agricultural water systems for different fields, the farm is required to prepare an agricultural water assessment for each of those systems in accordance with § 112.43(a).)

To the extent that different fields are exposed to varying degrees of sun exposure and temperature, the farm may note as much within its agricultural water assessment. Farms may find such information particularly helpful in considering the appropriateness of relying on in-field microbial die-off as a mitigation measure, if they determine mitigation measures under § 112.45(b) are reasonably necessary and increase the time interval between last direct water application and harvest as a result.

(Comment 73) Some comments seek clarity on how a farm should assess heavy rain that occurs several miles upstream.

(Response 73) Factors to consider in assessing heavy rains as part of an agricultural water assessment include,

but are not limited to, the frequency of such events occurring; whether the rain event is reasonably likely to introduce known or reasonably foreseeable hazards into the agricultural water system (such as through runoff); and whether the farm can expect any other changes to occur by the time the water reaches the farm (such as adequate time to allow any stirred-up sediments to settle out of the water column). Considering this information, alongside the other factors evaluated under § 112.43(a), will assist farms in determining whether measures are reasonably necessary under § 112.45.

(Comment 74) One comment notes that farms may not irrigate after a heavy rain since the crops do not need additional water during that time, and requests clarity on how this should be considered under the proposed rule.

(Response 74) We recognize that the various factors identified in § 112.43(a) are likely to be interrelated, such as when farms cease irrigating their crops following a rain event. If a farm adjusts its water use practices based on other elements evaluated within its agricultural water assessment, the farm must include that as part of its evaluation and use all information considered under § 112.43(a) in determining whether measures are reasonably necessary under § 112.45.

(Comment 75) One comment suggests that environmental conditions may differ for CEA operations compared to outdoor farming, and provides various examples of environmental conditions they consider relevant to CEA, including condensation and subsequent dripping; use, maintenance, and cleaning of heating, ventilation, and cooling equipment; opening or closing of vents to the outdoor environment; and local pest populations. Moreover, the comment suggests that CEA operations such as hydroponic and aquaponic systems have other factors that should be considered as part of an agricultural water assessment, such as cleaning and sanitizing procedures for food contact surfaces; solids management (*i.e.* the accumulation of organic matter in the water); and UV irradiation and ozone treatments for water, which the comment suggests may have unknown efficacy in such systems.

(Response 75) We recognize that CEA operations face a unique set of conditions compared to more traditional outdoor growing operations and that environmental conditions such as weather events (*e.g.,* rain and exposure to sun), may be less relevant to their agricultural water systems and covered produce than in open-field systems. We also recognize that CEA operations may have other factors that are more relevant to their operations than to those growing covered produce in an outdoor capacity that nonetheless have the potential to impact their agricultural water systems and covered produce. Each farm must capture those conditions that are unique to its operation as part of its agricultural water assessment.

5. Other Relevant Factors

Comments regarding other relevant factors, with the exception of those related to testing as part of an assessment under § 112.43(d), are discussed below. Comments on testing conducted under § 112.43(d) are discussed in section V.H.

(Comment 76) Several comments support the language in proposed § 112.43(1)(5) that requires consideration of ''other relevant factors'' to provide farms with the option to incorporate unique circumstances or new scientific data in their agricultural water assessments.

(Response 76) We agree that it will be helpful for farms to capture any additional factors that are unique to their operations within their agricultural water assessments.

We also emphasize that there are provisions in other subparts of the 2015 produce safety final rule, which we did not propose to change, that specify requirements for protecting agricultural water sources and distribution systems from potential sources of contamination. For example, farms are required to handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments (§ 112.52(a)). Additionally, subpart L of the 2015 produce safety final rule specifies requirements for ensuring that toilet facilities (§ 112.129(b)(1)); hand-washing facilities (§ 112.130(c)); sewage (§ 112.131(b) through (d)); trash, litter, and waste (§ 112.132(a)(2)); plumbing (§ 112.133(c) through (d)); and domesticated animal excreta and litter (§ 112.134(a)) do not serve as a source of contamination for covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems.

G. Outcomes (§ 112.43(c))

In § 112.43(c), we proposed for a farm to determine, based on the farm's evaluation under proposed § 112.43(a), whether corrective or mitigation measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with its agricultural water used in growing covered produce (other than sprouts). We proposed that if a farm's pre-harvest agricultural water does not meet certain criteria in § 112.43(c), the farm would be required to either implement mitigation measures or test the water, consider the test results as part of the assessment, and take appropriate action (proposed § 112.43(c)(4)). We also proposed to require farms to record their determination and take appropriate action (proposed § 112.43(c)).

We received several comments related to outcomes under proposed § 112.43(c) and discuss these comments in the following paragraphs. We discuss comments related to testing in section V.H. As discussed below, we are finalizing § 112.43(c) as proposed, with minimal changes.

(Comment 77) A few comments express concerns with § 112.43(c)(1) through (3), arguing that the ''tiered approach'' to hazard analysis may result in farms expending efforts and resources toward strategies for addressing hazards that do not represent the biggest risk, while expending less effort and resources to address risks that may be more critical. For example, one comment suggests there is a lack of framework for determining when a hazard warrants immediate action or not, noting in particular that animal activity, BSAAOs, or untreated or improperly treated human waste may result in water not being safe or of adequate sanitary quality for its intended use. This comment also suggests the proposed rule could create challenges for farms when deciding which hazards to prioritize addressing when most hazards fall within the same tier.

(Response 77) As discussed in response to comment 28, we consider that the requirements for agricultural water assessments, in which farms evaluate various factors identified in § 112.43(a)(1) through (5), provide a mechanism through which farms evaluate the risk associated with their pre-harvest agricultural water and use that information to determine if measures are reasonably necessary under § 112.45. Further, we have established timeframes for implementing corrective or mitigation measures commensurate with the risk associated with the relevant condition. For example:

• Under § 112.43(c)(1), if pre-harvest agricultural water is not safe or not of adequate sanitary quality for its intended use(s), farms are required to immediately discontinue such use(s) of water and take corrective measures under § 112.45(a) prior to resuming use. We consider such situations to reflect circumstances where it is most necessary to take immediate action in order to protect public health;

• Under § 112.43(c)(2), for conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are related to animal activity, application of a BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, the farm must implement mitigation measures under § 112.45(b) promptly, and no later than the same growing season as the agricultural water assessment. Because farms often do not have control over those potential hazards at their point of introduction into a water source or system, it is important that the farm not only implement mitigation measures that are under its control to reduce the risk associated with that water source or system, but that it do so on an expedited basis to protect public health; and

• Under § 112.43(c)(4)(i), for conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are not related to the aforementioned uses of adjacent or nearby lands, the farm must implement mitigation measures under § 112.45(b) as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment. We note that this timing is consistent with the timing for implementing measures in § 112.45(b) of the 2015 produce safety final rule.

We recognize that one potential source of hazards may be associated with various outcomes depending on conditions relevant to the farm. For example, animal activity associated with adjacent and nearby lands, along with the other information evaluated in § 112.43(a)(1) through (5), can result in: the farm immediately discontinuing that use of the water and implementing corrective measures prior to resuming use (§ 112.43(c)(1)); the farm implementing mitigation measures on an expedited basis (§ 112.43(c)(2)); or there not being any conditions for which measures under § 112.45 are reasonably necessary (§ 112.43(c)(3)). Evaluation of the factors identified in § 112.43(a), which we discuss in section V.F., will assist farms in determining which outcome in § 112.43(c) is appropriate for their circumstances.

With respect to the comment suggesting that some farms have multiple sources of hazards that result in the same outcome, we note that the requirements for pre-harvest agricultural water assessments are designed to provide a holistic evaluation of a farm's agricultural water system, water use practices, and other conditions relevant to the farm for hazard identification purposes. Consistent with the comprehensive nature of agricultural water assessments, the requirements for outcomes in § 112.43(c), too, are designed to be implemented on a systems-wide basis. To further clarify the systems-based nature of these requirements, we are revising the requirements related to outcomes of agricultural water assessments in § 112.43(c). (See § 112.43(c)(2), which we have revised to read ''If you have identified *one or more* conditions'' in lieu of ''*a* condition,'' as proposed (emphasis added).) As such, measures that a farm implements under § 112.45 may be appropriate in light of the totality of information evaluated under § 112.43(a), such as where changing the water application method to reduce the potential for contamination of covered produce may be adequate to address various conditions that result in the same outcome under § 112.43(c).

(Comment 78) Some comments request that FDA provide additional clarity on what constitutes a situation where a farm might determine the water is not safe or not of adequate sanitary quality for its intended uses which would trigger a corrective measure versus situations in which mitigation measures would be an appropriate means of reducing risk.

(Response 78) Section 112.45 outlines two different types of measures—corrective measures and mitigations measures—that are required under § 112.43(c) if certain conditions exist. For pre-harvest agricultural water, ''corrective measures'' refer to those that farms must implement under § 112.45(a) if the water is not safe or is not of adequate sanitary quality for its intended use. Corrective measures are used in circumstances where it is necessary to take immediate action to protect public health, in that farms are required to immediately discontinue use of the water and implement corrective measures prior to resuming that use. Conversely, ''mitigation measures'' in § 112.45(b) provide more flexibility in the timing of decisions as compared to the immediate action required under § 112.45(a), in that the mitigation measures must be implemented as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment (as required by § 112.43), except that mitigation measures in response to known or reasonably foreseeable hazards related to animal activity, BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented promptly, and no later than the same growing season as such assessment or reassessment.

Given the diversity that exists across industry, and that risk associated with pre-harvest agricultural water is a function of the various factors evaluated as part of an assessment under § 112.43(a), we do not expect that situations in which measures under § 112.45 are reasonably necessary for one farm will necessarily be the same for another. However, there are some conditions that, absent information or circumstances indicating otherwise (such as if the farm is not using pre-harvest agricultural water during the time period of interest), are likely to result in the outcome in § 112.43(c)(1), in which the water is not safe or is not of adequate sanitary quality for its intended use(s) and the farm is required to immediately discontinue use of the water and take corrective measures under § 112.45(a) before resuming such use. For example:

• Incidents in which raw sewage is introduced to an agricultural water system (for example, leakage of sewage from a ruptured pipe or improper release of sewage from a sewage treatment facility into an agricultural water system);

• Situations where a significant amount of animal waste is introduced to an agricultural water system (such as might result from a manure lagoon overflowing into an agricultural water system); and

• The presence of dead and decaying animals in an agricultural water system (for example, a well in which an animal has died, or a canal in which sheep have entered and drowned).

We emphasize that these examples are not the only circumstances in which the outcome under § 112.43(c)(1) will apply, nor do circumstances need to be as clear-cut as these in order for § 112.43(c)(1) to be appropriate. For example, due to the nature of the above examples and the high likelihood for those conditions to introduce human pathogens to pre-harvest agricultural water, such conditions are likely to result in the outcome under § 112.43(c)(1) regardless of the agricultural water practices, crop characteristics, and environmental conditions evaluated under § 112.43(a) (*e.g.,* even if affected water is only

applied early in the growing season, a determination under § 112.43(c)(1) is likely appropriate). However, there may be other conditions (such as runoff from certain uses of adjacent and nearby lands), for which the factors evaluated under § 112.43(a) play a larger role as to whether a determination under § 112.43(c)(1) is appropriate. Considering the diversity that exists across industry, the requirement for farms to evaluate a broad range of factors as part of their pre-harvest agricultural water assessments will assist them in identifying and managing risks associated with pre-harvest agricultural water as appropriate for their agricultural water systems, conditions, and practices.

(Comment 79) One comment notes that § 112.43(c) references an ''evaluation'' required in § 112.43(a). However, the comment suggests, § 112.43(a) does not require an ''evaluation'', it requires an ''assessment,'' and as such, requests FDA to revise the phrasing in §§ 112.43(a) and (c) to avoid potential confusion.

(Response 79) Proposed § 112.43(a), which we are finalizing here, requires that an agricultural water assessment identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, *based on an evaluation of* the factors identified in § 112.43(a)(1) through (5) (emphasis added). As this is consistent with use of the term ''evaluation'' in § 112.43(c), we decline to make the change requested by the comment.

(Comment 80) One comment recommends changes to the text of the codified to improve clarity, noting that, as written, § 112.43(c)(1) through (4) use both positive and negative criteria, which could lead to confusion.

(Response 80) We have considered the comment. To improve clarity, we are revising § 112.43(c)(3), which in the proposed rule read, ''If you have identified no conditions . . . ,'' to instead say ''If you have not identified any conditions . . .''. We also note that we have provided a plain language summary of the outcomes in § 112.43(c) in table 4 to aid in understanding of the requirements. See comment 81.

(Comment 81) One comment suggests that the third scenario described in table 4 of the 2021 agricultural water proposed rule (describing what must occur if there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary) is missing from § 112.43(c), and is therefore not enforceable.

(Response 81) In the preamble language accompanying the table referenced by the comment (86 FR 69120 at 69140), we explained that if a farm determines that mitigation measures are reasonably necessary to reduce the potential for contamination of such produce or food contact surfaces with a known or reasonably foreseeable hazard that is not related to animal activity, a biological soil amendment of animal origin, or untreated or improperly treated human waste on adjacent or nearby lands, the farm would be required to either: implement mitigation measures under § 112.45(b) as soon as practicable and no later than the following year; or test the water pursuant to § 112.43(d), consider the results as part of their assessment in making a determination under § 112.43(c), and implement measures as needed under § 112.45. This outcome corresponds to § 112.43(c)(4), which we are finalizing as proposed, without changes. However, we recognize that the phrasing used in the table may have resulted in uncertainty, and as such, we are revising the table to clarify the role that adjacent and nearby lands play in the outcomes under § 112.43(c). See table 4.

TABLE 4—SUMMARY OF OUTCOMES OF A PRE-HARVEST AGRICULTURAL WATER ASSESSMENT FOR COVERED PRODUCE (OTHER THAN SPROUTS)

[§ 112.43(c)]

If you determine . . .	Then you must . . .
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s).	immediately discontinue use(s) *AND* take corrective measures before resuming use of the water for pre-harvest activities.
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land for which mitigation is reasonably necessary.	implement mitigation measures promptly, and no later than the same growing season.
there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land, for which mitigation is reasonably necessary.	implement mitigation measures as soon as practicable and no later than the following year *OR* test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment.
there are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary.	regularly (at least once each year) inspect and adequately maintain the water system(s).

H. Testing as Part of an Assessment (§ 112.43(d))

For farms that test agricultural water as one part of an assessment, we proposed that such testing must use scientifically valid collection and testing methods and procedures (proposed § 112.43(d)). We proposed to require that samples of pre-harvest agricultural water be collected aseptically immediately prior to or during the growing season and be representative of the water used in growing non-sprout covered produce (proposed § 112.43(d)). We proposed to require that samples be tested for generic *E. coli* as an indicator of fecal contamination, or for another scientifically valid organism, index organism, or other analyte (proposed § 112.43(d)(2)). Additionally, we proposed to require that the frequency of testing and any microbial criteria applied be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph § 112.43(a), whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water (proposed § 112.43(d)(3)). We are finalizing the requirements as proposed, with minimal changes, and respond to the comments we received on testing as part of an assessment below.

1. General

(Comment 82) Some comments suggest that proposed § 112.43(d) should specify that when testing pre-harvest agricultural water as one part of an assessment, sample collection should occur at specific times, such as ''as close to harvest as reasonably possible,'' to reduce the opportunity for farms to ''cherry-pick'' collecting samples at times when water quality is expected to be good.

(Response 82) We do not consider it necessary to require farms that test pre-harvest agricultural water under § 112.43(c)(4) to collect samples at specific times (for example, as close to harvest as possible), as doing so may limit the usefulness of test results in further informing the farm's agricultural water assessment. For example, if a farm identifies a condition that may allow for the introduction of hazards to its agricultural water early in the growing season (*e.g.,* a well head that needs repairing) and tests pre-harvest agricultural water under § 112.43(c)(4), requiring that water samples be collected close to harvest would not provide the farm with information as to whether water quality was degraded and/or if repairs made to the well head were effective in as timely a manner as testing early in the growing season. As such, we decline to make this change.

(Comment 83) Several comments supportive of the general proposed approach for pre-harvest agricultural water assessments note that agricultural water testing only provides a ''snapshot in time'' of water quality. These comments suggest that because of this, water testing alone may be of limited effectiveness in ensuring produce safety.

(Response 83) While we have included a requirement in § 112.43(c)(4)(ii) for farms to test their pre-harvest agricultural water as part of an assessment in certain circumstances, it does not mean that farms can rely on test results alone in making decisions around the use of their water. Rather, results from pre-harvest agricultural water testing serve as an additional source of information that farms may use to further inform their agricultural water assessments. Specifically, farms that test their pre-harvest agricultural water as part of their assessment must consider the test results in concert with the other factors evaluated under § 112.43(a) and use information in making determinations under § 112.43(c) as to whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces due to hazards associated with pre-harvest agricultural water.

(Comment 84) Some comments express a concern that because farms are not required to test pre-harvest agricultural water under the proposed rule, inspectors and farms may come to different conclusions about situations in which testing should occur.

(Response 84) As discussed in response to comment 3, we are not requiring all farms to test their pre-harvest agricultural water. Rather, § 112.43(c)(4) requires that farms either test the water, consider the results as part of the assessment, and take appropriate action; or implement mitigations measures as soon as practicable and no later than 1 year after the date of the assessment. Whether or not to test pre-harvest agricultural water or to implement mitigation measures under § 112.43(c)(4) is up to the discretion of the farm.

(Comment 85) Some comments voice opposition to mandatory product testing as a follow-up activity when water test results reveal unacceptable results.

(Response 85) Farms are not required to conduct product testing as a follow-up to results of pre-harvest agricultural water testing under § 112.43(c)(4).

(Comment 86) Some comments seek clarity on testing requirements that would apply for rainwater that is collected and stored.

(Response 86) If a farm that collects rainwater to use for pre-harvest agricultural water tests the water as one part of its assessment, the requirements in § 112.43(d) apply.

(Comment 87) Some comments address testing of agricultural water used in CEA farms, such as hydroponic and aquaponic operations. Some comments suggest that water used in hydroponic of aquaponic systems should be performed on a risk- and science-driven basis (*e.g.,* as applicable to each individual farm's unique food safety hazards) to support requirements in the proposed rule. Other comments state that if a hydroponic or aquaponic farm test its pre-harvest agricultural water as part of an assessment, a sampling frequency of 20 samples over a 2 to 4 year period would likely not be adequate for detection of hazards due to the nature of such systems and the use of recirculating water.

(Response 87) As discussed in response to comment 93, we are not establishing a specific testing frequency that farms are required to follow if testing their pre-harvest agricultural water as one part of an assessment. Rather, § 112.43(d)(3) provides flexibility for farms to use a sampling frequency that is scientifically valid and appropriate. This enables farms that test their pre-harvest agricultural water as part of an assessment under § 112.43(c)(4)(ii) to take into account conditions that are unique to their operations and practices when establishing appropriate sampling frequencies under § 112.43(d)(3). We discuss conditions that may be relevant to some CEA farms in response to comments 39, 40 and 46, which farms may consider in establishing an appropriate sampling frequency under § 112.43(d)(3).

(Comment 88) Several comments express concerns about the availability and/or cost of laboratories that can perform testing for agricultural water.

(Response 88) Farms that test their pre-harvest agricultural water as one part of an assessment under § 112.43(c)(4)(ii) are not required to use a third-party laboratory to analyze test samples. See § 112.47, which we did not propose to change, which specifies that farms may meet the requirements related to agricultural water testing in § 112.43(c)(4)(ii) using results performed by the farm or by a person or entity acting on the farm's behalf, or data

collected by a third-party (or parties), provided applicable requirements are met. Additionally, we have provided flexibility in analytes, sampling frequency, and microbial quality criteria farms may use (§ 112.43(d)). The approach taken for testing as part of an assessment, which provides for flexibility as science evolves, will allow farms to make decisions around pre-harvest agricultural water testing as applicable to their given operations and the nature of current science. See also response to comment 98, where we discuss test methods that may be used if testing agricultural water for generic *E. coli.*

(Comment 89) Many comments request real-world examples of what acceptable testing approaches may look like given the variety in commodity production practices, seasonal lengths, and growing environments. Some comments note that development of technical tools, such as statistical toolkits, would be of benefit to farms. These comments suggest that FDA work with industry organizations and other partners to develop such resources.

(Response 89) We provide information on analytes, sampling frequencies, and microbial criterion (or criteria) that may be used in accordance with the requirements in § 112.43(d) throughout the remainder of this section. While we have provided examples of analytes, sampling frequencies, and microbial water quality criteria that farms may choose to use (see, *e.g.,* comments 90, 93 and 95, respectively), we recognize that there is interest in the development of testing frameworks that are specific to various circumstances, such as those based on hazards, commodity(ies) grown, and regional considerations. We encourage collaborations across various groups in the agricultural community (for example, produce farms, State and Federal Government agencies, academic researchers, and extension specialists) as they relate to pre-harvest agricultural water assessments, including frameworks for testing agricultural water that are reflective of the variety of water systems and practices that exist across industry. We remain committed to working with stakeholders to advance critical work in the realm of agricultural water quality science.

2. Generic E. coli and Other Analytes

(Comment 90) Some comments seek clarification on the extent of flexibility offered to a farm in using an appropriate analyte (*i.e.,* different than generic *E. coli*) in their testing protocol. A few comments ask if farms must determine that generic *E. coli* is an appropriate fecal indicator bacteria to test for, and how a farm may determine if a different fecal indicator bacteria is more appropriate. Some of these comments request clarity on whether farms using an alternate analyte still have to test for generic *E. coli.* A number of comments assert that farms should be able to select the most appropriate analyte for their circumstances. Some comments address water testing for hydroponic and aquaponic systems, noting that generic *E. coli* may not be the most relevant indicator of water quality in these systems.

(Response 90) Final § 112.43(d)(2) provides farms that test their pre-harvest agricultural water as one part of an assessment the flexibility to test for generic *E. coli* or for any other scientifically valid indicator organism, index organism, or other analyte. As such, if testing for any other scientifically valid indicator organism, index organism, or other analyte, a farm does not also have to test for generic *E. coli.*

While generic *E. coli* has an extensive history of use as an indicator of fecal contamination and is considered the best indicator for monitoring water quality (Ref. 73) (78 FR 3504 at 3562), the potential use of other indicator organisms, index organisms, or other analytes for monitoring water quality continues to be of interest for agricultural water, as well as related disciplines. For example, in its 2012 Recreational Water Quality Criteria (RWQC) EPA provided various examples of possible alternate indicators, including *Bacteroidales, Clostridium perfringens,* human enteric viruses, and coliphages (Ref. 74). We anticipate that as science evolves and more information about other indicator or index organisms is learned, testing for organisms other than generic *E. coli* may be used to inform pre-harvest agricultural water assessments by farms.

We note that we are not requiring farms to notify or seek approval from FDA as to the analytes, sampling frequencies, and microbial criterion (or criteria) the farm uses when testing agricultural water as part of an assessment. However, if a farm uses a scientifically valid indicator organism, index organism, or analyte other than *E. coli,* the farm is required to maintain records of scientific data or information it relies on to support the use of that organism or analyte in accordance with § 112.50(b)(3). (Farms are not required to keep such documentation if testing their agricultural water for generic *E. coli.*) We discuss the term ''scientifically valid'' in the 2015 produce safety final rule to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research (see 80 FR 74354 at 74371).

(Comment 91) Some comments seek clarity on whether farms will be expected to test for pathogenic microorganisms in their water, with some suggesting that doing so would not be of benefit to farms.

(Response 91) Farms are not required to test their pre-harvest agricultural water for human pathogens. As discussed in the 2015 produce safety final rule, we acknowledge that testing for pathogens allows for direct targeting of microorganisms in water that are a risk to public health; however, we continue to believe sampling water for pathogens presents challenges compared to sampling water for indicator organisms. For example, challenges associated with pathogen testing include those related to larger sample sizes; inherently higher costs; and the wide array of potential target pathogens (*i.e.,* the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See 80 FR 74354 at 74427–74428. As discussed in section I.A., we believe that this rule will enhance public health protections by setting forth procedures for comprehensive pre-harvest agricultural water assessments and corrective and mitigation measures that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated on account of those hazards.

(Comment 92) Some comments note that the bacteria detected in their water is often different than the bacteria found on their crops, and that water quality seems to change as it goes through their water distribution system. These comments seek clarity on how the rule would address such a situation.

(Response 92) In this scenario, if the farm tests its water under § 112.43, the farm must consider both its water test results as well as information about its water distribution system (in addition to the other factors evaluated under § 112.43(a)) in determining whether measures are reasonably necessary under § 112.45. For example, in preparing an agricultural water assessment under § 112.43(a), a farm finds that large flocks of birds rest in its open water distribution system, and that test results for samples collected upstream and downstream of the birds indicate that the birds are causing water

quality to degrade. In light of these findings, and depending on the other factors evaluated under § 112.43(a), the farm may determine that measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the farm's pre-harvest agricultural water for non-sprout covered produce.

3. Frequency of Sampling

(Comment 93) Some comments interpret the rule as requiring a specific number of testing samples per year and oppose this requirement. Some comments seek clarity about whether the minimum frequency of testing for pre-harvest agricultural water changed from 20 samples within 2 to 4 years per the 2015 produce safety final rule, to four times during the growing season or over a period of 1 year per § 112.44(b)(1) of the proposed rule. Other comments request clarity as to whether testing may be conducted at a lower frequency than that established in the 2015 produce safety final rule. A few comments suggest that one test per season prior to use would likely be sufficient for deep wells. Some comments request that FDA support research and education to help farms understand what sampling frequency is adequate.

(Response 93) Section 112.43(d)(3) requires that for farms that test their pre-harvest agricultural water as one part of an assessment, the frequency of testing samples must be scientifically valid and appropriate to assist in determining, in conjunction with other factors evaluated under § 112.43(a), whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with their agricultural water used in growing covered produce (other than sprouts).

Farms have the flexibility to use any sampling frequency, as long as the requirements in § 112.43(d)(3) are met. For example, this could include sampling frequencies a farm establishes based on its historical data and/or knowledge of water quality variability within its source. Sampling approaches that take into consideration other site- or region-specific data or information may also be appropriate. We recognize that agricultural water quality science is likely to continue to evolve and may inform sampling frequencies appropriate for use when testing pre-harvest agricultural water as part of an assessment. As agricultural water quality science continues to develop, and as farms learn more about water quality relevant to their sources, systems, and operations—for example, through an evaluation of data shared between farms, within water systems, and/or within regions—such information can, and should, be used to establish sampling frequencies that are appropriate to farms' specific circumstances and conditions.

While the sampling frequencies for untreated surface water and untreated ground water used for pre-harvest agricultural water in the 2015 produce safety final rule are examples of approaches that farms may choose to use to comply with § 112.43(d)(3) if testing their water for generic *E. coli,* they are not required to do so. Further, if a farm tests its water for generic *E. coli* and has scientifically valid data or information to support use of a sampling frequency that is more reflective of its unique conditions than that used in the 2015 produce safety final rule, the farm must use that information in establishing an appropriate sampling frequency under § 112.43(d)(3). Moreover, because the sampling frequencies in the 2015 produce safety final rule were developed for farms that test their pre-harvest agricultural water for generic *E. coli,* a farm that tests for any other scientifically valid indicator organism, index organism, or other analyte in accordance with § 112.43(d)(2) may not use those sampling frequencies unless it has scientific data or information supporting use of those frequencies for the relevant organism or analyte.

We note that farms are required to maintain records of scientific data or information they rely on to support the use of a sampling frequency in accordance with § 112.50(b)(4). As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69143), if a farm tests its water under § 112.43(d) for generic *E. coli* using the sampling frequencies and pre-harvest microbial water quality criteria outlined in the 2015 produce safety final rule, the farm can document its use of such sampling frequencies and microbial criteria in meeting the requirements of § 112.50(b)(4), as we have already determined these sampling frequencies and microbial criteria to be scientifically valid and appropriate for purposes of § 112.43(d). See also response to comment 95 regarding the use of the pre-harvest microbial water quality criteria from the 2015 produce safety final rule.

We would also like to clarify that the sampling frequency in § 112.44(b)(1) referenced by comments is specific to untreated ground water when used for any of the purposes specified in § 112.44(a) (*e.g.,* water used during or after harvest activities in a manner that directly contacts covered produce). This requirement does not apply for farms that test their pre-harvest agricultural water for non-sprout covered produce as part of an assessment under § 112.43(c)(4).

(Comment 94) Some comments seek clarity around whether historical test results can be used to justify the safety of their agricultural water. Several comments encourage flexibility with regard to sampling frequency requirements by allowing inclusion of historic testing data in an assessment that may not have been conducted at the same level of frequency as discussed in the proposed rule.

(Response 94) We recognize the value in utilizing historical test results, particularly when it comes to analyzing trends in water quality over time, which may help to further inform a farm's agricultural water assessment. Historical data may be particularly useful in situations in which potential hazards are introduced into a water system intermittently, such that a farm is able to compare data over time to further inform its conclusions of whether measures are reasonably necessary under § 112.45. For example, if a farm is concerned that the quality of its water may be affected by rain due to runoff into a water source and/or stirring up of sediments, the farm may use water quality data collected over time to determine if water quality is degraded following rain events compared to baseline (*i.e.,* limited or no rain) conditions.

As discussed in response to comment 93, we are not establishing a specific testing frequency that farms are required to follow if testing their pre-harvest agricultural water as one part of an assessment. Rather, if a farm tests its pre-harvest agricultural water as part of an assessment under § 112.43(c)(4)(ii), § 112.43(d)(3) provides flexibility regarding the frequency of sample collection. As also discussed in response to comment 93, farms can use historical data and/or knowledge of water quality variability within relevant water sources to inform sampling frequencies under § 112.43(d)(3) that are scientifically valid.

4. Microbial Water Quality Criteria

(Comment 95) Many comments support the additional flexibility in proposed § 112.43(d) for farms to apply any microbial criterion or criteria that would be scientifically valid and appropriate. Some comments support

inclusion of a GM of 126 or less CFU generic *E. coli* per 100 mL and an STV of 410 or less CFU generic *E. coli* per 100 mL in the preamble as a standard for agricultural water. In contrast, several comments oppose inclusion of these in the preamble, and suggest that because these standards were developed for recreational water, they are not suitable for agricultural water since agricultural water is not directly ingested by humans. Some of these comments request clarification on whether any studies have been conducted to determine thresholds of fecal indicator bacteria in agricultural water to levels of risk to human health. Some comments request FDA remove reference to the GM and STV in the preamble because, the comments state, use of those criteria, even if not included in the codified requirements, will result in the criteria continuing to be used as a benchmark even as new metrics are developed. Other comments suggest that FDA retain proposed § 112.43(d) as written and further clarify in the preamble that the 2015 microbial standards are not required in order to reduce confusion.

(Response 95) The microbial water quality criteria in the 2015 produce safety final rule for pre-harvest agricultural water consist of a GM of 126 or less CFU generic *E. coli* per 100 mL, and an STV of 410 or less CFU generic *E. coli* per 100 mL. We established these pre-harvest microbial water quality criteria using the science underlying EPA's 2012 RWQC (Ref. 74). We described the rationale for our use of the science underlying the RWQC and our thinking on its relevance to agricultural water in a reference memorandum that accompanied the 2014 supplemental proposed rule (Ref. 75). We are not aware of, and comments did not suggest, an alternative standard that is applicable across the diversity of operations, agricultural water sources, and agricultural water uses. However, we recognize that use of the GM and STV criteria for pre-harvest agricultural water for non-sprout covered produce is not without its challenges, particularly in light of information that has become available since 2015 indicating potential limitations in basing risk-management decisions on the 2015 pre-harvest agricultural water testing requirements.

Of particular note, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Additionally, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5–10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). In recognition of such limitations associated with the previous pre-harvest testing requirements, findings from our QAR (Ref. 17), other information we have gathered since 2015 (including findings from several produce-related outbreaks), as well as information and feedback from an array of stakeholders, we are replacing the pre-harvest water quality criteria and uniform testing requirements in the 2015 produce safety final rule with requirements for systems-based agricultural water assessments that include testing in certain circumstances. See comment 11.

Further, we acknowledge that science around agricultural water quality and related disciplines is likely to continue to evolve. For example, in EPA's second 5-year review of the 2012 RWQC (Refs. 76 and 77), EPA notes plans to develop new quantitative polymerase chain reaction (PCR)-based RWQC that better protect certain sensitive populations; expand its recommended RWQC to protect people from exposure to viruses; and explore new methods to determine whether a waterbody is contaminated with human feces.

Thus, to allow for scientific advancements, we have incorporated flexibility into § 112.43(d)(3) so that farms that test their pre-harvest agricultural water as part of an assessment can use any microbial criteria (or criterion) provided certain requirements are met. A farm can rely on a microbial criterion or criteria available in the scientific literature or made available by a third party (such as a trade association, commodity board, academia, or cooperative extension services) provided that the microbial criterion or criteria is scientifically valid and appropriate based on the circumstances. (We discuss the term ''scientifically valid'' in the 2015 produce safety final rule (see 80 FR 74354 at 74371).)

We recognize that agricultural water quality science is likely to continue to evolve and may inform standards appropriate for use when testing pre-harvest agricultural water as part of an assessment. While farms that test their pre-harvest agricultural water as one part of an assessment may choose to use the criteria established in the 2015 produce safety final rule to meet the requirements in § 112.43(d)(3), they are not required to do so. Further, if a farm has scientifically valid data or information to support use of a microbial criterion or criteria that is more reflective of its unique conditions, the farm must use that information in establishing an appropriate microbial criterion or criteria under § 112.43(d)(3).

As discussed in response to comment 83, we emphasize that farms must not rely on test results alone in making decisions around the use of their water; rather, results from pre-harvest agricultural water testing serve as an additional source of information that farms may use to further inform their agricultural water assessments.

We intend to issue guidance on the requirements in § 112.43(d)(3), as appropriate.

(Comment 96) Some comments suggest that farms should be required to take action based on an individual test result, as doing so would emphasize the short temporal nature of many microbial hazards. Some comments seek clarity as to whether water that meets the EPA recreational water standards should be considered low, medium, or high risk. A few comments ask whether farms could choose to comply with the new rule through the previous rule's testing thresholds (including the GM and STV) rather than through preparing an agricultural water assessment. Some comments request FDA clarify that if a farm is conducting surface water testing and finds that the water has a MWQP with a GM of 126 or less CFU generic *E. coli*/100 mL water and an STV of 410 or less CFU generic *E. coli*/100 mL water, then no further mitigation measures should be required to use that water for pre-harvest activities. Conversely, some comments suggest that it is inappropriate to assume that water above or below this benchmark is always going to be higher or lower risk, and other factors (such as how the water is used, crop characteristics, etc.) should be considered, rather than strict adherence to quantitative water quality criteria.

(Response 96) We agree with comments suggesting that water below or above a certain microbial water quality criterion (or criteria) based on indicator organisms does not guarantee the absence of pathogens that can contaminate covered produce as a result of pre-harvest agricultural water. See 80 FR 74354 at 74428. We are not aware of, and comments did not provide, information suggesting that this conclusion is incorrect. As such, whether or not agricultural water meets a microbial criterion (or criteria) established in accordance with § 112.43(d) is not the sole determinant of whether corrective or mitigation measures are reasonably necessary

under § 112.45. See also response to comment 83.

For example, if a farm tests its water as one part of an assessment per § 112.43(c)(4), in addition to determining whether the water meets the criterion (or criteria) established in accordance with § 112.43(c)(3), the farm can, for example, look at test results collected over time for potential insight into changes in water quality that might indicate hazards being introduced into the water system. Even if the water does not exceed the criterion (or criteria) the farm establishes, the farm may find, for example, that migratory birds are causing water quality to degrade when present in the area. As another example, the farm may find when looking at historical data that test results had at one time consistently shown lower levels of generic *E. coli* than more recent data, potentially indicating that a change occurred that is affecting the farm's water system.

In such circumstances, even if the water does not exceed the criterion (or criteria) the farm establishes, the trends in water quality changes over time show a potential source(s) of contamination to a farm's agricultural water. A farm must consider this information, along with other factors, in conducting its agricultural water assessment (§ 112.43(c)(4)(ii)). As discussed in response to comment 95, while farms that test their pre-harvest agricultural water as part of an assessment may choose to use the GM and STV criteria established in the 2015 produce safety final rule to meet the requirements in § 112.43(d)(3), they are not required to do so.

(Comment 97) Some comments suggest that FDA mandate presence/absence indicator testing for pre-harvest agricultural water to make testing more simplified than the 2015 produce safety final rule while still providing insight into whether and which mitigation and corrective actions are required.

(Response 97) We disagree with comments suggesting that it would be appropriate to require presence/absence testing for indicator organisms for pre-harvest agricultural water. We consider that the flexibility in § 112.43(d)(3) is appropriate to maintain due to the diversity in agricultural water systems and practices that exists across industry. For example, a farm that uses pre-harvest agricultural water from a ground water source such as a well may determine that presence/absence testing is appropriate to use, as ground water sources generally provide high quality water and show little variability due to the natural filtering capacity of soils (Ref. 17). However, another farm that uses agricultural water from a surface water source may determine that quantification methods are appropriate to use, as surface water sources are subject to the influence of various environmental factors that can impact and change the system continually (Ref. 17).

(Comment 98) Some comments ask FDA to identify a unit of measurement for analytes to be ''organism'' or ''counts'' per 100 mL instead of CFU, because in some methods of analysis, results are provided as a most probable number (MPN). The comment asserts that use of CFU limits allowable testing methods.

(Response 98) We do not consider this necessary to do, as we do not specify microbial water quality criteria in CFU when testing pre-harvest agricultural water as part of an assessment. See, for example, § 112.43(d)(3), which requires that ''. . . any microbial criteria applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph (a) of this section, whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts).''

Further, while the method of analysis in § 112.151(a) (EPA Method 1603) provides results for generic *E. coli* testing in terms of CFU, if a farm tests pre-harvest agricultural water for generic *E. coli* under § 112.43(d)(2), the farm may use a scientifically valid method that is at least equivalent to EPA Method 1603 in accuracy, precision, and sensitivity (§ 112.151(b)(1)). We have provided a list of testing methodologies that meet the requirements in § 112.151(b)(1) (Ref. 78). Included in this list are methods that report results in CFU and methods that report results as MPN, which farms may use when testing their agricultural water for generic *E. coli.*

I. Reassessment (§ 112.43(e))

In § 112.43(e)(1), we proposed that a farm must conduct an agricultural water assessment, at a minimum, each year that the farm applies pre-harvest agricultural water to non-sprout covered produce. In § 112.43(e)(2), we proposed that a farm must conduct a reassessment whenever a significant change occurs in its agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that would impact hazard identification or a risk management determination, as described in proposed § 112.43(c). For the reassessment in proposed § 112.43(e)(2), we proposed that a farm must evaluate the impacts of those changes on the factors in proposed § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under proposed § 112.43(c). We received several comments seeking clarification on the proposed reassessments and respond to the comments in the paragraphs below. We are finalizing the requirements for reassessments in § 112.43(c) as proposed, without change.

(Comment 99) Several comments seek clarity on what situations would be considered a ''significant change'' in an agricultural water system that would warrant a reassessment.

(Response 99) In the 2021 agricultural water proposed rule, we tentatively concluded that it would be reasonable and appropriate to require farms to conduct a written pre-harvest agricultural water assessment annually, and whenever a significant change would impact the hazard identification or risk management determination relating to pre-harvest agricultural water for non-sprout covered produce. We are not aware of, and comments did not provide, information suggesting that this conclusion is incorrect. However, we recognize that additional information on the requirements in § 112.43(e) will help support farms as they work to come into compliance.

Section 112.43(e) requires, in part, that a farm conduct a reassessment whenever a significant change occurs in its agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that impacts hazard identification or a risk management determination as described in § 112.43(c). For example, as discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69138), a change from an untreated ground water source to an untreated surface water source, or the installation and use of a new water distribution system, is a significant change that requires a reassessment under § 112.43(e), as the degree of protection and likelihood of hazards being introduced are likely to differ and may impact risk management determinations. As another example, some changes in the use of adjacent or nearby land—such as if adjacent or nearby land is used for a new dairy production operation—are significant changes, as the new use of that land may differ in its potential to introduce

hazards into the agricultural water system.

Changes in agricultural water practices, including the method or timing of water application, also are significant changes that require a reassessment, as different practices present different risks to the crop. For example, overhead sprinkler irrigation may increase the risk of contamination as compared with furrow and subsurface drip irrigation (Ref. 79). Furthermore, bacteria or pathogens in water that is applied early in the growing cycle are subject to greater die-off from several environmental forces, such as UV exposure, temperature, humidity, and the presence of competitive organisms compared to bacteria or pathogens in water that is applied late in the growing cycle (Ref. 65). See 86 FR 69120 at 69138. Similarly, growing a different type of covered produce than previously grown is a significant change, as the unique characteristics associated with the crop might affect whether it is vulnerable to contamination from agricultural water. See 86 FR 69120 at 69138. As discussed further in response to comment 100, various environmental conditions, such as unexpected flooding that may introduce new hazards into an agricultural water system, are also significant changes that require a farm to conduct a reassessment.

Other sources of information may also indicate that a significant change has occurred for which a reassessment is required, such as, for example, if information suggests that a pathogen may be present in a farm's pre-harvest agricultural water (which the farm may be aware of through voluntary testing, knowledge or experience, or other means), or if an outbreak investigation or other findings indicate a potential role for pre-harvest agricultural water in serving as a source or route of contamination to covered produce.

In instances where there is a significant change for which a farm is required to conduct a reassessment, the farm must evaluate the impacts of those changes on the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c).

(Comment 100) Several comments seek clarity as to whether a reassessment is necessary in response to extreme weather events if those events are normal, expected, and included in a farm's initial assessment. Some comments question whether a farm can amend an assessment following such an extreme weather event rather than conducting an entirely new one.

(Response 100) The requirement to consider environmental conditions as part of an agricultural water assessment in § 112.43(a)(4) includes not only general ''routine'' trends in environmental conditions (*e.g.,* yearly seasonal patterns in rainfall), but also those conditions that, based on knowledge, history or experience, are reasonably likely to happen on a less frequent basis, but that nonetheless have the potential to impact agricultural water systems or covered produce (*e.g.,* heavy rains that occur on occasion). This includes, if applicable, any extreme weather events that have the potential to affect the farm's agricultural water systems or operations. Thus, if a farm evaluated relevant extreme weather events as part of its agricultural water assessment under § 112.43(a), the farm is not required to conduct a reassessment each time such an event occurs. See also response to comment 69.

However, we also recognize that not all weather events can be anticipated. Unanticipated weather events or weather changes that go beyond what was considered as part of a farm's assessment (such as unexpected flooding that may introduce new hazards into a surface or ground water source, or an earthquake, which may affect a farm's piped distribution system) are significant changes that warrant a reassessment under § 112.43(e)(2). The reassessment must evaluate any factors and conditions that are affected by such change, including the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c).

(Comment 101) Some comments note that what may be considered a ''significant change'' for one farm would not be considered a significant change for another. For example, the comment notes that switching water sources is a common practice in some areas and may not be perceived by farms as significant.

(Response 101) We recognize that some farms may make changes to their pre-harvest agricultural water systems and practices as a routine matter, such as farms that routinely use one water source early in the growing season and switch to another water source after plants become established; or those that change water sources throughout the season as weather and water availability changes. Farms that make routine changes to their systems or operations may account for such activities in their annual assessment, rather than conducting a reassessment each time a change is made, provided they conduct and document an assessment that accurately describes and evaluates each of their agricultural water systems, the water use practices associated with each of their agricultural water systems, and other factors required by § 112.43(a).

(Comment 102) Noting that farms may not become immediately aware of changes to certain factors that are outside of their control (such as uses of adjacent and nearby lands), a few comments suggest that proposed § 112.43(e) be revised to clarify that a farm is only responsible for conducting a reassessment if the farm is *aware* of there being a significant change (emphasis added).

(Response 102) Farms are responsible for ensuring that all applicable requirements of subpart E are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use.

We recognize that farms may not always be made immediately aware of changes to factors that are outside of their control (such as adjacent and nearby land uses and other water users) that might affect their agricultural water systems. As discussed in response to comment 51, farms must include in their assessments information on sources of hazards that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water. Information as to the presence and nature of impacts that might affect the quality of their agricultural water can be acquired through a variety of resources, including from visual observation; local extension agents, industry associations, or local water management authorities; and online resources such as mapping tools, which may provide helpful information on topography and proximity to potential sources of hazards.

Further, § 112.42(b) requires farms to regularly monitor each system, to the extent that it is under the farm's control, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. If during such monitoring a farm identifies a condition that that is considered a ''significant change,'' the farm must conduct a reassessment under § 112.43(e). See also response to comment 25, in which we discuss the relationship between inspections, maintenance, and pre-harvest agricultural water assessments.

Given the various resources available to farms that can provide information regarding factors that might otherwise be outside a farm's control (see

comment 51), we do not believe it is necessary to modify the language regarding significant changes that require a reassessment under § 112.43(e).

J. Corrective and Mitigation Measures (§ 112.45)

We proposed requirements for implementing corrective and mitigation measures for pre-harvest agricultural water that are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water for covered produce (§ 112.45). We did not propose to change the requirement from § 112.45(a) of the 2015 produce safety final rule that if agricultural water is not safe or not of adequate sanitary quality for its intended use(s) as required under § 112.41, and/or if a farm's agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in § 112.44(a) (including the microbial quality criterion), the farm must immediately discontinue such use(s) and implement corrective measures prior to resuming such use. In § 112.45(b), we proposed various mitigation measures for pre-harvest agricultural water that farms would implement to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the water.

We discuss comments received on proposed § 112.45 below. Note that in this section, we include comments specific to use of treatment as a corrective or mitigation measure; we discuss general comments related to agricultural water treatment and the pre-harvest agricultural water treatment efficacy testing protocol in section V.K.

1. General

(Comment 103) Several comments express general support for the range of options FDA has outlined as possible measures to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. In contrast, many comments suggest the rule lacks sufficient criteria on when measures are necessary or which measures are effective in various scenarios. Some comments express a concern that the proposed rule places too much responsibility on farms to make decisions about mitigation measures without sufficient guidance or input from FDA. The comments request that FDA consider delineating specific requirements regarding necessary measures for the highest risk situations.

(Response 103) The provisions for pre-harvest agricultural water assessments are designed to be flexible to account for the diversity of operations, practices, and conditions that may impact the pre-harvest agricultural water used by foreign and domestic farms for non-sprout covered produce. Given the diversity that exists across industry, we recognize that measures implemented under § 112.45 will vary by farm.

By providing a range of possible measures, farms will be able to make decisions around their agricultural water as appropriate to their agricultural water systems, water use practices, operations, and local conditions. However, we recognize the need for clarity, and we have provided general principles throughout the preamble to assist farms in determining whether (and what kind of) measures may be appropriate for their given circumstances. For example, in our response to comment 105, we discuss that measures under § 112.45(b)(1)(i), which entails making necessary changes (for example, repairs), generally are more relevant when the farm has some control over the potential source of known or reasonably foreseeable hazards. However, that may not always be the case, such as if a farm builds a berm to reduce runoff from a source of hazards into an agricultural water system. As another example, in response to comment 123, we explain that changing the water application method under § 112.45(b)(1)(iv) for root crops may not be an appropriate mitigation measure, as it may be difficult to effectively minimize contact between agricultural water and the harvestable portion of the crop. For additional examples and information, see section V.G. for comments related to outcomes, and the remainder of this section for comments related to corrective and mitigation measures.

Further, we recognize the need to provide farms with education, outreach and technical assistance to facilitate compliance with the rule, and we intend to pursue various mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including working with other stakeholders (such as State agencies, educators, and extension agents), to do so.

(Comment 104) Some comments express concerns that the corrective and mitigation measures included in the proposed rule are not feasible for many farms due to challenges associated with increased costs, water scarcity, environmental conditions, farm setup/infrastructure, labor shortages, and the need to use water for pest management practices. Some of these comments suggest that measures like water treatment, which comments note can be costly and complex to implement, calibrate, and operate, may be particularly challenging for small farms. Many comments request that FDA explicitly allow for other mitigation measures beyond those specifically listed in the codified.

(Response 104) Given the diversity that exists across industry, we recognize the importance of flexibility in § 112.45, which we have included by providing a range of possible measures, including the option in § 112.45(b) to use an alternative mitigation measure that meets the requirements in § 112.12.

With respect to comments about small farms, we note that we are finalizing staggered compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce based on farm size as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. See also section VI for a discussion of comments about compliance dates. We expect that the flexibility in § 112.45, along with the extended compliance dates, will provide sufficient time and flexibility for small and very small farms to receive education and adjust their practices (if needed) to comply in a cost-effective manner with the requirements in subpart E.

Also with respect to comments about costs, we estimate costs of measures in our FRIA (Ref. 26).

(Comment 105) Some comments assert that the proposed rule lacks clarity on corrective or mitigation measures for farms to effectively control hazards from adjacent or nearby cattle operations and requests that FDA establish educational resources that define effective strategies, based on science and research. Some comments suggest that the farm's responsibility over the quality of water (including steps the farm takes to implement mitigation measures) should be based on the degree of control the farm has over the water, and that the farm should not be responsible for activities on adjacent or nearby lands or upstream water users that are not under the farm's control.

(Response 105) We recognize that farms may have little or no control over adjacent and nearby land uses and other

water users, and do not require farms to access areas that are not under their control to meet relevant requirements in subpart E. However, while farms may have little or no control of such uses of land and other water users, the requirement to consider these potential sources of hazards as part of an agricultural water assessment will help farms determine the appropriate and safe use of their water source(s). See also response to comment 15. While it is generally preferred that sources of known or reasonably foreseeable hazards be addressed at the point where potential hazards are introduced to an agricultural water system, we recognize that this may not always be feasible for farms (such as where hazards may originate from adjacent or nearby land uses or from other water users), nor are we suggesting that farms gain access to such lands or other water uses to do so.

Taking measures under § 112.45(a)(1) (which includes, but is not limited to, re-inspecting the affected agricultural water system and making necessary changes) and § 112.45(b)(1)(i) (which entails making necessary changes (for example, repairs)) generally are more relevant when the farm has some control over the potential source of known or reasonably foreseeable hazards. However, this may not always be the case. For example, even if a source of hazards is outside of a farm's control, depending on the circumstances, measures such as building a berm to reduce runoff, installing a windbreak, or making repairs to a well-head may be appropriate to reduce the potential for known or reasonably foreseeable hazards being introduced into its agricultural water system.

We have incorporated a range of options for measures in § 112.45 in the recognition that not every measure will be an appropriate or viable option for every farm. See also response to comment 103. We note in particular that the mitigation measures identified in § 112.45(b) include those that a farm can implement whether or not the farm has control over the potential source of known or reasonably foreseeable hazards at the point where hazards may be introduced to an agricultural water system. For example, while a farm may have little or no control over adjacent and nearby land uses, if the farm determines that mitigation measures are reasonably necessary under § 112.45(b), depending on the circumstances, the farm might determine that changing the water application method is appropriate to reduce the likelihood of contamination of the covered produce.

(Comment 106) While supportive of the proposed rule, some comments request that water testing be required as a way to verify that corrective or mitigation measures were effective. These comments seek clarity on how, without test results, farms might demonstrate that their water is safe and of adequate sanitary quality. One comment notes that the proposed rule differs from LGMA metrics in its omission of a retesting requirement for agricultural water that fails to meet a specified standard for generic *E. coli* and requests that FDA include such a retesting requirement, suggesting that retesting is essential to determine whether mitigation measures were effective.

(Response 106) We disagree that testing is essential to determine if corrective or mitigation measures were effective, as there are other actions farms may take to verify the effectiveness of such measures. For example, if a farm makes necessary changes as a mitigation measure under § 112.45(b)(1)(i), such as repairing a leak within the farm's piped distribution system in order to protect it from possible sources of contamination, re-inspection of the agricultural water system to visually confirm that the repair was successful may be sufficient. As another example, if a farm changes the method of water application to reduce the likelihood of contamination of covered produce as a mitigation measure under § 112.45(b)(1)(iv), the farm might regularly monitor the system while the covered produce is being irrigated to confirm that the water application method is limiting contact with the produce as intended. In yet other instances, such as when treating agricultural water as a mitigation measure (§ 112.45(b)(1)(v)); applying a time interval between last direct water application and harvest to allow for microbial die-off (§ 112.45(b)(1)(ii)); or applying a time interval between harvest and end of storage and/or using other activities during or after harvest to allow for microbial die-off and/or removal (§ 112.45(b)(1)(iii)), the farm is required to maintain scientifically valid data or information to support use of those measures (see § 112.50(b)(8) and (10)). While farms may choose to test their water to assist them in evaluating the efficacy of corrective or mitigation measures that they implement, we emphasize that as discussed in comment 83, farms must not rely on test results alone in making decisions around the safe use of their agricultural water.

If a farm determines that its mitigation measures are not effective to reduce the potential for contamination of the covered produce or food contact surfaces with known or reasonably foreseeable hazards, it must discontinue use of the agricultural water until it has implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41 (§ 112.45(b)(2)).

(Comment 107) Some comments request that FDA provide specifics around when pre-harvest water must be treated as a corrective or mitigation measure. A few comments suggest FDA specify ''high-risk'' situations in which water must be treated, such as requiring that all surface water must be treated unless the farm has data demonstrating that pathogens are not present in the water. These comments note that farms participating in LGMA are not permitted to use untreated surface water in overhead irrigation systems in the 3 weeks leading up to harvest, and suggest that FDA could similarly specify uses for which untreated surface water is prohibited. Some comments suggest that treatment would be the only viable mitigation measure for some operations. A few comments suggest the rule state that if other effective options for mitigation are not available, then farms would be required to treat their water.

(Response 107) Recognizing the wide degree of diversity that exists in industry—including in potential sources of known or reasonably foreseeable hazards, agricultural water systems, growing operations, water use practices, crop characteristics, and environmental conditions—what might be considered ''low'' or ''high'' risk for one farm may not necessarily be the same for another. See comment 31. Moreover, given the diversity that exists in industry, we recognize that not every mitigation measure will be appropriate for every farm to use. As such, we do not consider it appropriate to specify situations in which farms are required to implement mitigation measures, or more specifically, treat their pre-harvest agricultural water.

With respect to commenters' suggestion to specify that if other mitigation measures identified in § 112.45(b) are not available to a farm that the farm would be required to treat the water, we note that § 112.45(b)(2) requires that if a farm fails to implement appropriate mitigation measures, or if the farm determines that the measures were not effective, the farm must discontinue use of the pre-harvest agricultural water until adequate mitigation measures have been implemented. As such, it is likely that farms will implement any of the measures available to them and

appropriate to their conditions, including treatment, to avoid being required to cease that use of pre-harvest agricultural water. As such, we consider the change requested in the comments to be unnecessary.

We also disagree with commenters' suggestion to require treatment of agricultural water unless the farm has data indicating that pathogens are not present in the agricultural water system. In the 2015 produce safety final rule, we discuss various challenges associated with sampling water for pathogens. These include challenges related to larger sample sizes; inherently higher costs, and the wide array of potential target pathogens (*i.e.,* the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See 80 FR 74354 at 74427–74428. We are not aware of, and comments did not provide, information to suggest otherwise. See also comment 91. As such, we decline this suggestion.

(Comment 108) A few comments ask for clarity regarding whether pre-harvest water treatment must be done during the entire growing season, or only a certain amount of time before harvest.

(Response 108) If a farm treats its pre-harvest agricultural water based on its agricultural water assessment, the necessary timing for implementing agricultural water treatment will depend on the specific conditions at the farm. For example, if the farm treats its pre-harvest agricultural water in response to a condition in which there may be ongoing introduction of known or reasonably foreseeable hazards into the agricultural water system, it may be an appropriate response for the farm to treat that water each time it is used as pre-harvest agricultural water. For example, in situations where runoff introduces known or reasonably foreseeable hazards into the agricultural water system, and the farm is not able to prevent such events from occurring, it may be appropriate for the farm to treat the water each time it is used. Or, depending on the nature of the potential source of hazards as well as other information evaluated under § 112.43(a), treatment of agricultural water only during certain times of the growing season may be sufficient to reduce the potential for contamination of covered produce. For example, depending on the circumstances, the farm might determine that treatment is only necessary when agricultural water is applied close to harvest.

Conversely, if a farm determines that the introduction of known or reasonably foreseeable hazards is not on-going, it may be appropriate to treat the water as an isolated event. For example, if the farm is able to prevent additional runoff from being introduced to the agricultural water system, it may be appropriate to treat contaminated water still residing in the water distribution system as a one-time event, rather than treating the water as a regular practice.

If a farm treats its pre-harvest agricultural water, it is required to comply with the requirements in § 112.46, which we did not propose to substantively revise, including that the treatment be effective to make the water safe and of adequate sanitary quality for its intended use, and be delivered and monitored in a manner and with a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

2. Corrective Measures

(Comment 109) A few comments request clarity on what corrective measures would be appropriate for the example provided in the proposed rule in which a dead and decaying sheep results in water being not safe or not of adequate sanitary quality for its intended use.

(Response 109) In the 2021 agricultural water proposed rule, we provided the example that, if in performing the agricultural water assessment a farm finds that there is a dead and decaying sheep in the canal upstream and at a close distance to where it draws water, the farm would have reason to believe that the agricultural water is not safe or not of adequate sanitary quality for its intended use because the water is reasonably likely to contain human pathogens transferred by the dead and decaying sheep. Therefore, the farm would have to immediately discontinue that use of the water and take corrective measures under § 112.45(a) before resuming such use(s). 86 FR 69120 at 69141.

In this scenario, one appropriate response is for the farm to re-inspect the entire affected agricultural water system to the extent it is under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate measures to determine if the changes were effective (§ 112.45(a)(1)). Steps the farm takes to meet the requirements in § 112.45(a)(1) include, at a minimum:

- Re-inspecting the entire water system potentially affected by the dead sheep to the extent it is under the farm's control to identify any relevant conditions (such as additional dead sheep, including carcass materials that may have contaminated the farm's water distribution system if applicable);
- Removing the dead sheep and any related hazards identified during the re-inspection and allowing time for contaminants to clear the canal and bypass the point at which the farm draws water from the canal;
- Cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the sheep); and
- Visually verifying that all carcass materials have been removed.

Once the farm has taken all of the appropriate steps in light of its specific circumstances, it may resume using the water for direct water application irrigation of its covered produce.

(Comment 110) With respect to the requirements in proposed § 112.45(a)(1), some comments seek clarity as to whether pre-harvest agricultural water for produce commodities other than sprouts needs to meet the water microbial quality criterion in § 112.44(a).

(Response 110) The requirements in § 112.44(a), including the microbial criterion of no detectable generic *E. coli* per 100 mL of agricultural water, do not apply to pre-harvest agricultural water for non-sprout covered produce (see § 112.40), and as such, the reference to § 112.44(a) within § 112.45(a)(1) also does not apply to pre-harvest agricultural water for non-sprout covered produce.

3. Mitigation Measures

In § 112.45(b), we proposed various mitigation measures for pre-harvest agricultural water that farms would implement to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the water. We received various comments requesting clarification on the proposed mitigation measures and respond to such comments below.

Consistent with the requirements for pre-harvest agricultural water assessments that are designed to be adaptable to future advancements in agricultural water quality science, we are revising § 112.45(b)(1)(ii) regarding use of a time interval between last direct application or agricultural water and harvest to remove reference to a ''minimum interval of 4 days.'' We are also removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to further emphasize that other post-harvest activities may be used as mitigation measures.

We did not receive comments on the proposed mitigation measure in § 112.45(b)(1)(i), in which farms would make necessary changes (such as repairs) to address any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, and are finalizing that provision as proposed, without change. As noted above, we discuss general comments related to agricultural water treatment and the pre-harvest agricultural water efficacy testing protocol in section V.K.

a. General

(Comment 111) Several comments urge FDA to allow more time for farms to undertake mitigation measures, citing supply chain constraints. A few comments suggest that it may not be practical to implement mitigation measures (such as those requiring construction) mid-season. In contrast, several other comments express concern that the rule, as proposed, gives farms too much time to implement mitigation measures. Some comments are particularly concerned that the rule appears to allow farms up to 1 year to undertake mitigation measures for hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby lands and question whether that timing adequately protects public health. Similarly, some comments question whether making mitigations for hazards related to animal activity, BSAAOs, or human waste on adjacent or nearby lands within the growing season is sufficiently protective of public health, particularly since growing seasons can span many months and include the growth of multiple covered crops. The comments seek clarity on the meaning of ''growing season'' within the rule.

(Response 111) The mitigation measures listed in § 112.45(b) provide greater flexibility in the timing of decisions as compared to the immediate action required under § 112.45(a), in that the mitigation measures must be implemented as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment (as required by § 112.43), except that mitigation measures for known or reasonably foreseeable hazards related to animal activity, the application of BSAAOs or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented promptly, and no later than the same growing season as such assessment or reassessment. While the requirement that mitigation measures be implemented as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment is consistent with the timing for implementing measures in § 112.45(b) of the 2015 produce safety final rule, as discussed in the 2021 agricultural water proposed rule, we have incorporated expedited mitigation measures for hazards related to certain activities associated with adjacent and nearby lands in light of several produce-related outbreaks that occurred since we issued the 2015 produce safety final rule. See 86 FR 69120 at 69145.

We have incorporated this flexibility to allow sufficient time to make any necessary adjustments to farms' current practices. For example, we recognize that some mitigation measures identified in § 112.45(b)(1), such as making necessary changes (for example, repairs) or changing the method of water application, may take time to implement, as they might entail changes to current, or adoption of new, infrastructure and equipment on the farm. Conversely, other mitigation measures, such as increasing the time interval between last direct water application and harvest to allow for microbial die-off, may be relatively easily adopted by farms without need for significant advance preparation or changes to the farm's infrastructure or operations.

The allowable timeframes for implementing mitigation measures in §§ 112.43(c)(4)(i) and 112.43(c)(2) (*i.e.,* ''no later than one year after the date of the agricultural water assessment'' and ''no later than the same growing season as the assessment,'' respectively) are included in the recognition that, as discussed above, farms may not be able to immediately implement mitigation measures in every circumstance. Moreover, these end points are important in that they provide a basis after which, if a farm does not implement mitigation measures, the farm is required to discontinue such use of the water until the farm has implemented adequate mitigation measures in accordance with § 112.45(b)(2). However, inclusion of these end points in § 112.43(c)(4)(i) and 112.43(c)(2) does not permit farms to wait until the end of the year after the date of the assessment or the end of the same growing season as the assessment (as applicable) to implement mitigation measures under § 112.45(b). Rather, farms must implement mitigation measures ''as soon as practicable'' or ''promptly,'' respectively, as applicable to their circumstances.

For example, if a farm determines that mitigation measures are reasonably necessary under § 112.45 in accordance with § 112.43(c)(4)(i), the farm must implement mitigation measures ''as soon as practicable.'' Various timeframes may be ''practicable,'' depending on circumstances relevant to the farm. For example, it may be practicable for the farm to make modifications for the crop in the field at the time the farm makes the determination; during the next harvest if the farm has multiple harvests of a crop; or during the next growing season if the farm has multiple growing seasons within a year. If none of these timeframes are practicable or applicable to the farm's operation, it must make the modifications to its water use practices no later than 1 year after the date of the agricultural water assessment. For this reason, too, we disagree with comments suggesting it would be appropriate to provide additional time to implement mitigation measures, and we are finalizing the timing for implementing mitigation measures as proposed, without change.

(Comment 112) Some comments seek clarification about whether crop characteristics should influence mitigation measures and, if so, request that FDA provide examples.

(Response 112) We recognize that appropriate mitigation measures in § 112.45(b) are likely to depend, in part, on the characteristics of the commodity being grown. For example, the effectiveness of microbial die-off (such as might occur prior to harvest and/or during post-harvest storage) and changing the water application method in reducing the risk associated with covered produce as a result of agricultural water are all likely to depend, in part, on the characteristics of the commodity. We discuss these measures further in comments 115, 121 and 123.

(Comment 113) Some comments seek guidance on when and how to mitigate hazards after a weather event, such as heavy rain, has occurred.

(Response 113) If a farm determines that mitigation measures under § 112.45(b) are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water, the nature of the mitigation measure and timing for implementation will depend on the specific circumstances relevant to the farm, including the nature of the other information evaluated under § 112.43(a).

For example, if rain events are expected to increase runoff from adjacent or nearby lands used to graze sheep, a farm might determine, after also considering the other factors required to be evaluated in § 112.43(a)(1) through (5), that mitigation measures are reasonably necessary under § 112.45(b). Depending on the circumstances, the farm might increase the time interval between last direct application of water and harvest based on scientifically valid data and information, which the farm is required to do promptly, and no later than the same growing season as the assessment in accordance with § 112.43(c)(2). Or, if appropriate to the covered produce being grown, the farm might change the water application method to reduce the likelihood of contamination of the covered produce.

As another example, if a farm experiences an earthquake and observes seepage on the soil surface above an underground pipe that carries spent wash water, it might indicate that the pipe ruptured. If the seepage is in proximity to a well used as pre-harvest agricultural water, depending on the information evaluated under § 112.43(a), the farm might determine that mitigation measures under § 112.45(b) are reasonably necessary. In this scenario, the farm might decide that making necessary changes (for example, repairs) to the piping system, as well as making any necessary repairs to protect the well from contamination, together is an effective mitigation measure, which the farm is required to do as soon as practicable, and no later than 1 year after the date of the farm's agricultural water assessment in accordance with § 112.43(c)(4)(i).

b. Time Interval Between Last Application and Harvest

(Comment 114) Several comments support the ability to increase the time interval between last water application and harvest to a minimum of 4 days as a mitigation measure under proposed § 112.45(b)(1)(ii). These comments suggest that this option is effective, adds flexibility, and does not require a farm to have extensive knowledge of mathematics or microbial science. In contrast, some comments voice concern over the use of a 4-day interval. Some of these comments suggest that by including a time interval of 4 days, it places a burden on regulators to develop evidence justifying why longer die-off may be necessary in some circumstances. Other comments oppose inclusion of a 4-day time interval because, comments state, it effectively creates a scientifically unsupported ''safe harbor'' for farms, with limited parameters on the conditions in which application of such a time interval may not be warranted. Several comments ask that FDA remove the 4-day time interval from codified and instead include it in subsequent guidance which can be more easily updated as science evolves.

(Response 114) Consistent with the requirements for pre-harvest agricultural water assessments that are designed to be adaptable to future advancements in agricultural water quality science, we are revising § 112.45(b)(1)(ii) to remove reference to a ''minimum interval of 4 days.'' Instead, final § 112.45(b)(1)(ii) entails farms ''increasing the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided [the farm has] scientifically valid supporting data and information.'' We expect this change will further reinforce that farms may consider and adopt scientifically valid approaches other than that established for the 2015 produce safety final rule, both now and as agricultural water quality science continues to evolve. Further, recognizing that survival of pathogens and other microorganisms on produce commodities prior to harvest is dependent upon various factors (see response to comment 115), such a change will reinforce that farms may utilize scientifically valid time intervals as appropriate to their unique conditions.

While we are removing reference to a ''minimum interval of 4 days'' from § 112.45(b)(1)(ii), we continue to believe it is appropriate for farms to use a time interval between last direct water application and harvest based on that used in the 2015 produce safety final rule. As such, if a farm does not test its pre-harvest agricultural water but increases the time interval between last direct application of water and harvest as an appropriate mitigation measure, the farm may choose to increase its time interval to a minimum of 4 days, based on the data used to support the approach in the 2015 produce safety final rule. (See also response to comment 117, in which we discuss ''maximum'' vs. ''minimum'' intervals.) If a farm tests its pre-harvest agricultural water and increases the time interval between last direct application of water and harvest as a mitigation measure, in light of the approach established for the 2015 produce safety final rule, the farm may choose to use a microbial die-off rate of 0.5 log per day, for potentially less than 4 days between last direct water application and harvest, to achieve a calculated log reduction to meet the criteria the farm establishes in accordance with § 112.43(d)(3).

We consider the scientific data and information used to support the approach to a pre-harvest time interval established for the 2015 produce safety final rule as an example of adequate supporting scientific data and information farms may use in accordance with § 112.45(b)(1)(ii) (Refs. 60 and 61). See also 80 FR 74354 at 74444–74445. As such, a farm may use one of the approaches described immediately above for implementing a pre-harvest time interval as a mitigation measure under § 112.45(b) without having to develop and maintain additional supporting scientific data and information. Prior to using one of these approaches, however, the farm should consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm. If a farm has scientifically valid data or information to support use of an increased time interval that is more reflective of its unique conditions, the farm must use that information in establishing an appropriate time interval under § 112.45(b)(1)(ii). See also comment 115.

(Comment 115) Several comments note that it may be difficult for a farm to make decisions regarding sufficient time intervals for microbial die-off due to lack of scientific information or expertise, and seek further guidance from FDA. Some of these comments contend that the effectiveness of microbial die-off as a mitigation method depends on various factors that are not listed in the proposed rule (*e.g.,* climate and environmental conditions, differences between pathogens, and crop characteristics that could impact bacterial survival). Some comments request that FDA clarify how pathogens capable of longer-term survival (*e.g., Listeria*) are to be considered in determining time intervals between last water application and harvest. Several comments ask FDA to provide scientific data for microbial die-off in response to UV rays and for specific pathogens and commodities. Some comments request that farms be required to ensure that any die-off period used is validated for the conditions of their operation and specific hazards being targeted.

(Response 115) We agree that microbial die-off between last direct water application and harvest can be impacted by a broad range of conditions, such as timing of water application, environmental conditions, crop characteristics, and pathogen characteristics. As discussed in

response to comment 114, we are revising § 112.45(b)(1)(ii) to remove reference to a ''minimum interval of 4 days.'' Instead, final § 112.45(b)(1)(ii) provides farms the opportunity to increase the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided the farm has scientifically valid supporting data and information. We expect that such a change will further reinforce that farms may utilize scientifically valid time intervals as appropriate to their unique conditions.

As discussed in response to comment 114, we consider the scientific data used to support the approach to a time interval between last direct water application and harvest in the 2015 produce safety final rule to be one example of scientifically valid data and information (Refs. 60 and 61) (80 FR 74354 at 74444–74445). Further, we recognize that as science continues to evolve, time intervals that are more appropriate for a farm to use may become increasingly available.

For example, the studies we reviewed in determining an appropriate time interval for the 2015 produce safety final rule included those that looked at various types of leafy greens, carrots, and grass (the latter of which we considered a useful surrogate for at least some produce commodities with regard to leaf structure, and noted that particulates are just as likely to occur in grass irrigation water as in irrigation water used on produce crops) (Refs. 60 and 61). However, we recognize that microbial die-off on produce surfaces prior to harvest may differ for other commodities. Moreover, the studies evaluated included five field trials for *E. coli* O157:H7 (including surrogates), one field trial and one greenhouse study examining *Salmonella,* and three trials examining viral decay. While the studies evaluated reflect a few different growing conditions, we recognize that some farms may face different environmental conditions, which could affect the microbial die-off that occurs between last water application and harvest. Similarly, we recognize that not all pathogens or other microbial organisms will necessarily follow the same die-off kinetics as those assessed in studies evaluated for the 2015 produce safety final rule.

As more studies are conducted that examine in-field die-off for various circumstances (for example, different regions, environmental conditions, commodities, pathogens, and crop growth characteristics) (Refs. 46–49), it is likely that the science will continue to evolve. As we learn more about microbial die-off on produce surfaces prior to harvest, those findings can, and should, be accounted for if a farm increases the time interval between last direct application of agricultural water and harvest as a mitigation measure under § 112.45(b).

Scientific data and information used in support must be relevant to the farm's conditions (such as the region, crop, and environment), and be characterized in a manner that addresses the likely biphasic nature of microbial die-off (*i.e.,* rapid short-term die-off and a gradual long-term die-off) under § 112.45(b)(1)(ii). Evaluating various factors under § 112.43(a), such as the timing of water applications, environmental conditions, and crop characteristics, will help farms identify conditions relevant to establishing an increased time interval between last direct water application and harvest in accordance with § 112.45(b)(1)(ii). We intend to issue guidance on this topic, as appropriate.

(Comment 116) Several comments assert that a time interval for in-field microbial die-off only makes sense if preceded by microbial water testing, which would allow farms to calculate an acceptable die-off interval rate that may differ from 4 days. These comments note that the 2015 final rule indicated the importance of sampling water sources when a die-off period is used as a mitigation measure, whereas the 2021 proposed rule did not propose to require sampling to establish a baseline understanding of the microbial presence in the water.

(Response 116) While we recognize that pre-harvest agricultural water testing may provide information for farms to consider in implementing an increased time interval between last direct water application and harvest under § 112.45(b)(1)(ii), we disagree that farms should be required to test their pre-harvest agricultural water to do so. For example, if a farm increases the time interval between last direct water application and harvest as a mitigation measure, and in doing so, decides to only apply water from that agricultural water system early in the growing season (which could be, for example, weeks to months prior to harvest), calculations based on test results may not be needed in order to justify use of that time interval as a mitigation measure. Rather, the farm must implement that increased time interval as supported by scientifically valid data and information in accordance with § 112.45(b)(1)(ii). See also comment 115.

(Comment 117) A few comments note perceived inconsistencies as to whether the 4 days referenced in proposed § 112.45(b)(1)(ii) is intended to be a minimum interval between last direct application of agricultural water and harvest or a maximum interval. For example, these comments note that the 2015 final rule references research to determine that a maximum die-off period of four days is appropriate, but suggest that FDA now uses the same research in the 2021 proposed rule to say a minimum of 4 days for die-off is appropriate.

(Response 117) The mitigation measure involving an increased time interval between last direct application of agricultural water and harvest in the 2015 produce safety final rule consisted, in part, of using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of the farm's GM and STV to meet the microbial water quality criteria in previous § 112.44(b), for no greater than 4 consecutive days (see § 112.45(b)(1)(i)(A) in the 2015 produce safety final rule). In light of our proposal to remove the quantitative pre-harvest microbial quality criteria in the 2015 produce safety final rule, we revised our approach to the mitigation measure involving an increased time interval between last direct application of agricultural water and harvest to better reflect the proposed requirements for systems-based pre-harvest agricultural water assessments.

As discussed in the 2015 produce safety final rule, a 4-day interval corresponds to the general mid-point in time representing neither end of the range where microbial die-off can be expected to occur (Refs. 60 and 61) (80 FR 74354 at 74445). In the proposed rule, we stipulated a minimum (as opposed to a maximum) time interval of 4 days in the recognition that not all farms will have the benefit of quantitative test data to support a time interval of fewer than 4 days, and that additional die-off is likely to occur beyond 4 days, even if not at the same rate.

However, as discussed in response to comment 114, we are removing reference to ''4 days'' from the codified provision at § 112.45(b)(1)(ii) to further reinforce that farms may use approaches based on scientific data and information other than that used to establish the 2015 produce safety final rule, both now and as agricultural water quality science continues to evolve. While farms may use an approach to a time interval between last direct water application and harvest based on that established for the 2015 produce safety final rule (see comment 114), the farm should first consider whether the studies evaluated in support of pre-harvest microbial die-

off in the 2015 produce safety final rule are reflective of conditions relevant to the farm (Refs. 60 and 61). See also 80 FR 74354 at 74444–74445 and response to comment 115.

(Comment 118) Many comments assert that a 4-day time interval between water application and harvest, or between harvest and the end of storage, is not feasible in some environments or for some crops. For example, some of these comments note that shippers sometimes request application of water to ''freshen'' crops before shipping, and that farms are unable to prevent this practice, which presents a challenge for using a 4-day time interval as a mitigation. Other comments suggest that a pre-harvest time interval may not be feasible for crops (such as strawberries, cabbages, and peas) that require frequent water applications to support crop viability (for example, due to soils being sandy, to reduce heat stress on crops, or as part of the farm's pest management strategy). A few comments note that some farms, for example, hydroponic and aquaponic operations, irrigate their produce continuously and that therefore, there is no interval between water application and harvest that would be applicable to their practices.

(Response 118) As discussed in comment 114, we are revising § 112.45(b)(1)(ii) to remove reference to a minimum interval of 4 days, as we expect this will further reinforce that farms may consider and adopt scientifically valid approaches other than that established in the 2015 produce safety final rule, both now and as agricultural water quality science continues to evolve. However, we recognize that even with this change, an increased time interval between last direct water application and harvest may not be appropriate for every farm to use as a mitigation measure. We expect that providing a range of possible measures, of which a time interval between last direct water application and harvest is only one, will assist farms in making decisions about their agricultural water use that reflects their agricultural water systems, operations, and conditions.

We would also like to clarify that the 4-day time interval referenced in the 2021 agricultural water proposed rule was specific to the time interval between last direct water application and harvest (proposed § 112.45(b)(1)(ii)), and not the time interval between harvest and end of storage (proposed § 112.45(b)(1)(iii)), for which we are not establishing a specific, broadly applicable, microbial die-off rate or time interval. See also comment 121.

(Comment 119) Some comments seek clarity on whether a farm can use the sampling framework in the 2015 final rule to define a time interval between last application of agricultural water and harvest of fewer than 4 days. Several comments ask whether FDA recognizes the MWQP calculator by University of California, Davis as ''other scientifically valid data'' and, if so, request clarification on whether a 1-day interval would be acceptable if justified by the calculator.

(Response 119) In comments 93, 95 and 114, we explain that the sampling frequency, microbial quality criteria, and approach to a time interval between last direct water application and harvest established for the 2015 produce safety final rule are examples of approaches supported by scientifically valid data or information that fulfill applicable requirements under §§ 112.43(d)(3) and 112.45(b)(1)(ii). (We discuss the term ''scientifically valid'' in the 2015 produce safety final rule (see 80 FR 74354 at 74371).) As such, farms that test pre-harvest agricultural water as one part of an assessment and increase the time interval between last direct application of water and harvest as a mitigation measure can choose to use those methods and approaches. However, as discussed in response to comment 114, if a farm considers using an approach to a pre-harvest time interval based on that established for the 2015 produce safety final rule, the farm should first consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm (Refs. 60 and 61). See 80 FR 74354 at 74444–74445 and response to comment 115. To the extent that a farm uses a calculator or other tool to provide decision-making support, the farm remains responsible for ensuring that all applicable requirements are met, including that any microbial criteria (or criterion), sampling frequencies, pre- or post-harvest time intervals, or other activities (as applicable) be supported by scientifically valid data or information.

c. Time Interval Between Harvest and End of Storage and/or Conducting Other Activities

(Comment 120) A few comments request that increasing the time interval between harvest and the end of storage be removed as a mitigation measure in the final rule, since, the comments suggest, the factors associated with microbial die-off during storage are complex and may make it difficult to determine the adequacy of a post-harvest time interval. Other comments suggest that commercial washing specifically should be removed as an allowable mitigation, as including it reinforces an inaccurate perception that commercial washing always reduces pathogens on produce surfaces. A few comments note that commercial washing with an antimicrobial is designed to prevent the spread of pathogens from contaminated produce to other, uncontaminated produce, and not to remove microorganisms from contaminated produce. Some comments note that farms are not required to use an antimicrobial in their post-harvest wash water and suggest that including commercial washing as a mitigation measure may ultimately increase risk if water is not managed properly.

(Response 120) We recognize that microbial die-off and/or removal during post-harvest storage and as a result of other post-harvest activities is likely dependent on a variety of factors, such as commodity characteristics, storage time and conditions, and relevant production practices. Farms are not required to treat their post-harvest agricultural water, and post-harvest agricultural water, if not adequately managed, has the potential to serve as a source or route of contamination. However, if properly performed and scientifically valid given a farm's production practices, commercial washing has the potential to result in microbial die-off or removal from produce surfaces. For example, the World Health Organization has attributed a 1-log reduction in microbial load to washing (Ref. 65). See also 79 FR 58434 at 58446. As such, we are not removing § 112.45(b)(1)(iii) as an allowable mitigation measure.

However, we recognize there may be post-harvest activities other than commercial washing that have the potential to result in microbial die-off or removal on covered produce. See, for example, 80 FR 74354 at 74370, where we provide controlled atmosphere storage as another example of a post-harvest activity that may be appropriate for use as a mitigation measure with adequate supporting data and documentation. As such, we are removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to further reinforce that farms may use other activities during or after harvest as a mitigation measure, provided the farm has adequate supporting data and documentation. This revision will further encourage farms to consider other post-harvest activities that may result in microbial die-off or removal from produce surfaces both now, and in the future as potential advancements in

post-harvest handling practices occur (Refs. 80 and 81). In light of our removal of the pre-harvest agricultural water microbial quality and testing requirements in the 2015 produce safety final rule, we are also revising § 112.45(b)(1)(iii) to remove reference to microbial die-off ''rates'' and microbial removal ''rates,'' specifically.

(Comment 121) A number of comments request that FDA provide further guidance, scientific information, and examples on how farms may use a time interval between harvest and end of storage or commercial washing as mitigation measures under proposed § 112.45(b)(1)(iii). For example, a few comments request additional guidance, noting that the factors associated with microbial die-off during post-harvest storage and handling are complex and may depend, for example, on crop characteristics. Some comments request clarity on what type of organisms should be studied in order to justify the use of post-harvest storage or handling as a mitigation measure, noting that if producers attempt to develop data in-house, they will not be able to use pathogens to conduct in-house studies.

(Response 121) As discussed in the 2014 supplemental proposed rule and the 2015 produce safety final rule, we do not have sufficient information to support the derivation of appropriate, broadly applicable microbial die-off or removal rates between harvest and end of storage or during post-harvest activities such as commercial washing. See 79 FR 58434 at 58446 and 80 FR 74354 at 74444. We have not been provided with and are not aware of information that changes our position. Rather, farms that increase the time interval between harvest and the end of storage and/or conduct other post-harvest activities as a mitigation measure in accordance with § 112.45(b)(1)(iii) must establish parameters for such practices as appropriate to their circumstances (for example, in consideration of commodity characteristics, storage time and conditions, and/or other relevant production practices), as supported by scientifically valid data and information.

For example, a farm that uses commercial washing as a mitigation measure under § 112.45(b)(1)(iii) must do so as appropriate to its circumstances. The appropriateness of using commercial washing as a mitigation measure may be affected by, for example, the characteristics of the covered produce being washed (such as where commodity characteristics may protect potential contaminants from removal); the method of commercial washing (such as through a single-pass system vs. one that uses recirculated water); and any monitoring or management practices the farm has in place to reduce the potential for the agricultural water to serve as a source or route of contamination to covered produce (for example, the practices specified in § 112.44(d)).

We are not requiring farms to conduct ''in-house'' studies in order to support use of a mitigation measure under § 112.45(b)(1)(iii), nor are we establishing parameters on what studies conducted to support such practices should entail. Rather, we require that any increased time interval between harvest and the end of storage and/or other post-harvest activities used in accordance with § 112.45(b)(1)(iii) be supported by scientifically valid data or information. See 80 FR 74354 at 74371.

(Comment 122) Some comments seek clarity around the term ''commercial washing'' in proposed § 112.45(b)(1)(iii), such as whether it would include processes that use water for cooling purposes (for example, hydrocooling, dump tank, spray bar, and ice-injection processes), and whether it is an available mitigation measure for all covered produce, or just select commodities.

(Response 122) As discussed in response to comment 120, we are removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to reinforce that farms may use other activities during or after harvest that result in microbial die-off or removal, provided the farm has adequate supporting data and documentation. While post-harvest activities conducted under § 112.45(b)(1)(iii) could involve the use of agricultural water, it is not required, such as where controlled atmosphere storage may result in microbial die-off or removal (as supported by scientifically valid data and information). (See 80 FR 74354 at 74371).

Additionally, we note that activities allowed as mitigation measures under § 112.45(b)(1)(iii) are not limited to any commodities in particular. However, as discussed in response to comment 121, farms must establish parameters for any post-harvest activities used in accordance with § 112.45(b)(1)(iii) as appropriate to their circumstances (*e.g.,* in consideration of commodity characteristics, storage conditions, and/or other relevant production practices) and as supported by scientifically valid data and information.

d. Changing the Method of Water Application

(Comment 123) Some comments request that FDA identify use of drip and seepage irrigation as effective strategies for reducing risk because in such systems, the water distribution occurs below the soil surface (never touching any above-ground portion of the plant) and the soil naturally filters out any potential microbial hazards.

(Response 123) It is unclear to us whether comments are requesting that we identify drip and seepage irrigation as methods that do not result in contact between agricultural water and the crop, or that we identify use of drip and seepage irrigation as water application methods that could be broadly applied as mitigation measures under § 112.43(b)(1)(iv).

To the extent that comments are requesting we identify drip and seepage irrigation as broadly applicable mitigation measures in § 112.43(b)(1)(iv), we decline to do so, as the effectiveness of using those application methods as a mitigation measure is a function of multiple factors, including the water application method, characteristics of the crop (such as whether the harvestable portion grows near, on, or in the ground), and any relevant practices the farm may have in place. For example, changing the water application method for root crops may not be an appropriate mitigation measure, as it may be difficult to effectively minimize contact between agricultural water and the harvestable portion of the crop while allowing the crop access to water needed to survive and grow. However, for non-root crops, changing the water application method may be effective as a mitigation measure under § 112.45(b), if making the change minimizes the water that is in direct contact with the harvestable portion of the crop. For example, changing from overhead to microjet irrigation for some tree fruit (such as citrus) or from microjet to drip irrigation for some covered produce that grows near the ground (such as bell peppers) may reduce the likelihood of contamination of the covered produce in accordance with § 112.45(b)(1)(iv). Additionally, there may be instances where multiple practices—such as the use of plastic mulch along with changes in water application methods—together serve as effective mitigation measures under § 112.45(b)(1)(iv).

e. Alternative Mitigation Measure

(Comment 124) Several comments suggest that changing water sources (from surface water to ground water, for

instance) might be considered a possible alternative mitigation measure.

(Response 124) We have incorporated flexibility in § 112.45 to provide farms viable options to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water without needing to alter the source of agricultural water, such as making necessary changes (for example, repairs) or changing the method of water application to reduce the potential for contamination of covered produce. However, if a farm changes the water source it uses for pre-harvest agricultural water, it is a significant change, and a reassessment under § 112.43(e) is required. The reassessment must evaluate the impacts of the change on the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c). See also section V.I.

We believe that providing a range of mitigation measures for farms to use in § 112.45(b), including the ability to use an alternative mitigation measure provided the requirements in § 112.12 are met, provides farms with an appropriate level of flexibility in selecting mitigation measures that are reasonably necessary to reduce the potential for covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.

K. Treatment of Agricultural Water

The proposed rule contained edits designed to provide clarity, such as reorganizing subpart E to group provisions of a similar nature, which included moving the provisions related to agricultural water treatment to § 112.46. Additionally, as discussed in the 2021 agricultural water proposed rule, although we are not requiring farms to treat their agricultural water, scientists from FDA's Center for Food Safety and Applied Nutrition, in collaboration with EPA, developed a testing protocol for evaluating the efficacy of antimicrobial chemical treatments against certain foodborne pathogens in agricultural water sources (Ref. 82). Since the efficacy protocol was approved by EPA on April 29, 2020, we have worked with EPA to provide various updates to enhance flexibility (where appropriate) and meet the current needs scientifically and practically (Ref. 83).

We received various comments on agricultural water treatment in general, as well as the pre-harvest agricultural water efficacy testing protocol, which we discuss below. For comments regarding treatment as a corrective or mitigation measure, see section V.J.

As discussed in section V.A., we did not propose to substantively revise the requirements for agricultural water treatment in § 112.46; therefore, comments on § 112.46 are outside the scope of this rule. However, we intend to issue guidance on these requirements in the future.

(Comment 125) Many comments note that there are currently no chemical treatment options approved by EPA for use in pre-harvest agricultural water against human pathogens, and express concerns that this may prohibit the use of water treatment as a corrective or mitigation measure until such products are approved. Some comments suggest that the lack of available chemical treatments may result in some farms using pesticides in an unapproved manner in order to comply with the proposed rule.

(Response 125) Farms are not required to treat their agricultural water. Rather, farms have a range of options, and treatment of water is one such option. Additionally, if a farm treats agricultural water, § 112.46 allows for non-chemical suitable methods of treatment. See 80 FR 74354 at 74436–74437. Further, as discussed in the 2015 produce safety final rule, like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. See 80 FR 74354 at 74436.

(Comment 126) Some comments voice concern that farms are not required to test the quality of their water prior to treating it. These comments suggest that the chemicals approved using the treatment efficacy protocol have limited usefulness in ensuring that treated pre-harvest water contains no detectable generic *E. coli* per 100 mL of water, as a farm would be unable to document that an EPA-labeled treatment that achieves 3-log removal is expected to result in pre-harvest water containing no detectable generic *E. coli* per 100 mL of water unless the farm knows that the starting concentration of generic *E. coli* is less than 1,000 CFU per 100 mL.

(Response 126) We understand commenters to be referring to language in the pre-harvest agricultural water treatment efficacy protocol specifying that results of testing should demonstrate a minimum of 3-log reduction of each of the test organisms as compared to the control count (Ref. 82). We understand that a 3-log reduction is the minimum level of reduction of pathogens the EPA will consider when registering an antimicrobial treatment that includes a public health claim. While the requirements for agricultural water treatment in § 112.46 refer in part to § 112.44(a) (which includes a microbial criterion of no detectable generic *E. coli* per 100 mL of water), we note that the requirements in § 112.44(a) do not apply to pre-harvest agricultural water for non-sprout covered produce (see § 112.40).

We did not propose to substantively revise § 112.46, which includes requirements related to treatment efficacy.

(Comment 127) Some comments request that FDA remove chemical treatment of irrigation water as an allowable mitigation strategy in the proposed rule so as to avoid potential effects on the environment.

(Response 127) As discussed in response to comment 125, farms are not required to treat their agricultural water. Rather, farms have a range of options, and treatment of water (such as with physical treatment, chemical treatment, or other suitable method) is one such option. With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use. See 80 FR 74354 at 74434–74435.

However, we recognize that improper use, management, or disposal associated with chemical treatment of agricultural water can create adverse environmental impacts. During rulemaking for the 2015 produce safety final rule, and in accordance with the National Environmental Policy Act and its implementing FDA regulations, we evaluated the potential effects of the 2015 produce safety final rule on the human environment in the United States in an EIS (Ref. 50). That document has a detailed discussion of the potential impacts such as those related to pesticide use, chemical treatment of agricultural water, and changes in ground water demand. See also 80 FR 74354 at 74434–74435. At the time of this rulemaking, as was also the case at the time of preparation of the Agency's finding of no significant impact and environmental assessment for the 2021 agricultural water proposed rule (Refs. 51 and 52), there are no pesticide products which have been registered by EPA for treatment of agricultural water during pre-harvest activities. No significant adverse environmental impacts have been identified with this final rule (Ref. 53).

We are not aware of, and comments did not provide, data or information suggesting these findings are incorrect. Therefore, further analysis of potential impacts would be speculative.

(Comment 128) Several comments agree with FDA's tentative conclusion that the proposed rule does not conflict with or duplicate the requirements of organic certification under USDA's National Organic Program (NOP) standards (7 CFR part 205). However, a few comments express concern that chemical products approved by the EPA for use on pre-harvest water in the future (such as chlorine compounds) may not be allowed for use under the NOP.

(Response 128) As discussed in the 2015 produce safety final rule (80 FR 74354 at 74439–74440), compliance with the provisions of the 2015 produce safety final rule, including the provisions related to agricultural water in subpart E, does not preclude compliance with the requirements for organic certification in 7 CFR part 205. We continue to conclude that in accordance with section 419(a)(3)(E) of the FD&C Act, this rule does not include any requirements that conflict with or duplicate the requirements of the NOP established under the Organic Foods Production Act of 1990. See also 86 FR 69120 at 69132.

If a farm treats its agricultural water, non-chemical water treatment options (including pesticide devices such as filter units, UV light units, and ozonator units) may be also used in compliance with § 112.46, which we did not propose to substantively revise. Thus, this rule does not require organic farms to use a substance that is prohibited in organic production. We also note that the provisions for treatment of agricultural water in § 112.46 are not in conflict with or duplicative of NOP regulations which permit the use of chlorine materials in organic production and handling in accordance with certain limitations (see 7 CFR 205.601(a) and 205.605(b)). Additionally, NOP guidance, ''The Use of Chlorine Materials in Organic Production and Handling'' (Ref. 84), provides information about compliant use of chlorine under the organic regulations. See 86 FR 69120 at 69131.

(Comment 129) Some comments suggest that treatments that are effective against the bacterial pathogens identified in the efficacy protocol cannot necessarily be expected to have the same level of effectiveness against viral and protozoan pathogens, such as *Cyclospora cayatanensis.* Moreover, comments claim that in many situations, a farm may not know what specific microbial hazards may be present in an agricultural water and request that FDA clarify whether all known or reasonably foreseeable hazards must be considered when selecting a treatment.

(Response 129) We recognize that pathogens present in agricultural water systems may vary, and that not every treatment will be effective against every possible pathogen. While farms are required to consider the *conditions* that are reasonably likely to introduce known or reasonably foreseeable hazards as part of their pre-harvest agricultural water assessments (emphasis added), we do not necessarily expect farms to identify the specific microbial hazards associated with each condition in order to treat their water as a corrective or mitigation measure. Nonetheless, if a pathogen is known to be, or is likely to be, associated with a farm's pre-harvest agricultural water (which the farm may be aware of through voluntary testing, knowledge or experience, or other means) and the farm treats the water, the farm must consider the presence of that pathogen in selecting an appropriate method of treatment.

For example, the efficacy protocol for the development and registration of antimicrobial treatments for pre-harvest agricultural water, as updated in January 2023 (Ref. 82), specifies Shiga-toxin producing *E. coli* and *Salmonella enterica* as test organisms. As such, any chemistries approved using this protocol will specify those organisms on their labels. (While the protocol originally included *L. monocytogenes,* in a January 2023 update (Ref. 83), we explained that we were removing *L. monocytogenes* from the protocol at that time.) We emphasize that a variety of measures are available for farms to use in § 112.45, not just those related to chemical treatment of agricultural water. As we continue to learn more about the known or reasonably foreseeable hazards present in pre-harvest agricultural water sources and systems, we will consider working with EPA to account for other pathogens in efficacy protocols to support registration of chemical treatments.

(Comment 130) Some comments disagree with what they suggest is a requirement under the proposed rule for farms to treat their water with products labeled for specific pathogens. A few comments request that FDA provide flexibility related to the treatment efficacy protocol and requirements that chemical treatments be validated for efficacy against specific test organisms.

(Response 130) As discussed in the 2015 produce safety final rule, although some antimicrobial substances are regulated by FDA, most antimicrobial substances that might be used by farms in agricultural water are regulated by the EPA (Ref. 85) (80 FR 74354 at 74439). We anticipate that the treatment efficacy protocol (Ref. 82), which EPA approved, will facilitate the registration of chemical treatments and increase the options for corrective and mitigation measures available to farms. We anticipate that having several chemical treatment options available encompassing a range of chemistries and applications will help ensure coverage over an industry with such variable practices and conditions.

L. Records Relating to Agricultural Water (§ 112.50)

We proposed to add new requirements in § 112.50 for records relating to pre-harvest agricultural water assessments. We also made revisions to conform with the proposed changes to the subpart E provisions, including to revise the requirements of § 112.161(b) to require supervisory review of records of pre-harvest agricultural water assessments and determinations.

We received various comments on the recordkeeping requirements in § 112.50 and respond to those comments in the following paragraphs. As discussed below, we are revising § 112.50(b)(7) to further reinforce flexibility afforded to farms in establishing records related to certain actions taken under § 112.45. We are also revising § 112.50(b)(8) to reflect the changes we are making to § 112.45(b)(1)(ii) and (iii) (see section V.J.). Additionally, consistent with § 112.50(b)(8) in the 2015 produce safety final rule, we are adding the following record requirement: for farms using an alternative mitigation measure in accordance with § 112.45(b)(1)(vi), records of scientific data or information the farm relies on to support that measure (§ 112.50(b)(9)). We have renumbered the subsequent recordkeeping provisions accordingly. We received no comments on the conforming revisions to § 112.161(b) and are finalizing it without change.

(Comment 131) Some comments seek clarity on what standards of Subpart O, ''Records,'' apply for pre-harvest agricultural water assessments. A few comments request that FDA clarify which records, including those for agricultural water reassessments, are required to be in writing. A few comments request that FDA provide templates for records, with a few of those comments seeking clarity on whether a printed copy of the Agricultural Water Assessment Builder tool would satisfy the records

requirements in § 112.50. Others request that FDA provide sufficient education and outreach to assist farms in complying with the recordkeeping requirements.

(Response 131) Subpart O of the 2015 produce safety final rule established the general requirements applicable to documentation and records that farms must establish and maintain under part 112, including records related to agricultural water. We discuss the requirements in subpart O in the 2015 produce safety final rule. See 80 FR 74354 at 74510–74514.

Section 112.43(a) requires that farms, in part, prepare a *written* agricultural water assessment (emphasis added). The requirement that agricultural water assessments be in writing also applies for any reassessments conducted under § 112.43(e).

As referenced by the comments, we have made an Agricultural Water Assessment Builder (Ref. 24) available to help stakeholders understand the requirements in the 2021 agricultural water proposed rule for pre-harvest agricultural water assessments. While we expect to update the Builder to reflect this final rule, use of the Builder does not mean that farms are in compliance with the relevant requirements.

(Comment 132) A few questions seek clarity on whether agricultural water assessments prepared by farms will be accessible to outside parties.

(Response 132) Records obtained by FDA in accordance with part 112, including agricultural water assessments, are subject to the disclosure requirements under 21 CFR part 20 (§ 112.167). Our disclosure of information is subject to the Freedom of Information Act (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under 21 CFR part 20, which include protection for confidential commercial information and trade secrets. See 80 FR 74354 at 74514.

(Comment 133) Several comments request that FDA clarify which records can satisfy multiple requirements both for subpart E and for other sections of the rule that may be related (for example, subparts I and F). Many comments ask whether records used for water system inspections can also be used to satisfy the agricultural water assessment recordkeeping requirements.

(Response 133) Under § 112.163(a), farms are not required to duplicate any existing records, including those for agricultural water assessments, if those records contain all of the required information and satisfy the relevant requirements. Similarly, if a farm has records containing some but not all of the required information, § 112.163(b) provides the flexibility to keep any additional information required either separately or combined with existing records.

With respect to comments asking about records for agricultural water system inspections and agricultural water assessments, we note that records of a farm's agricultural water system inspection in § 112.50(b)(1) may not be appropriate to fulfill, in full, the requirement to maintain records of written agricultural water assessments in § 112.50(b)(2), as the requirements in § 112.43 for agricultural water assessments require consideration of a broader range of factors than those considered for water system inspections under § 112.42(a). See also response to comment 25.

(Comment 134) Some comments request that FDA simplify the recordkeeping requirements for farms that choose to wait at least 4 days between the last direct water application and harvest by allowing farms to document practices in written standard operating procedures instead of requiring farms keep records documenting each individual time they use the 4-day interval on each crop.

(Response 134) We agree that flexibility with respect to records of certain mitigation measures is warranted and are revising proposed § 112.50(b)(7) to remove specific reference to § 112.45(b)(1)(ii) and (iii) (regarding a time interval between last water application and harvest, and a time interval between harvest and end of storage (and/or conducting other post-harvest activities), respectively). For example, if a farm implements an increased time interval between last direct water application and harvest as a mitigation measure under § 112.45(b)(1)(ii) and adopts that increased time interval as a routine practice, capturing that practice in a single record suffices such that maintaining a record of each individual instance the time interval is applied is not necessary. This, too, applies to any increased time intervals between harvest and end of storage and/or other post-harvest activities that a farm implements as a mitigation measure under § 112.45(b)(1)(iii), if the farm adopts the relevant practice(s) as a routine activity.

(Comment 135) One comment notes that proposed § 112.45(b) requires the implementation of certain ''mitigation measures'' under specified conditions, yet the associated records requirement in § 112.50(b)(7) requires ''documentation of actions you take in accordance with § 112.45.'' The comment requests that § 112.50(b)(7) be modified to read, ''Written documentation of mitigation measures you take in accordance with § 112.45.''

(Response 135) We decline to make this change, as § 112.45 includes required actions beyond the mitigation measures specified in § 112.45(b). See § 112.45(a), which requires, in certain circumstances, that a farm immediately discontinue use of agricultural water and, before resuming use of the water, implement corrective measures in § 112.45(a)(1) or (2).

VI. Effective and Compliance Dates

In the 2021 agricultural water proposed rule, we proposed to establish an effective date 60 days after the date of publication of the final rule. In the 2022 supplemental proposed rule, we proposed to establish dates for compliance with the pre-harvest agricultural water provisions for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. We also specified the duration of the period of enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts until January 26, 2025, for very small businesses; January 26, 2024, for small businesses, and January 26, 2023, for all other businesses.

We received several comments in response to the 2021 proposed rule as well as the 2022 supplemental proposed rule regarding the proposed effective date for a final rule as well as the proposed compliance dates for the requirements that apply for pre-harvest agricultural water for non-sprout covered produce. We respond to these comments here. While in the 2022 supplemental proposed rule we noted that we were reopening the comment period only with respect to the compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts, we received some comments related to the end of our intended period of enforcement discretion for the harvest and post-harvest agricultural water requirements for non-sprout covered produce.

After considering comments, we are finalizing the effective date as proposed, *i.e.,* 60 days after publication of this rule. We are also finalizing compliance dates as proposed, such that compliance dates are those shown in table 5.

TABLE 5—COMPLIANCE DATES FOR REQUIREMENTS IN SUBPART E FOR COVERED ACTIVITIES INVOLVING COVERED PRODUCE

[Except sprouts subject to subpart M]

Size of covered farm	Provisions related to harvest and post-harvest agricultural water	Provisions related to pre-harvest agricultural water
	Compliance date	Proposed compliance date
Very Small Business	January 26, 2024	2 years and 9 months after the effective date of this rule.
Small Business	January 26, 2023	1 year and 9 months after the effective date of this rule.
All Other Businesses	January 26, 2022	9 months after the effective date of this rule.

(Comment 136) Several comments support FDA's proposed compliance dates for pre-harvest agricultural water requirements, suggesting that the proposed compliance dates allow sufficient time for farms to understand and comply with the requirements. In contrast, other comments express a concern that the proposed compliance dates for pre-harvest agricultural water requirements do not allow sufficient time for on-farm preparedness and development of educational and training materials to support successful implementation. A few comments suggest specific compliance dates from 1 to 3 years after the final rule publishes based on farm size would be appropriate, whereas others suggest that a single compliance date for all agricultural water provisions 2 years after publication of the final rule would be more appropriate.

(Response 136) In light of the extensive outreach we conducted following issuance of the proposed rule and anticipated education, outreach and training on this final rule, we decline commenters' request to provide additional time for farms to come into compliance with the pre-harvest agricultural water requirements for non-sprout covered produce and are finalizing compliance dates for those provisions as proposed, without change. To the extent that comments are suggesting we establish a single set of compliance dates for all uses of agricultural water (pre-harvest, harvest, and post-harvest) and/or establish a single compliance date that applies for farms of all sizes, we discuss such feedback in response to comments 141 and 137, respectively.

Regarding outreach conducted following issuance of the 2021 proposed rule, as discussed in further detail in section III.F., we conducted numerous outreach activities following issuance of the agricultural water proposed rule. These included participation in various webinars; consultations, two virtual public meetings; regional meetings sponsored by State regulatory partners; and numerous other meetings and speaking engagements to discuss the proposed rule, respond to questions, and receive feedback. Further, we are exploring other mechanisms, such as webinars, updated training programs, workshops, and educational resources, to provide industry with information to facilitate compliance the requirements we are finalizing here. We also anticipate updating our Agricultural Water Assessment Builder, including both the online and paper-based versions, to reflect the pre-harvest agricultural water requirements we are finalizing here.

Additionally, we note that although the compliance dates we are finalizing here apply for all requirements for pre-harvest agricultural water for non-sprout covered produce, many of these requirements have not changed since publication of the 2015 produce safety final rule. See § 112.40 and response to comment 9. For example, other than technical amendments to provide additional clarity (such as adding descriptive headings and consolidating certain requirements), the requirements in § 112.42 for agricultural water system inspections and maintenance remain the same as when the 2015 produce safety final rule published. As such, we expect that many farms may already be aware of, and have received education and training on, some of the requirements that apply for pre-harvest agricultural water that are not changing with this final rule. While we recognize the value of outreach and training regarding the requirements in § 112.43 for pre-harvest agricultural water assessments and outcomes, we disagree that farms will need more than the established compliance periods to adapt their programs to the specific requirements of this rule.

(Comment 137) Many comments support staggered compliance dates for the pre-harvest agricultural water provisions based on farm size. Some comments note that extended compliance dates are especially important in order to provide enough time for training, technical assistance, and updates to practices, infrastructure, and equipment to occur. Conversely, some comments do not support staggered compliance dates based on farm size, contending that staggered compliance dates create unnecessary complexity for organizations that conduct training since they will first have to target only large farms, and then conduct training for small farms as the different compliance dates grow near.

(Response 137) We disagree that we should establish a uniform compliance period for the pre-harvest agricultural water requirements for non-sprout covered produce across all farm sizes. The purpose of staggered compliance dates is to give businesses of various sizes time to come into compliance with the rule technically, financially, and operationally. In light of practical considerations for small and very small businesses, we consider that additional time for small and very small farms to come into compliance is warranted. Moreover, we note that staggered compliance dates based on farm size is consistent with compliance dates for requirements in the 2015 produce safety final rule that we did not propose to change, and is consistent with the statutory provisions in section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, which direct us to provide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses.

(Comment 138) Some comments urge FDA to set pre-harvest compliance dates only after sufficient research is conducted regarding the impact of farming practices on pre-harvest agricultural water quality and safety, and mitigation measures that are appropriate to address various conditions. Several comments suggest that ''proven'' mitigation measures need to be made available before farms should be expected to implement the requirements for agricultural water assessments.

(Response 138) We disagree with these comments. While we have designed the rule to be adaptable to future scientific advancements, we note that there is long-standing scientific

support for the mitigation measures identified in § 112.45(b). See, for example, the GAPs Guide (Ref. 59) and the QAR (Ref. 17). We also discuss the scientific reasoning behind the proposed requirements for agricultural water assessments (including mitigation measures) throughout the 2021 agricultural water proposed rule and in section V of this final rule. To the extent that science related to pre-harvest agricultural water quality continues to evolve, farms will be able to use such information to further inform covered their pre-harvest agricultural water assessments. We anticipate that as new information becomes available, it will be shared with covered entities through various means. See response to comment 19.

(Comment 139) A few comments suggest that FDA and States will need time to make progress on partnerships related to the pre-harvest agricultural water provisions. These comments suggest that partnerships should be in place before compliance with the pre-harvest requirements is required.

(Response 139) FSMA recognizes a critical role for FDA's State regulatory partners. To this end, FDA has established the FDA-State Produce Safety Implementation Cooperative Agreement Program,[8] through which most states have developed produce safety programs (Ref. 86).

(Comment 140) Several comments disagree with the proposed effective date of 60 days after publication of the final rule, arguing that 60 days is not enough time for farms to implement necessary changes in order to come into compliance with the proposed requirements.

(Response 140) ''Effective date'' and ''compliance date'' do not mean the same thing. The effective date is the date that requirements amend the current CFR; and for this rule, the compliance date is the date at which a farm is required to be in compliance with the pre-harvest agricultural water requirements for non-sprout covered produce.

We proposed that the effective date of this rule would be 60 days after the date of publication of the final rule in the **Federal Register**. However, we proposed to provide for a longer timeline for farms to come into compliance with the pre-harvest agricultural water provisions depending on the size of the farm—*i.e.,* 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. See also table 5. As discussed throughout this section, we are finalizing the effective and compliance dates as proposed.

(Comment 141) We also received various comments on FDA's intention to exercise enforcement discretion for harvest and post-harvest agricultural water. One comment notes that most farms have already begun complying with the harvest and post-harvest agricultural water requirements, and voices support for FDA's intent to exercise enforcement discretion for those requirements as described in the 2022 supplemental proposed rule. In contrast, some comments request that FDA provide more time for training and other outreach. A few of these comments note that even though FDA did not propose changes to the requirements for harvest and post-harvest agricultural water, some of the provision numbers for those requirements may change with a final rule, which could result in confusion. A few comments assert that bifurcated compliance dates will be confusing, and create unnecessary complexity by, for instance, requiring educators to conduct separate trainings for the harvest/post-harvest and pre-harvest agricultural water requirements.

(Response 141) As discussed in the 2022 supplemental proposed rule, we reopened the comment period on the 2021 proposed rule solely to request public comment on the proposed compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts. As we did not propose to change the requirements that apply for harvest and post-harvest agricultural water, we did not propose a compliance date extension for those provisions for covered produce other than sprouts. However, we stated our intent to exercise enforcement discretion for the harvest and post-harvest agricultural water requirements for non-sprout covered produce until specific dates, which were staggered according to the size of the farm, to provide farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those provisions.

With respect to comments suggesting there will be confusion due to the renumbering of various provisions that apply for harvest and post-harvest agricultural water, we note that § 112.40 specifies which provisions in subpart E are applicable to harvest and post-harvest agricultural water. Additionally, our response to comment 9 summarizes the major changes being made to the agricultural water provisions in subpart E between the 2015 produce safety final rule and this final rule, including the location of the relevant requirements. We expect this information, along with training, technical assistance, educational visits, and on-farm readiness reviews, will reduce potential confusion associated with reorganizing the provisions of subpart E.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small entities may incur costs larger than 3 percent of annual revenues, we cannot certify that the final rule will not have a significant

[8] See ''FDA-State Produce Safety Implementation Cooperative Agreement Program'' at *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/fda-state-produce-safety-implementation-cooperative-agreement-program.*

economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

We estimate costs of the rule resulting from reading the rule, conducting pre-harvest agricultural water assessments, conducting mitigation measures when reasonably necessary based on the outcomes of the pre-harvest agricultural water assessments, and recordkeeping as a result of the pre-harvest agricultural water assessments. Our primary estimates of annualized costs are approximately $17.5 million at a 3 percent discount rate and approximately $17.7 million at a 7 percent discount rate over 10 years.

We estimate benefits of this rule resulting from the dollar burden of foodborne illnesses averted, and we estimate forgone benefits of this rule resulting from foodborne illnesses not averted due to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule. Our primary estimates of annualized benefits are approximately $10.3 million at a 3 percent discount rate and approximately $10.1 million at a 7 percent discount rate over 10 years. In the FRIA, we discuss non-quantified benefits of the rule stemming from avoiding overly broad recalls of products that would have occurred absent the rule. We also discuss non-quantified benefits relating to increased flexibility for covered farms to comprehensively evaluate their agricultural water systems, in light of the requirements for pre-harvest agricultural water assessments being designed to accommodate a wide range of agricultural water sources, uses, and practices.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 26) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VIII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. We have considered the changes made between the 2021 proposed rule and this final rule and have concluded that the Agency's finding of no significant impact for the proposed rule, and the evidence supporting that finding, contained in an environmental assessment, continue to apply (Refs. 51–53 and 87). The Agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the Description section with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Standards for the Growing, Harvesting, Packing, and Holding of Produce; Recordkeeping—OMB Control Number 0910–0816—Revision.

Description: This rule replaces recordkeeping requirements (found in part 112, subpart E) associated with sampling and testing of pre-harvest agricultural water for non-sprout covered produce with requirements to prepare and maintain documentation of written pre-harvest agricultural water assessments for non-sprout covered produce.

Description of Respondents: Farms subject to the regulation in part 112.

In the following paragraphs, we describe and respond to the comments pertaining to the proposed information collection.

(Comment 142) One comment seeks clarity on how this rule adds to the paperwork burden of the produce safety rule in terms of hours and numbers of records. This comment also requests clarification as to whether the calculated time burden in the 2021 agricultural water proposed rule includes reassessments and maintenance activities, and expresses a view that FDA may have underestimated the time burden of this rule if such activities were not included in the calculations.

(Response 142) Our estimates of the burden of the information collection in the 2021 agricultural water proposed rule and this final rule reflect only the requirements that we are finalizing here for pre-harvest agricultural water assessments for non-sprout covered produce. This includes the requirement in § 112.43(e) for farms to conduct a reassessment at least once annually, and whenever a significant change occurs in their agricultural water system that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces through direct application of agricultural water during growing activities. See the third column in table 6 below, in which we assume 1.1 agricultural water assessments per year in light of this requirement, consistent with our FRIA (Ref. 26). Comments did not provide information to suggest that revisions to this approach are necessary or appropriate. As such, we use the same approach to estimating the burden of information collection in this final rule as we did in the 2021 agricultural water proposed rule, with the only change being to update farm counts based on more recent data sources used in the FRIA compared to that used in the PRIA. For discussion related to the estimated time to conduct recordkeeping specifically, see comment 143.

(Comment 143) A few comments suggest that the estimates in the proposed rule for time to conduct recordkeeping for pre-harvest agricultural water assessments, which ranged from 4–9 hours depending on farm size, is too low in light of challenges that some farms may face. For example, a few comments suggest that some farms may face challenges in conducting agricultural water assessments, such as the following: having multiple water sources; having long growing seasons; having water sources than span long distances; lacking historical knowledge of water systems and adjacent lands; lacking technical background; having limited personnel and/or financial resources; and not speaking or reading English.

(Response 143) We recognize that the time it takes farms to conduct recordkeeping for pre-harvest agricultural water assessments is likely to range for a variety of reasons, including those referenced in the comments. To account for a range in the amount of time recordkeeping for

agricultural water assessments may take, in the FRIA (Ref. 26), we provide low, most likely, and high estimates based on farm size (see tables 31–33 in that document). To estimate the burden of information collection associated with the requirements for pre-harvest agricultural water assessments, we use the ''most likely'' values in the FRIA for each farm size. We are not aware of, and comments did not provide, data or information suggesting estimates that are more applicable across the diversity that exists in industry in agricultural water systems, operations, and conditions. As such, we use the same estimates for the time to conduct pre-harvest agricultural water assessments when estimating the burden of information collection in this final rule as we did in the 2021 agricultural water proposed rule, consistent with estimates in the PRIA (Ref. 88) and FRIA (Ref. 26).

Burden Table: Upon consideration of these comments and in light of updated farm count data in the FRIA compared to the PRIA, we estimate the burden of the information collection as follows:

TABLE 6—CUMULATIVE AVERAGE ANNUAL BURDEN, COVERED FARMS OF ALL SIZES

21 CFR part 112, subpart E: requirements that apply regarding records	Number of respondents	Number of records per respondent	Total annual records	Average burden per farm (in hours)	Total hours
Agricultural Water Assessment and Records Maintenance—Very small covered farms (§ 112.50(b)(2))	9,911	1.1	10,902	4	43,608
Agricultural Water Assessment and Records Maintenance—Small covered farms (proposed § 112.50(b)(2))	2,057	1.1	2,263	8	18,102
Agricultural Water Assessment and Records Maintenance—All other (Large) Covered Farms (proposed § 112.50(b)(2))	5,392	1.1	5,931	9	53,381
Cumulative totals for covered farms of all sizes	17,360	.....	19,096	7	11,5091
Cumulative average 7 burden hours per covered farm annually.					

Farms using pre-harvest agricultural water for non-sprout covered produce are required to prepare and maintain records of their agricultural water assessments unless exempt under § 112.43(b). We estimate that a total of 17,360 farms (9,911 very small farms, 2,057 small farms, and 5,392 other (large) farms) will be subject to information collection requirements under this rule, consistent with figures in our FRIA (Ref. 26) for this final rule and informed by a 2018 USDA survey of farms' irrigation practices (Ref. 89). The change in these numbers compared to estimates provided in the 2021 agricultural water proposed rule are a result of updates to farm counts between the PRIA for the 2021 agricultural water proposed rule (Ref. 88) and the FRIA for this final rule (Ref. 26). The PRIA relied on farm counts from the FRIA for the 2015 produce safety final rule (based on 2012 National Agricultural Statistics Service (NASS) Census of Agriculture data), whereas the FRIA relies on 2017 NASS Census of Agriculture data (the most recent available).

We assume affected farms will conduct approximately 1.1 assessments annually, in accordance with the requirement to conduct assessments annually and whenever a significant change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces (Ref. 26). We are assuming a range of burden: 4 hours of burden for very small farms, 8 hours of burden for small farms, and 9 hours for other (large) farms, based on estimates of the amount of time in hours to conduct recordkeeping for pre-harvest agricultural water assessments (Ref. 26). These numbers are consistent with that used in the 2021 agricultural water proposed rule as well as the PRIA (Ref. 88) and the FRIA for this final rule (Ref. 26).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*1. Bowers, J., ''Memorandum to the File—Minimum Sample Size for Rolling Calculation of Microbial Water Quality Profile of Surface Water Sources to be Used for Agricultural Water.'' September 24, 2015. FDA.

*2. FDA, ''FDA Considering Simplifying Agricultural Water Standards,'' 2017. Available at: *https://wayback.archive-it.org/org-1137/20180908124905/https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm*.

*3. Collaborative Food Safety Forum, ''Agricultural Water Standards and Testing Protocols: Summary,'' November 11, 2017.

4. Wall, G., D. Clements, C. Fisk, et al., ''Meeting Report: Key Outcomes from a Collaborative Summit on Agricultural Water Standards for Fresh Produce.'' *Comprehensive Reviews in Food Science and Food Safety* 18, no. 3 (2019): 723–737.

5. Draper, A.D., S. Doores, H. Gourama, et al., ''Microbial Survey of Pennsylvania Surface Water Used for Irrigating Produce Crops.'' *Journal of Food Protection* 79, no. 6 (2016): 902–912.

6. Pagadala, S., S.C. Marine, S.A. Micallef, et al., ''Assessment of region, farming system, irrigation source and sampling time as food safety risk factors for tomatoes.'' *International Journal of Food Microbiology* 196 (2015): 98–108.

7. Havelaar, A.H., K.M. Vazquez, Z. Topalcengiz, et al., ''Evaluating the U.S. Food Safety Modernization Act Produce Safety Rule Standard for Microbial Quality of Agricultural Water for Growing Produce.'' *Journal of Food Protection* 80, no. 11 (2017): 1832–1841.

8. Lothrop, N., K.R. Bright, J. Sexton, et al., ''Optimal strategies for monitoring irrigation water quality.'' *Agricultural Water Management* 199 (2018): 86–92.

9. Goh, S.G., N. Saeidi, X. Gu, et al., ''Occurrence of microbial indicators, pathogenic bacteria and viruses in tropical surface waters subject to contrasting land use.'' *Water Research* 150 (2019): 200–215.

10. Partyka, M.L., R.F. Bond, J.A. Chase, et al., ''Spatial and temporal variability of bacterial indicators and pathogens in six California reservoirs during extreme drought.'' *Water Research* 129 (2018): 436–446.

11. Partyka, M.L., R.F. Bond, J.A Chase, et al., ''Spatiotemporal Variability in Microbial Quality of Western US Agricultural Water Supplies: A Multistate Study.'' *Journal of Environmental Quality* 47, no. 5 (2018).

12. Harris, C.S., M. Tertuliano, S. Rajeev, et al., ''Impact of storm runoff on *Salmonella* and *Escherichia coli* prevalence in irrigation ponds of fresh produce farms in southern Georgia.'' *Journal of Applied Microbiology* 124, no. 3 (2018): 910–921.

*13. Topalcengiz, Z., L.K. Strawn, and M.D. Danyluk, ''Microbial quality of agricultural water in Central Florida.'' *PLOS One* 12, no. 4 (2017).

14. Antaki, E.M., G. Vellidis, C. Harris, et al., ''Low Concentration of *Salmonella enterica* and Generic *Escherichia coli* in Farm Ponds and Irrigation Distribution Systems Used for Mixed Produce Production in Southern Georgia.'' *Foodborne Pathogens and Disease* 13, no. 10 (2016): 551–558.

*15. Truitt, L.N., K.M. Vazquez, R.C. Pfuntner, et al., ''Microbial Quality of Agricultural Water Used in Produce Preharvest Production on the Eastern Shore of Virginia.'' *Journal of Food Protection* 80, no. 10 (2018): 1661–1672.

16. Lee, D., Tertuliano, M., G. Vellidis, et al., ''Evaluation of Grower-Friendly, Science-Based Sampling Approaches for the Detection of *Salmonella* in Ponds Used for Irrigation of Fresh Produce.'' *Foodborne Pathogens and Disease* 15, no. 10 (2018): 627–636.

*17. FDA, ''Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce,'' 2015. Available at: *https://www.fda.gov/media/116766/download*.

*18. FDA, ''Environmental Assessment of Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in a Multi-State Outbreak of *E. coli* O157:H7,'' November 1, 2018. Available at: *https://www.fda.gov/food/outbreaks-foodborne-illness/environmental-assessment-factors-potentially-contributing-contamination-romaine-lettuce-implicated*.

*19. Gerrity, K., ''Memorandum to the File on the Environmental Assessment; Yuma 2018 *E. coli* O157:H7 Outbreak Associated with Romaine Lettuce.'' October 24, 2018. FDA. Available at: *https://www.fda.gov/media/117512/download*.

*20. FDA, ''Investigation Summary: Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Fall 2018 Multi-State Outbreak of E. coli O157:H7,'' February 13, 2019. Available at: *https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-summary-factors-potentially-contributing-contamination-romaine-lettuce-implicated-fall*.

*21. FDA, ''Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Three Outbreaks of *E. coli* O157:H7 During the Fall of 2019,'' May 21, 2020. Available at: *https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-romaine-lettuce-implicated-three-outbreaks-e-coli*.

*22. FDA, ''Factors Potentially Contributing to the Contamination of Leafy Greens Implicated in the Fall 2020 Outbreak of *E. coli* O157:H7,'' April 6, 2021. Available at: *https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-leafy-greens-implicated-fall-2020-outbreak-e-coli*.

*23. FDA, ''Investigation Report: Factors Potentially Contributing to the Contamination of Red Onions Implicated in the Summer 2020 Outbreak of Salmonella Newport,'' May 13, 2021. Available at: *https://www.fda.gov/food/foodborne-pathogens/factors-potentially-contributing-contamination-red-onions-implicated-summer-2020-outbreak-salmonella*.

*24. FDA, ''FDA Launches Agricultural Water Assessment Builder to Help Farms Understand Agricultural Water Proposed Rule Requirements,'' March 21, 2022. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-agricultural-water-assessment-builder-help-farms-understand-agricultural-water-proposed*.

*25. FDA, ''FDA Releases Spanish and English Paper-Based Versions of the Agricultural Water Assessment Builder Tool,'' August 11, 2022. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-spanish-and-english-paper-based-versions-agricultural-water-assessment-builder-tool*.

*26. FDA, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2024. Available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

27. Carrillo, M., E. Estrada, and T.C. Hazen, ''Survival and Enumeration of the Fecal Indicators *Bifidobacterium adolescentis* and *E. coli* in a Tropical Rain Forest Watershed.'' *Applied and Environmental Microbiology* 50, no. 2 (1985): 468–476.

28. Gauthier, F., and F. Archibald, ''The Ecology of ''Fecal Indicator'' Bacteria Commonly Found in Pulp and Paper Mill Water Systems.'' *Water Research* 35, no. 9 (2001): 2207–2218.

29. McElhany, K.G. and S.. Pillai, ''Prevalence and Fate of Gut-Associated Human Pathogens in the Environment.'' *The Fecal Bacteria,* edited by M.J. Sadowsky and R.L. Whitman, pp 217–240. Washington, DC: American Society for Microbiology, 2011.

*30. Cooley, M., D. Carychao, L. Crawford-Miksza, et al., ''Incidence and Tracking of *Escherichia coli* O157:H7 in a Major Produce Production Region in California.'' *PLOS One* 2, no. 11 (2007).

31. National Research Council Committee on Indicators for Waterborne Pathogens. *Indicators for Waterborne Pathogens.* Washington, DC: The National Academies Press, 2004.

32. Howell, J.M., M.S. Coyne, and P.L. Cornelius, ''Fecal Bacteria in Agricultural Waters of the Bluegrass Region of Kentucky.'' *Journal of Environmental Quality* 24 (1995): 411–419.

*33. Interagency Food Safety Analytics Collaboration, ''Foodborne Illness Source Attribution Estimates for 2019 for *Salmonella, Escherichia coli* O157, *Listeria monocytogenes,* and *Campylobacter* Using Multi-Year Outbreak Surveillance Data,'' October 2021. Available at: *https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf?utm_medium=email&utm_source=govdelivery*.

*34. Interagency Food Safety Analytics Collaboration, ''Foodborne Illness Source Attribution Estimates for 2020 for *Salmonella, Escherichia coli* O157, and *Listeria monocytogenes* Using Multi-Year, Outbreak Surveillance Data,'' November 2022. Available at: *https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf*.

*35. Interagency Food Safety Analytics Collaboration, ''Foodborne Illness Source Attribution Estimates for *Salmonella, Escherichia coli* O157, and *Listeria monocytogenes*—United States, 2021,'' November 2023. Available at: *https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2021-report-TriAgency-508.pdf*.

36. Berger, C.N., S.V. Sodha, R.K. Shaw, et al., ''Fresh Fruit and Vegetables as Vehicles for the Transmission of Human Pathogens.'' *Environmental Microbiology* 12 (2010): 2385–2397.

*37. EPA, ''Summary of the Clean Water Act,'' 2023. Available at: *https://www.epa.gov/laws-regulations/summary-clean-water-act*.

*38. Monterey County Farm Bureau, ''California Agricultural Neighbors,'' 2022. Available at: *https://montereycfb.com/california-agricultural-neighbors/*.

*39. California Department of Food and Agriculture and Monterey County Farm Bureau, ''California Agricultural Neighbors: Neighbor-to-neighbor best practices to help enhance localized food safety efforts,'' June 2022. Available at: *https://montereycfb.com/wp-content/uploads/2022/10/CAN-Action-Report-063022.pdf*.

40. Alegbeleye, O.O., I. Singleton, and A.S. Sant'Ana, ''Sources and Contamination Routes of Microbial Pathogens to Fresh Produce During Field Cultivation: A Review.'' *Food Microbiology* 73 (2018): 177–208.

*41. Rothrock M.J., K.E. Gibson, A.C. Micciche et al., ''Pastured Poultry Production in the United States: Strategies to Balance System Sustainability and Environmental Impact.'' *Frontiers in Sustainable Food Systems* 3, no. 74 (2019): 1–10.

42. Bradshaw, J.K., B.J. Snyder, A. Oladeinde, et al., ''Characterizing Relationships Among Fecal Indicator Bacteria, Microbial Source Tracking Markers, and Associated Waterborne Pathogen Occurrence in Stream Water and Sediments in a Mixed Land Use Watershed.'' *Water Research* 101 (2016): 498–509.

43. Jay-Russell, M.T., ''What is the Risk From Wild Animals in Food-Borne Pathogen Contamination of Plants?'' *CAB Reviews* 8, no. 40 (2013).

*44. FDA, ''FDA and USDA announce key step to advance collaborative efforts to streamline produce safety requirements for farmers,'' June 5, 2018. Available at: *https://www.fda.gov/news-events/press-announcements/fda-and-usda-announce-key-step-advance-collaborative-efforts-streamline-produce-safety-requirements*.

*45. FDA, ''The FDA Concludes Voluntary Pilot Program to Evaluate Alignment of Third-Party Food Safety Standards with FSMA Rules,'' October 30, 2023. Available at: *https://www.fda.gov/food/new-era-smarter-food-safety/fda-concludes-voluntary-pilot-program-evaluate-alignment-third-party-food-safety-standards-fsma*.

*46. Chhetri, V.S., K. Fontenot, R. Strahan, et al., ''Effect of Surrounding Vegetation on Microbial Survival or Die-Off on Watermelon Surface in an Agriculture Setting.'' *Journal of Food Safety* 38, no. 6 (2018): 1–7.

*47. Chhetri, V.S., K. Fontenot, R. Strahan, et al., ''Attachment Strength and On-Farm Die-Off Rate of *Escherichia coli* on Watermelon Surfaces.'' *PLOS One* 14, no. 1 (2019): 1–14.

48. Weller, D.L., J. Kovac, S. Roof, et al., ''Survival of *Escherichia coli* on Lettuce under Field Conditions Encountered in the Northeastern United States.'' *Journal of Food Protection* 80, no. 7 (2017): 1214–1221.

*49. Belias, A.M., A. Sbodio, P. Truchado, et al., ''Effect of Weather on the Die-Off of *Escherichia coli* and Attenuated *Salmonella* enterica Serovar Typhimurium on Preharvest Leafy Greens following Irrigation with Contaminated Water.'' *Applied and Environmental Microbiology* 87, no. 17 (2020): 1–25.

*50. FDA, ''Final Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' October 2015. Available at: *https://www.fda.gov/food/food-safety-modernization-act-fsma/environmental-impact-statement-eis-fsma-final-rule-produce-safety*.

*51. FDA, ''Environmental Assessment for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,'' November 9, 2021.

*52. FDA, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water: Finding of No Significant Impact,'' November 9, 2021.

*53. FDA, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water: Supplement to the Finding of No Significant Impact,'' April 22, 2024.

*54. FDA, ''Environmental Studies,'' August 24, 2023. Available at: *https://www.fda.gov/food/science-research-food/environmental-studies*.

*55. FDA, ''FDA Partners with the University of Arizona, Wellton-Mohawk Irrigation and Drainage District, and Yuma Area Leafy Greens Stakeholders to Enhance Food Safety,'' September 23, 2019. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-partners-university-arizona-wellton-mohawk-irrigation-and-drainage-district-and-yuma-area-leafy*.

*56. FDA, ''FDA Partners with the California Department of Food and Agriculture, Western Center for Food Safety, and California Agricultural Stakeholders to Enhance Food Safety,'' November 19, 2020. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-partners-california-department-food-and-agriculture-western-center-food-safety-and-california*.

*57. California Food Emergency Response Team, ''Investigation of an *Escherichia coli* O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach,'' March 21, 2007. Available at: *https://www.marlerblog.com/files/2013/02/2006_Spinach_Report_Final_01.pdf*.

*58. Jay, M.T., M. Cooley, D. Carychao, et al., ''*Escherichia coli* O157:H7 in Feral Swine Near Spinach Fields and Cattle, Central California Coast.'' *Emerging Infectious Diseases* 13, no. 12 (2007): 1908–1911.

*59. FDA, ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' October 1998. Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables*.

*60. Snellman, E.A., M. Fatica, K. Ravaliya, et al., ''Memorandum to the File—Review of Microbial Decay Constants Reported in Field Trials of Contaminated Produce.'' September 16, 2014. FDA.

*61. Assar, S., et al., ''Memorandum to the File—Addendum to the September 16, 2014 Memo on the Review of Microbial Decay Constants Reported in Field Trials of Contaminated Produce.'' October 30, 2015. FDA.

*62. FDA, ''Investigation Report: Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of *Salmonella* Typhimurium During the Summer of 2021,'' 2022. Available at: *https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-packaged-leafy-greens-implicated-outbreak-salmonella*.

*63. FDA, ''Lettuce: FDA Investigation Summary—Multistate Outbreak of *E. coli* O157:H7 Illnesses Linked to Ready-to-Eat Salads,'' December 11, 2013. Available at: *http://wayback.archive-it.org/7993/20171114154923/https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm374327.htm*.

*64. Crawford, W., M. Baloch, and K. Gerrity, ''Environmental Assessment: Non-O157 Shiga Toxin-Producing *E. coli* (STEC): Findings and Potential Preventive Control Strategies,'' December 2010.

Available at: *http://wayback.archive-it.org/7993/20171114155100/https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235477.htm*.

65. World Health Organization and United Nations Environmental Programs. *WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater*. Geneva, Switzerland: WHO Press, 2006.
66. Stine SW, I. Song, C.Y. Choi, et al., ''Application of Microbial Risk Assessment to the Development of Standards for Enteric Pathogens in Water Used to Irrigate Fresh Produce.'' *Journal of Food Protection* 68, no. 5 (2005): 913–918.
67. Barak J.D. and B.K. Schroeder, ''Interrelationships of Food Safety and Plant Pathology: The Life Cycle of Human Pathogens on Plants.'' *Annual Reviews in Phytopathology* 50 (2012): 241–266.
68. Uyttendaele, M., L.-A. Jaykus, P. Amoah, *et al.*, ''Microbial Hazards in Irrigation Water: Standards, Norms, and Testing to Manage Use of Water in Fresh Produce Primary Production.'' *Comprehensive Reviews in Food Science and Food Safety* 14 (2015): 336–356.
69. Gerba, C.P., ''The Role of Water and Water Testing in Produce Safety.'' *Microbial Safety of Fresh Produce,* edited by Fan, X., B.A. Niemira C.J. Doona, F.E. Feeherry, and R.B. Gravani, pp. 129–142. Ames, IA: Wiley-Blackwell, 2009.
*70. Codex Alimentarius Commission, ''Code of Hygienic Practice for Fresh Fruits and Vegetables, CXC 53–2003,'' 2017. Available at: *http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B53-2003%252FCXC_053e.pdf*.
71. Muirhead, R.W., R.J. Davies-Colley, A.M. Donnison, *et al.*, ''Faecal Bacteria Yields in Artificial Flood Events: Quantifying In-Stream Stores.'' *Water Research* 38 (2004): 1215–1224.
72. Bach, S. and P. Delaquis, ''The Origin and Spread of Human Pathogens in Fruit Production Systems.'' *Microbial Safety of Fresh Produce,* edited by Fan, X., B.A. Niemira, C.J. Doona, F.E. Feeherry, and R.B. Gravani, pp. 43–53. Ames, IA: Wiley-Blackwell, 2009.
73. Tallon, P., B. Magajna, C. Lofranco, *et al.*, ''Microbial Indicators of Faecal Contamination in Water: A Current Perspective.'' *Water, Air, & Soil Pollution* 166, no. 1–4 (2005): 139–166.
*74. EPA, ''Recreational Water Quality Criteria,'' 2012. Available at: *https://www.epa.gov/sites/production/files/2015-10/documents/rwqc2012.pdf*.
*75. Ravaliya, K., M. Fatica, E. Snellman, *et al.*, ''Memorandum to the File—Review of Water Quality Standards in Development of Proposed Microbial Standard in § 112.44(c) of the Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' September 16, 2014. FDA.
*76. EPA, ''Report on the 2nd Five-Year Review of EPA's Recreational Water Quality Criteria,'' May 2023. Available at: *https://www.epa.gov/system/files/documents/2023-05/2023-5year-review-rwqc-report.pdf*.
*77. EPA, ''Fact Sheet: Report on the Second Five-Year Review of EPA's Recreational Water Quality Criteria,'' May 2023. Available at: *https://www.epa.gov/system/files/documents/2023-05/2023-5year-review-rwqc-factsheet.pdf*.
*78. FDA, ''Equivalent Testing Methodology for Agricultural Water,'' 2024. Available at: *https://www.fda.gov/food/laboratory-methods-food/equivalent-testing-methodology-agricultural-water*.
*79. Jung, Y., H. Jang, and K. Matthews, ''Effect of the Food Production Chain from Farm Practices to Vegetable Processing on Outbreak Incidence.'' *Microbial Biotechnology* 7, no. 6 (2014): 517–527.
*80. Murray, K., F. Wu, J. Shi, *et al.*, ''Challenges in the microbiological food safety of fresh produce: Limitations of post-harvest washing and the need for alternative interventions.'' *Food Quality and Safety* 1, no. 4 (2017):289–301.
81. Olaimat, A.N. and R.A. Holley, ''Factors Influencing the Microbial Safety of Fresh Produce: A Review.'' *Food Microbiology* 32 (2012): 1–19.
*82. Blackburn, T., ''Memorandum: Revised Protocol Review for Reg. No. 94151PA7; DP Barcode: 455973; Submission #: 1044629.'' April 29, 2020. EPA. Available at: *https://www.fda.gov/media/140640/download*.
*83. FDA, ''FDA Updates Protocol for the Development and Registration of Treatments for Preharvest Agricultural Water,'' January 6, 2023. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-updates-protocol-development-and-registration-treatments-preharvest-agricultural-water*.
*84. USDA National Organic Program, ''Guidance: The Use of Chlorine Materials in Organic Production and Handling,'' July 22, 2011. Available at: *https://www.ams.usda.gov/sites/default/files/media/5026.pdf*.
*85. FDA, ''Determining Regulatory Authority for Antimicrobial Substances,'' December 14, 2017. Available at: *https://www.fda.gov/food/packaging-food-contact-substances-fcs/determining-regulatory-authority-antimicrobial-substances*.
*86. FDA, ''FDA-State Produce Safety Implementation Cooperative Agreement Program,'' November 9, 2023. Available at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/fda-state-produce-safety-implementation-cooperative-agreement-program*.
*87. FDA, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water: Supplement to the Finding of No Significant Impact,'' July 1, 2022.
*88. FDA, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2021. Available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.
*89. Astill, G., T. Minor, L. Calvin, et al., ''Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers,'' 2018. Available at: *https://www.ers.usda.gov/publications/pub-details/?pubid=89720*.

List of Subjects in 21 CFR Part 112

Administrative practice and procedure, Agriculture, Animals, Food grades and standards, Foods, Fruits, Packaging and containers, Reporting and recordkeeping requirements, Safety, Vegetables, Waste treatment and disposal.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 112 is amended as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

■ 2. Amend § 112.3 by adding in alphabetical order the definitions for ''Agricultural water assessment'' and ''Agricultural water system'' to read as follows:

§ 112.3 What definitions apply to this part?

* * * * *

Agricultural water assessment means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to:

(1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and

(2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

Agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water

distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities.

* * * * *

■ 3. In § 112.12, revise paragraph (a) to read as follows:

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.45(b), provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

* * * * *

■ 4. Revise subpart E to read as follows:

Subpart E—Agricultural Water

Sec.

Subpart E—Agricultural Water

§ 112.40 What requirements of this subpart apply to my covered farm?

This subpart applies to agricultural water used for, or intended for use in, growing, harvesting, packing, or holding covered produce. If you are using agricultural water for a covered activity listed in the first column, then you must meet the requirements in the second column. You also must meet the requirements in the third column, if applicable.

TABLE 1 TO § 112.40

If you use agricultural water for this covered activity	Then you must meet these requirements		If applicable, you also must meet these requirements	
(a) Growing covered produce (other than sprouts)	§ 112.41	(quality standard)	§ 112.45	(measures).
	§ 112.42	(inspections and maintenance).	§ 112.46	(treatment).
	§ 112.43	(agricultural water assessment).	§ 112.47	(who may test).
	§ 112.50	(records)	§ 112.151	(test methods).
(b) Sprout irrigation water	§ 112.41	(quality standard)	§ 112.44(b)	(testing untreated ground water).
	§ 112.42	(inspections and maintenance).	§ 112.45	(measures).
	§ 112.44(a)	(microbial quality criterion).	§ 112.46	(treatment).
	§ 112.50	(records)	§ 112.47	(who may test).
			§ 112.151	(test methods).
(c) Harvesting, packing, or holding covered produce	§ 112.41	(quality standard)	§ 112.44(b)	(testing untreated ground water).
	§ 112.42	(inspections and maintenance).	§ 112.45	(measures).
	§ 112.44(a)	(microbial quality criterion).	§ 112.46	(treatment).
	§ 112.44(d)	(additional management and monitoring).	§ 112.47	(who may test).
	§ 112.50	(records)	§ 112.151	(test methods)

§ 112.41 What requirements apply to the quality of my agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to inspecting and maintaining my agricultural water systems?

(a) *Inspection of your agricultural water systems.* At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, including consideration of the following:

(1) The nature of each agricultural water source (for example, whether it is ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent and nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) *Maintenance of your agricultural water systems.* You must adequately maintain all agricultural water systems, to the extent they are under your control, as necessary and appropriate to prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. Such maintenance includes:

(1) Regularly monitoring each system to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces;

(2) Correcting any significant deficiencies (such as control of cross-connections and repairs to well caps, well casings, sanitary seals, piping tanks, and treatment equipment);

(3) Properly storing equipment and keeping the source and distribution system free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances; and

(4) As necessary and appropriate, implementing measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards resulting from contact of covered produce with pooled water (for example, through use of protective barriers or through equipment adjustments).

§ 112.43 What requirements apply to assessing agricultural water used in growing covered produce (other than sprouts)?

(a) *Elements of an agricultural water assessment.* Based in part on the results of any inspections and maintenance you conducted under § 112.42, at the beginning of the growing season, as appropriate, but at least once annually, you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities. The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, based on an evaluation of the following factors:

(1) Each agricultural water system you use for growing activities for the covered produce, including:

(i) The location and nature of the water source (for example, whether it is ground water or surface water);

(ii) The type of water distribution system (for example, open or closed conveyance); and

(iii) The degree of protection from possible sources of contamination, including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste;

(2) Agricultural water practices associated with each agricultural water system, including the type of direct application method (such as foliar spray or drip irrigation of covered produce growing underground) and the time interval between the last direct application of agricultural water and harvest of the covered produce;

(3) Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;

(4) Environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments) or covered produce (such as damage to edible leaves) during growing activities, air temperatures, and sun exposure; and

(5) Other relevant factors, including, if applicable, the results of any testing conducted pursuant to paragraph (d) of this section.

(b) *Exemptions.* You do not need to prepare a written agricultural water assessment for water that you directly apply during growing activities for covered produce (other than sprouts), if your water meets the criteria in paragraphs (b)(1) and (2) of this section.

(1) You can demonstrate that the water:

(i) Meets the requirements in § 112.44(a), including the microbial quality criterion and the prohibition on the use of untreated surface water, and if untreated ground water, also meets the testing requirements in §§ 112.44(b), 112.47, and 112.151;

(ii) Meets the requirements in § 112.44(c) for water from a public water system or public water supply; or

(iii) Is treated in accordance with § 112.46.

(2) It is reasonably likely that the quality of water in paragraph (b)(1)(i), (ii), or (iii) of this section will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed).

(c) *Outcomes.* Based on your evaluation under paragraph (a) of this section, you must determine whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts). You must record your determination in the assessment, and you must take necessary and appropriate action, as follows:

(1) If your agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), as required under § 112.41, you must immediately discontinue use of the water and take corrective measures under § 112.45(a) before resuming such use(s);

(2) If you have identified one or more conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, you must implement any mitigation measures under § 112.45(b) promptly, and no later than the same growing season as the agricultural water assessment;

(3) If you have not identified any conditions that are reasonably likely to introduce a known or reasonably foreseeable hazard for which measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces, you must:

(i) Regularly inspect and adequately maintain your agricultural water system(s) under § 112.42; and

(ii) Reassess your agricultural water annually and whenever a significant change occurs (such as a change in the manner or timing of water application) that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces; and

(4) If your agricultural water does not meet the criteria in paragraphs (c)(1), (2), or (3) of this section, you must either:

(i) Implement mitigation measures under § 112.45(b) as soon as practicable and no later than 1 year after the date of the agricultural water assessment (as required by this section); or

(ii) Test the water pursuant to paragraph (d) of this section, consider the results as part of your assessment, and take appropriate action under paragraphs (c)(1), (2), or (3), or (c)(4)(i) of this section.

(d) *Testing as part of an assessment.* In conducting testing to be used as part of your assessment under paragraph (a)(5) of this section, you must use scientifically valid collection and testing methods and procedures, including:

(1) Any sampling conducted for purposes of paragraph (c)(4)(ii) of this section must be collected aseptically immediately prior to or during the growing season and must be representative of the water you use in growing covered produce (other than sprouts).

(2) The sample(s) must be tested for generic *Escherichia coli* (*E. coli*) as an indicator of fecal contamination (or for another scientifically valid indicator organism, index organism, or other analyte).

(3) The frequency of testing samples and any microbial criterion (or criteria) applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph (a) of this section, whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts).

(e) *Reassessment.* You must conduct an agricultural water assessment and take appropriate action under paragraph (c) of this section:

(1) At least once annually when you apply agricultural water to covered produce (other than sprouts) during growing activities; and

(2) Whenever a significant change occurs in your agricultural water system(s) (including changes relating to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste associated with adjacent or nearby land uses), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces through direct application of agricultural water during growing activities. Your reassessment must evaluate any factors and conditions that are affected by such change.

§ 112.44 What requirements apply to agricultural water used as sprout irrigation water and in harvesting, packing, and holding covered produce?

(a) *Microbial quality criterion.* When you use agricultural water for any one or more of the following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

(1) Used as sprout irrigation water;

(2) Used during or after harvest activities in a manner that directly contacts covered produce (for example, water that is applied to covered produce for washing or cooling activities, water that is applied to harvested crops to prevent dehydration before cooling, and water that is used to make ice that directly contacts covered produce during or after harvest activities);

(3) Used to contact food contact surfaces or to make ice that will contact food contact surfaces; and

(4) Used for washing hands during and after harvest activities.

(b) *Untreated ground water.* You must test any untreated ground water used as sprout irrigation water or for harvesting, packing, or holding covered produce to determine if it meets the microbial quality criterion in paragraph (a) of this section, as follows:

(1) You must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected aseptically and representative of the intended use(s). Based on these results, you must determine whether the water can be used for the intended purpose(s), in accordance with § 112.45(a).

(2) If your four initial sample results meet the microbial quality criterion, you may test once annually thereafter, using a minimum of one sample collected aseptically and representative of the intended use(s).

(3) If any annual test fails to meet the microbial quality criterion, you must:

(i) Immediately discontinue the use(s) and meet the requirements of § 112.45(a) before resuming such use(s); and

(ii) Resume testing at least four times per growing season or year, as required under paragraph (b)(1) of this section, until all of the survey results collected in a year meet the microbial quality criterion.

(4) You may meet these testing requirements using test results or data collected by a third party, as provided in § 112.47.

(c) *Exemptions.* There is no requirement to test agricultural water that is used as sprout irrigation water or for harvesting, packing, or holding covered produce when:

(1) You receive the water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets those microbial requirements;

(2) You receive the water from a public water supply that furnishes water that meets the microbial quality criterion in paragraph (a) of this section, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.46.

(d) *Additional management and monitoring practices.* (1) You must manage water used in harvesting, packing, and holding covered produce as necessary, including by establishing and following water change schedules for non-single-pass water (including recirculated water or reused water) to maintain its safe and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(2) You must visually monitor the quality of water that you use during harvesting, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks; and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(3) You must maintain and monitor the temperature of water that you use during harvesting, packing, and holding activities for covered produce at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and that is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.45 What measures must I take for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

(a) *Discontinue use(s).* If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use(s) in growing, harvesting, packing, or holding covered produce as required under § 112.41, and/or if your agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in § 112.44(a) (including the microbial quality criterion), you must immediately discontinue such use(s). Before you may use the water source and/or distribution system again for the intended use(s), you must either:

(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably

foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective, and as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or

(2) Treat the water in accordance with the requirements of § 112.46.

(b) *Implement mitigation measures.* (1) You must implement any mitigation measures that are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water. Such measures must be implemented as soon as practicable and no later than 1 year after the date of your agricultural water assessment or reassessment (as required by § 112.43), except that mitigation measures for known or reasonably foreseeable hazards related to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented promptly, and no later than the same growing season as such assessment or reassessment. Mitigation measures include:

(i) Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces;

(ii) Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided you have scientifically valid supporting data and information;

(iii) Increasing the time interval between harvest and the end of storage to allow for microbial die-off, and/or conducting other activities during or after harvest to allow for microbial die-off or removal, provided you have scientifically valid supporting data and information;

(iv) Changing the method of water application to reduce the likelihood of contamination of the covered produce (such as by changing from overhead spray to subsurface drip irrigation of certain crops);

(v) Treating the water in accordance with § 112.46; and

(vi) Taking an alternative mitigation measure, provided that you satisfy the requirements of § 112.12.

(2) If you fail to implement appropriate mitigation measures in accordance with paragraph (b)(1) of this section, or if you determine that your mitigation measures were not effective to reduce the potential for contamination of the covered produce or food contact surfaces with known or reasonably foreseeable hazards, you must discontinue use of the agricultural water until you have implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41.

§ 112.46 What requirements apply to treating agricultural water?

(a) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use(s) and/or meet the microbial quality criterion in § 112.44(a), as applicable;

(b) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a); and

(c) You must monitor any treatment of agricultural water using an adequate method and frequency to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a).

(d) Treatment may be conducted by you or by a person or entity acting on your behalf.

§ 112.47 Who must perform the tests required under this subpart?

(a) You may meet the requirements related to agricultural water testing required under §§ 112.43(c)(4)(ii) and 112.44 using:

(1) Results from agricultural water testing performed by you or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water sampled by the third party or parties adequately represents your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using methods as set forth in § 112.151, as applicable.

§§ 112.48–112.49 [Reserved]

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records, as applicable:

(1) The findings of inspections of your agricultural water systems in accordance with the requirements of § 112.42(a);

(2) Your written agricultural water assessments, including descriptions of factors evaluated and written determinations, in accordance with § 112.43;

(3) Scientific data or information that you rely on to support the use of an index organism, indicator organism, or other analyte, other than testing for generic *E.coli* for purposes of § 112.43(c)(4)(ii);

(4) Scientific data or information that you rely on to support the frequency of testing and any microbial criterion (or criteria) you applied for purposes of § 112.43(c)(4)(ii), if applicable;

(5) Documentation of the results of all analytical tests for purposes of compliance with this subpart, including any testing conducted under §§ 112.43 and 112.44;

(6) Annual documentation of the results or certificates of compliance from a public water system required under § 112.44(c)(1) or (2), if applicable;

(7) Documentation of actions you take in accordance with § 112.45;

(8) Scientific data or information you rely on to support the time interval between last direct application of agricultural water and harvest in § 112.45(b)(1)(ii), and/or the time interval between harvest and end of storage and/or use of other activities during or after harvest in § 112.45(b)(1)(iii);

(9) Scientific data or information you rely on to support an alternative mitigation measure that you establish and use in accordance with § 112.45(b)(1)(vi).

(10) Scientific data or information you rely on to support the adequacy of a treatment method used to satisfy the requirements of § 112.46(a) and (b);

(11) Documentation of the results of water treatment monitoring under § 112.46(c); and

(12) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

■ 5. In § 112.151, revise the section heading and paragraph (b)(2) to read as follows:

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of subpart E of this part?

* * * * *

(b) * * *

(2) For any other indicator of fecal contamination, index organism, or other analyte you may test for pursuant to § 112.43(d), a scientifically valid method.

■ 6. In § 112.161, revise paragraph (b) to read as follows:

§ 112.161 What general requirements apply to records required under this part?

* * * * *

(b) Records required under §§ 112.7(b); 112.30(b); 112.50(b)(2), (5), (7), and (11); 112.60(b)(2); 112.140(b)(1) and (2); and 112.150(b)(1), (4), and (6) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

Dated: April 24, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–09153 Filed 5–2–24; 11:15 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 89 Monday,
No. 88 May 6, 2024

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 457, et al.

45 CFR Parts 80, 84, 92, et al.

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 457, and 460

Office of the Secretary

45 CFR Parts 80, 84, 92, 147, 155, and 156

RIN 0945–AA17

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights, Office of the Secretary, Department of Health and Human Services; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule and interpretation.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing this final rule regarding section 1557 of the Affordable Care Act (ACA) (section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of section 1557. The Department is also revising its interpretation regarding whether Medicare Part B constitutes Federal financial assistance for purposes of civil rights enforcement. Additionally, the Department is revising provisions prohibiting discrimination on the basis of sex in regulations issued by the Centers for Medicare & Medicaid Services (CMS) governing Medicaid and the Children's Health Insurance Program (CHIP); Programs of All-Inclusive Care for the Elderly (PACE); health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers providing essential health benefits (EHB); and qualified health plan issuers.

DATES: *Effective date:* July 5, 2024.

Applicability dates: Unless otherwise specified, the provisions of this final rule apply on or after July 5, 2024. See the **SUPPLEMENTARY INFORMATION** section for additional information.

FOR FURTHER INFORMATION CONTACT:

Office for Civil Rights

Daniel Shieh, Associate Deputy Director, HHS Office for Civil Rights (202) 240–3110 or (800) 537–7697 (TDD), or via email at *1557@hhs.gov*, for matters related to section 1557.

Centers for Medicare & Medicaid Services

John Giles, (410) 786–5545, for matters related to Medicaid.

Meg Barry, 410–786–1536, for matters related to CHIP.

Timothy Roe, (410) 786–2006 for matters related to Programs of All-Inclusive Care for the Elderly.

Becca Bucchieri, (301) 492–4341 or Leigha Basini, (301) 492–4380, for matters related to 45 CFR 155.120, 155.220, 156.125, 156.200, and 156.1230.

Lisa Cuozzo, (410) 786–1746, for matters related to 45 CFR 147.104.

Hannah Katch, (202) 578–9581, for general questions related to CMS amendments.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: Upon request, the Department will provide an accommodation or appropriate auxiliary aid or service to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the final rule. To schedule an appointment for this type of accommodation or auxiliary aid, please call (202) 240–3110 or (800) 537–7697 (TDD) for assistance or email *1557@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Section 1557 of the Affordable Care Act (ACA) (section 1557), 42 U.S.C. 18116, prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, except where otherwise provided in title I of the ACA. Section 1557 also prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any program or activity that is administered by an executive agency, or any entity established under title I of the ACA or its amendments. The statute cites title VI of the Civil Rights Act of 1964 (title VI), 42 U.S.C. 2000d *et seq.,* title IX of the Education Amendments of 1972 (title IX), 20 U.S.C. 1681 *et seq.,* the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.,* and section 504 of the Rehabilitation Act of 1973 (section 504), 29 U.S.C. 794, to identify the grounds of discrimination prohibited by section 1557. The entities to which section 1557 and this final rule apply (*i.e.,* recipients of Federal financial assistance, the Department, and title I entities) are collectively referred to as ''covered entities.'' The statute further specifies that the enforcement mechanisms provided for and available under title VI, title IX, the Age Act, or section 504 shall apply for purposes of violations of section 1557, 42 U.S.C. 18116(a). The statute authorizes the Secretary of the U.S. Department of Health and Human Services (HHS or the Department) to promulgate implementing regulations for section 1557, 42 U.S.C. 18116(c).

A. Regulatory History

On August 1, 2013, the HHS Office for Civil Rights (OCR) published a Request for Information in the **Federal Register**, 78 FR 46558,[1] followed by issuance of a notice of proposed rulemaking (NPRM) on September 8, 2015 (2015 NPRM), 80 FR 54171.[2] OCR finalized the first section 1557 regulation on May 18, 2016 (2016 Rule), 81 FR 31375. On June 14, 2019, the Department published a new section 1557 NPRM (2019 NPRM), 84 FR 27846, proposing to rescind and replace large portions of the 2016 Rule.[3] On June 12, 2020, OCR publicly posted its second section 1557 final rule (2020 Rule), which was published in the **Federal Register** on June 19, 2020, 85 FR 37160. The 2020 Rule remains in effect, save for the parts enjoined or set aside by courts, until the effective date of this final rule. In the meantime, entities that are subject to the 2020 Rule must continue to comply with the parts of the 2020 Rule that remain in effect.

On January 5, 2022, the Department proposed to amend CMS regulations such that Exchanges, issuers, and agents and brokers would be prohibited from discriminating against consumers based on their sexual orientation or gender identity in the HHS Notice of Benefit and Payment Parameters for 2023 NPRM, 87 FR 584 (January 5, 2022). CMS did not finalize the amendments in the Notice of Benefit and Payment Parameters for the 2023 final rule, 87 FR 27208 (May 6, 2022); instead, CMS proposed to make the amendments to its regulations in forthcoming Departmental rulemaking.

On July 25, 2022, OCR publicly posted the section 1557 NPRM associated with this rulemaking (2022 NPRM or Proposed Rule), which was published in the **Federal Register** on August 4, 2022, 87 FR 47824. OCR invited comment on the Proposed Rule by all interested parties. The comment period ended on October 3, 2022. In total we received 85,280 comments on the Proposed Rule.[4] Comments came from a wide variety of stakeholders, including but not limited to: civil rights/advocacy groups, including language access organizations, disability rights organizations, women's advocacy organizations, and organizations serving lesbian, gay, bisexual, transgender, queer, or intersex (LGBTQI+) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal entities. Of the total comments, 79,126 were identified as being submitted by individuals. Of the 85,280 comments received, 70,337 (80 percent) were form letter copies associated with 30 distinct form letter campaigns.

B. Overview of the Final Rule

Section 1557

This preamble is divided into multiple sections: section II describes changes to the section 1557 regulation and contains four subparts: subpart A sets forth the rule's general provisions; subpart B contains the rule's nondiscrimination provisions; subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and subpart D describes the procedures that apply to enforcement of the rule. Section III provides official notice of HHS's change in interpretation that Medicare Part B meets the definition of ''Federal financial assistance.'' Section IV describes changes to CMS regulations.

OCR has made some changes to the Proposed Rule's provisions, based on the comments we received. Among the changes are the following:

OCR modified proposed § 92.4 (Definitions) to include new definitions for telehealth, State, relay interpretation, and patient care decision support tools.

OCR modified proposed § 92.201 (Meaningful access for individuals with limited English proficiency) to change ''limited English proficient individual'' to ''individual with limited English proficiency'' where applicable in this provision and elsewhere where the term is used. The text for proposed § 92.201(a) was updated to include ''companions with limited English proficiency'' for clarity and parity with the rule's effective communication

[1] Responses are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2013-0007/comments.*

[2] The 2015 NPRM received roughly 2,160 comments, which are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2015-0006/comments.*

[3] The 2019 NPRM received roughly 198,845 comments, which are available for public inspection at *https://www.regulations.gov/document/HHS-OCR-2019-0007-0001.* This count includes bundled submissions, including petitions and form letter campaigns, which were counted as individual comment submissions.

[4] This count includes bundled submissions, including petitions. The number of submission entries in the Federal Docket Management System is 75,254 submissions. Responses are available for public inspection at *https://www.regulations.gov/docket/HHS-OS-2022-0012.*

provision. OCR also modified proposed § 92.201(f) and proposed § 92.201(g) to address concerns that audio and video remote interpreting may not be appropriate to provide meaningful access in certain circumstances.

OCR modified proposed § 92.206 (Equal program access on the basis of sex) to clarify a covered entity's ability to raise legitimate and nondiscriminatory reasons for the denial of care under this provision, while stating that the basis for a denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination.

OCR modified the text of proposed § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage), consistent with changes to § 92.206(c) to clarify that covered entities may raise a legitimate, nondiscriminatory reason for denials or limitations of health services in benefit design and in individual cases, while stating that the basis for a denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination.

OCR revised proposed § 92.210 (Nondiscrimination in the use of clinical algorithms in decision-making) to change ''clinical algorithms'' and ''clinical algorithms in decision-making'' to ''patient care decision support tools.'' OCR further specified the scope of the application of this provision and the requirement that covered entities take reasonable steps to mitigate discrimination once made aware of the potential for discrimination resulting from use of these tools.

OCR modified proposed § 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws) to clarify the application of religious freedom and conscience laws, and aspects of the administrative process set forth in the provision, including that a recipient may request an assurance of an exemption under such laws, the availability of a temporary exemption, and the availability of an administrative appeal process.

CMS Amendments

In response to comments, CMS is finalizing the proposed amendments to the CMS regulations with a revision to scope of sex discrimination to be consistent with section 1557's regulatory text at § 92.101(a)(2).

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In the 2022 NPRM, proposed § 92.1(a) explained that the purpose of 45 CFR part 92 is to implement section 1557, which prohibits discrimination in certain health programs and activities on the ''ground[s] prohibited'' under title VI, title IX, the Age Act, or section 504. Section 1557 adopts the grounds of these statutes and prohibits discrimination based on race, color, national origin, sex, age, or disability.[5]

Proposed § 92.1(b) provided that the effective date of the section 1557 implementing regulation shall be 60 days after the publication of a final rule in the **Federal Register** and provided a delayed implementation date (referred to as ''applicability date'' in this final rule) for provisions of this part that require changes to health insurance or group health plan benefit design.

The comments and our responses regarding the purpose and effective date are set forth below.

Comment: Several commenters noted that the regulatory purpose described in the 2022 NPRM strengthens nondiscrimination protections in health care, and appropriately aligns with section 1557's statutory text and Congressional intent.

Response: As commenters noted, the 2022 NPRM's purpose is to prohibit discrimination in accordance with section 1557's statutory text. The Proposed Rule mirrors the statutory text and clarifies that the purpose of this rule is to regulate health programs and activities conducted and funded by the Department and those of title I entities. Thus, we maintain the regulatory language for § 92.1(a) as proposed in the 2022 NPRM.

Comment: One commenter observed that, in addition to title IX's general prohibition of discrimination on the ground of ''sex,'' section 904 of title IX (20 U.S.C. 1684) also prohibits discrimination on the ground of blindness or severe vision impairment.

Response: Both HHS's and the Department of Education's title IX regulations define title IX to exclude section 906. *See* 45 CFR 86.2(a); 34 CFR 106.2(a). While 20 U.S.C. 1684 prohibits certain forms of discrimination on the ground of blindness or severe vision impairment, such conditions are disabilities and section 1557 prohibits discrimination on the basis of disability as it is the ''ground'' of discrimination prohibited by the statute's reference to section 504. Accordingly, we decline to revise the regulatory text at § 92.1(a).

Comment: OCR received many comments about the proposed 60-day effective date for requirements other than those related to health insurance or group health plan coverage benefit design. Commenters identified several tasks covered entities would need to accomplish to comply with the final rule requirements within the proposed 60 days, including updating existing policies and procedures; developing and reviewing new content; developing written communications with members and distributing written documents, including preparing additional mailings; and familiarizing themselves with new requirements and OCR-provided tools and resources.

Most of these commenters expressed concern that covered entities would not be able to develop and implement the required policies and procedures (§ 92.8) and notices (§ 92.10, § 92.11), or complete the proposed training requirement (§ 92.9) within the allotted 60 days. A variety of commenters argued that the 60-day effective date for §§ 92.7 through 92.11 would be unreasonable for all covered entities, requesting that OCR consider allowing covered entities more time to come into compliance with the final rule.

Commenters' recommended compliance timeframes varied widely, from 180 days to three years following publication of the final rule in the **Federal Register**. One commenter asked that, for the first 18 to 24 months following publication of the final rule in the **Federal Register**, OCR's section 1557 enforcement efforts, including complaint investigations, primarily focus on providing covered entities technical assistance with respect to their section 1557 obligations.

Response: OCR appreciates comments regarding the effective date and commenters' identification of factors influencing feasibility of a single effective date for all section 1557 requirements. We are maintaining the overall 60-day effective date related to the general prohibition on discrimination on the basis of race, color, national origin, sex, age, and disability. This is consistent with the approach taken with respect to the effective date of our previous

[5] *See Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 953 (9th Cir. 2020) (''Section 1557(a) incorporates only the prohibited 'ground[s]' and '[t]he enforcement mechanisms provided for and available under' the four civil rights statutes. A prohibited 'ground' for discrimination . . . is simply the protected classification at issue.'').

rulemakings.[6] However, in light of the comments received, OCR has determined that it is reasonable to allow additional time for covered entities to comply with certain procedural requirements. The additional time will provide covered entities with the opportunity to properly designate a Section 1557 Coordinator and designee(s) (as applicable); develop and tailor to their respective organization's policies and procedures; train relevant staff; and develop their required notices. For this reason, we are adopting phased-in applicability dates for certain provisions, as reflected in the chart at the end of this section.

Comment: Some commenters requested that OCR allow for temporary safe harbors for covered entities' compliance with certain aspects of the final rule. Specifically, commenters suggested that the final rule allow for an 18-month good faith safe harbor for covered entities currently operating in accordance with the 2016 Rule language access requirements, particularly the notice and tagline requirements at former 45 CFR 92.8.

Response: OCR declines to grant safe harbors for covered entities that are or have been operating in accordance with the 2016 Rule's notice and tagline requirements. Granting such a safe harbor would fail to recognize the importance of this final rule's requirement. The Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (''Notice of Availability'') at § 92.11 requires notice of auxiliary aids and services in addition to language assistance services, which we have now revised to reflect a delayed applicability date of one year from the effective date. This revised applicability date reasonably allows enough time for covered entities to come into compliance with the Notice of Availability provision.

Comment: Comments from organizational health insurance issuers generally supported the Proposed Rule's delayed applicability date for provisions that require changes to health insurance or group health plan coverage benefits or benefit design, which proposed a delayed applicability date of the first day of the first plan year beginning on or after the year following the effective date of the final rule's publication in the **Federal Register**.[7] One commenter generally requested that OCR provide flexibility for plans depending on when the rule is finalized. Another commenter specifically requested that OCR consider allowing a temporary safe harbor compliance exception for group health plans and health insurance issuers of group health insurance coverage so that plan design changes for non-calendar-year plans may be implemented the first day of the new plan year occurring on or after January 1, 2024.

Response: OCR is cognizant that health insurance issuers and group health plans develop their health insurance coverage and other health-related coverage benefit designs in advance of the plan year that the coverage is offered. Accordingly, we are including a delayed applicability date to the extent that the final rule's provisions require changes to health insurance coverage or other health-related coverage, including group health plan coverage benefit design for health insurance coverage or other health-related coverage that is newly subject to certain provisions of § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage). In such circumstances, the final rule's applicability date is the first day of the first plan year beginning on or after January 1, 2025. This delayed applicability date applies equally to health insurance issuers and group health plans that are offering calendar-year and non-calendar-year plans. For example, a newly covered group health plan eligible for the delayed applicability date that offers a non-calendar year plan effective July 1, 2024, would have until the following plan year, effective July 1, 2025, to comply with the benefit design requirements, as July 1, 2025, would be the first day of the first plan year beginning on or after January 1, 2025.

The 2020 Rule remains in effect until the effective date of this final rule. In the interim, covered entities that are subject to the 2020 Rule must continue to comply with the parts of the 2020 Rule that remain in effect. Notwithstanding the repeal of the former § 92.207 (2016 Rule), the 2020 Rule prohibits discrimination in health insurance coverage that receives Federal financial assistance. Consistent with the 2020 Rule preamble, OCR interprets and enforces section 1557 under the 2020 Rule to prohibit discrimination in benefit design in health insurance coverage and other health-related coverage that receive Federal financial assistance.[8]

As such coverage is currently prohibited from having discriminatory benefit designs, the obligation to comply with this final rule's § 92.207(b)(1) through (5) does not require a delayed applicability date. Therefore, we have revised the delayed applicability date for § 92.207(b)(1) through (5) under § 92.1(b) to reflect that the delayed applicability date is for health insurance coverage and other health-related coverage that are not already subject to this part as of the date of publication of this final rule. Because § 92.207(b)(6) (most integrated setting) describes a category of prohibited benefit design features that OCR is not explicitly enforcing under the 2020 Rule, OCR will not enforce this provision until the delayed applicability of the first day of the first plan year beginning on or after January 1, 2025. The delayed applicability date for all provisions of § 92.207 is in effect for covered health insurance coverage and other health-related coverage that are not subject to the 2020 Rule as of the date of publication of this final rule and are therefore newly subject to this final rule.

Examples of health insurance coverage or other health-related coverage subject to the 2020 Rule (and thus the benefit design provisions under § 92.207(b)(1) through (5) as of July 5, 2024) include but are not limited to Medicare Advantage plans, Medicare Part D plans, Medicaid managed care plans, and qualified health plans.[9] For complaints received prior to January 1, 2025 alleging discrimination related to benefit design, OCR will examine whether the health insurance coverage or other health-related coverage is subject to the 2020 Rule. If OCR determines the coverage was subject to

[6] The 2016 Rule's effective date was 60 days after publication of the final rule, with the exception of the provisions on health insurance and benefit design, which went into effect the first day of the first plan year following the effective date. 81 FR 31375. The 2020 Rule's effective date was 60 days after publication, with no exceptions. 85 FR 37160.

[7] The term ''group health plan'' is generally used to refer to a health benefit arrangement that is a distinct legal entity and can also be used to refer to the underlying health coverage or benefits. For ease of reference, this document uses the term ''group health plan'' when referring the plan as a distinct legal entity and uses the term ''group health plan coverage'' to refer to the underlying health coverage or benefits provided by the group health plan.

[8] *See* 85 FR 37160 (stating the rule prohibits age discrimination, ''including [in] health plan marketing and benefit design''); *id.* at 37177 (stating that HHS ''will enforce vigorously Section 1557's prohibition on discrimination on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design''); *id.* at 37201 (''OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design.'').

[9] Qualified health plans are covered by the 2020 Rule as a program or activity administered by an entity established under title I of the ACA (*i.e.,* an Exchange), pursuant to § 92.3(a)(3). *See* 85 FR 37174. Qualified health plans are also subject to the 2020 Rule to the extent they receive Federal financial assistance. *Id.*

the 2020 Rule, the covered entity providing the coverage is responsible for complying with the specific benefit design provisions of § 92.207(b)(1) through (5) on July 5, 2024. In its review of such complaints, OCR will consider the nature of the challenged benefit design feature and whether it would have been prohibited under the 2020 Rule. For example, a Medicare Advantage plan that imposes additional cost-sharing for health services related to a particular disease but not for other diseases would be investigated as potentially discriminatory under the 2020 Rule and under this final rule as of its general 60-day effective date. However, if a Medicare Advantage plan contains a potentially discriminatory design feature related to integration, OCR would not investigate such an allegation under this final rule unless the alleged discrimination took place after the delayed applicability date of the first day of the first plan year beginning on or after January 1, 2025.

Further, OCR clarifies that any covered entity offering health insurance coverage or other health-related coverage subject to the delayed applicability date for benefit design is still required to comply with all other provisions of this final rule, as of the general effective dates and specific applicability dates set forth under § 92.1(b).

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions in § 92.1(a) as written and amending § 92.1(b), with modifications.

In § 92.1(b), we have included a table that clearly provides the applicability date for each provision. It appears below:

Section 1557 Requirement and provision	Date by which covered entities must comply
§ 92.7 Section 1557 Coordinator	Within 120 days of effective date.
§ 92.8 Policies and Procedures	Within one year of effective date.
§ 92.9 Training	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than one year of effective date.
§ 92.10 Notice of nondiscrimination	Within 120 days of effective date.
§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.	Within one year of effective date.
§ 92.207(b)(1) through (5) Nondiscrimination in health insurance coverage and other health-related coverage.	For health insurance coverage or other health-related coverage that was not subject to this part as of the date of publication of this rule, by the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.207(b)(6) Nondiscrimination in health insurance coverage and other health-related coverage.	By the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.210(b), (c) Use of patient care decision support tools.	Within 300 days of effective date.

Application (§ 92.2)

Proposed § 92.2 addressed the application of this regulation. OCR proposed in § 92.2(a) to apply the final rule, except as otherwise provided in the regulation, to: (1) every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department; (2) every health program or activity administered by the Department; and (3) every program or activity administered by a title I entity. Title I entities include State Exchanges (including those on the Federal platform) and Federally-facilitated Exchanges, both of which were created under title I of the ACA.[10]

In § 92.2(b), we proposed that this regulation would not apply to an employer with regard to its employment practices, including the provision of employee health benefits. We noted that, although the 2016 and 2020 Rules applied to employment in very limited circumstances, OCR determined that the proposed approach would minimize confusion among individuals seeking relief under Federal Equal Employment Opportunity laws and would promote clarity regarding the filing and processing of employment discrimination complaints. We stated our belief that, as is the case with employment discrimination complaints generally, concerns regarding the provision of employee health benefits are best resolved by our Federal partners.

In § 92.2(c), we proposed that if any provision of this regulation is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

We invited comment on the effects of the proposed scope of application of the regulation, including the application of this part to recipients of Federal financial assistance from executive agencies other than the Department; the application to programs and activities of the Department and other executive agencies; and the application to employment.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Many commenters supported § 92.2(a), which commenters said would reinstate the scope of the section 1557 implementing regulation to that of the 2016 Rule and recognizes that section 1557 applies to Federal programs like Medicaid and Medicare, the State and Federal Marketplaces (referred to as ''Exchanges'' in this final rule) and the plans sold through them, as well as other commercial health plans if the issuer receives any form of Federal financial assistance. Commenters noted that ensuring section 1557 protections apply broadly to an array of entities and programs will ensure the greatest level of protection for individuals against discriminatory actions that may interfere with access to health care and health care coverage.

Many commenters noted that the Proposed Rule was consistent with congressional intent. These commenters noted that Congress was clear in extending nondiscrimination protections to a broad array of health programs and activities, and that section 1557 was intended to build and expand upon existing civil rights laws, while

[10] Section 1311 of the ACA (codified at 42 U.S.C. 18031) (establishing grants and requiring those grants to be used by States to create ''American Health Benefit Exchanges'') and section 1321(c) of the ACA (codified at 42 U.S.C. 18041(c)) (providing for the Secretary to establish an Exchange if a State elects not to establish an Exchange or fails to establish an Exchange under section 1311 of the ACA).

providing broad protection against discrimination in health care. These commenters further noted that Congress has repeatedly expressed that it intends civil rights laws to be broadly interpreted in order to effectuate their remedial purposes. Commenters also noted that the purpose of the ACA itself is to ensure broad access to and coverage of health care.

Response: We agree that section 1557 protections apply broadly and that this final rule is the best reading of the statute regarding the scope of applicability; as such, the 2022 NPRM properly identified those entities that are covered under section 1557.

Regarding plans sold through State and Federally-facilitated Exchanges, as discussed under the definition of ''Federal financial assistance'' at § 92.4, such plans are covered under this rule as a health program or activity when in receipt of Federal financial assistance, such as advance payments of the premium tax credit. This is consistent with the 2016 Rule. Further, as discussed under the definition of ''health program or activity'' at § 92.4, a health insurance issuer's other commercial health plans are covered under this final rule as part of the issuer's operations where the issuer is principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings. For more information on the final rule's application to all operations of a health insurance issuer that is so principally engaged, please see the discussion below under the definition of ''health program or activity'' at § 92.4.

Comment: Some commenters requested that OCR clarify the extent to which a covered entity is required to oversee the section 1557 compliance of its vendors and subcontractors. For example, a health insurance issuer commented that an issuer should not be responsible for the discriminatory actions of a provider or facility with which the issuer has contracted for the provision of medical services. Another commenter requested clarification on when health insurance agents and brokers are subject to the rule, particularly when they are working under the auspices of a covered entity, such as an Exchange or a health insurance issuer. Other commenters suggested that subcontractors should be considered recipients by virtue of contracting with a recipient of Federal financial assistance.

Response: Health programs or activities may comprise more than one recipient of Federal financial assistance. For example, a primary recipient (or ''direct'' recipient) is an entity that accepts Federal financial assistance from a Federal agency. The direct recipient may then distribute the Federal financial assistance to a subrecipient (or ''indirect'' recipient) to carry out all or part of the health program or activity. Primary recipients and all subrecipients are covered and must comply with section 1557.[11] Under general civil rights principles, both the primary recipient and subrecipient are responsible for complying with applicable civil rights laws.[12] Therefore, if an entity receives Federal financial assistance—directly as a primary recipient or indirectly as a subrecipient—it would be a covered entity and responsible for complying with section 1557 and the part.

While both direct and indirect recipients must comply with section 1557 independently, a direct recipient may not absolve itself of its obligations by contracting with another entity to provide services or assistance for which it received Federal financial assistance or using an agent to do so.[13] Covered entities are responsible for the conduct of their subcontractors and cannot contract away their civil rights obligations through contractual arrangements with subcontractors. For example, section 1557 and the statutes referenced therein may cover a contractor that performs an essential function for the recipient, making the contractor itself a recipient. In *Frazier* v. *Board of Trustees,* 765 F.2d 1278, amended, 777 F.2d 329 (5th Cir. 1985), a case involving section 504, the court noted that the defendant hospital contracted out core medical functions, for which it received Federal financial assistance. The court ruled that this financial assistance to the hospital ''would not have been [provided] at all were it not for [the contractor's] performance as a de facto subdivision of [the hospital],'' and thus the contractor qualified as a recipient for purposes of section 504, *id.* at 1289–90.[14]

The obligation of health insurance agents and brokers as subcontractors is a fact-specific analysis depending on the contractual arrangement with a covered entity. If an Exchange or recipient, such as a health insurance issuer, contracts with an agent or broker to carry out responsibilities of the covered entity's health program or activity and uses Federal financial assistance to pay the agent or broker, then the agent or broker is a subrecipient and thus independently subject to all the provisions of section 1557. If a contractor does not receive Federal financial assistance—either as a primary recipient or subrecipient—it is not a recipient of Federal financial assistance and not subject to section 1557. We note that agents and brokers under contract with an Exchange could also be covered by the final rule as a health program or activity administered by a title I entity under § 92.2(a)(3). Conversely, if the agent or broker is assisting the public with purchasing health insurance coverage without any contractual arrangement on behalf of an Exchange or recipient and is not otherwise receiving Federal financial assistance, then they would not be considered subrecipients or subcontractors subject to the rule.

Comment: Some commenters stated that because the Federal Government now extensively subsidizes both medical care and health insurance coverage and other health-related coverage, the final rule will apply to practically all health care entities. They argued that because of this, it would be nearly impossible for medical professionals to work free of these regulations and, as a result, physicians and faith-based health care entities would effectively be barred from refusing to participate in pregnancy termination procedures.

Response: It has long been established that when an entity receives Federal funds, conditions may be placed on the receipt of those funds.[15] Not all providers receive Federal financial assistance; however, when they do, they must comply with applicable law. The

[11] For further discussion of this issue, *see* U.S. Dep't of Justice, Title VI Legal Manual, sec. V.D.4.

[12] Often, a recipient receives funds with the purpose and expectation that it will distribute the funds to one or more sub-grantees or indirect recipients. For example, in *Moreno* v. *Consol. Rail Corp.,* 99 F.3d 782 (6th Cir. 1996) (en banc), the U.S. Department of Transportation provided funds to the State of Michigan for use in upgrading railroad crossings. The state, in turn, provided these funds to Conrail. The Sixth Circuit found that Conrail was a recipient of Federal financial assistance, noting ''[i]t makes no difference, in our view, that the Federal funds of which Conrail is the recipient come to it through the State of Michigan rather than being paid to it by the United States directly.'' *Id.* at 787.

[13] U.S. Dep't of Justice Title VI Legal Manual, Sec. V.D.5.

[14] *But see Rose* v. *Cahee,* 727 F. Supp. 2d 728, 739 (E.D. Wis. 2010) (court declined to follow *Frazier,* limiting coverage of the funding assistance nondiscrimination cover the contractor of a recipient requirement to those entities receiving the funds directly and that ''are in a position to choose whether to do so'').

[15] The Supreme Court has generally treated these civil rights statutes as enacted based on Congress's Spending Clause Power, which generally permits Congress to attach conditions to the receipt of Federal financial assistance. *See Barnes* v. *Gorman,* 536 U.S. 181, 189 n.3 (2002) (referring to the Rehabilitation Act as ''Spending Clause legislation''); *id.* at 185–86 (''Title VI invokes Congress's power under the Spending Clause, U.S. Const., Art. 1. § 8, cl. 1, to place conditions on the grant of federal funds.'').

rule, however, does not ban physicians and faith-based or other health care entities from refusing to participate in pregnancy termination procedures. On the contrary, the ACA itself provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A).[16] In addition, the rule has been revised at § 92.3(c) to recognize that, ''[i]nsofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required.'' Further, in this final rule, the process regarding exemptions related to religious freedom and conscience protections has been clarified. *See* § 92.302.

Comment: Some commenters supported the restoration of section 1557's application to all health programs or activities administered by the Department under § 92.2(a)(2). These commenters noted that the 2020 Rule exempts from section 1557 most of the Department's programs and activities by limiting the application to only those programs and activities established under title I of the ACA. These commenters opined that such an interpretation is contrary to the statutory text, design, and intent of section 1557 and the ACA generally. Other commenters noted that consistently applying section 1557 requirements throughout various programs, including the Department's programs, creates continuity in the interpretation and implementation of nondiscrimination standards. However, some commenters stated that OCR did not provide adequate explanation as to why this change in application is necessary or appropriate.

Response: For the reasons discussed in the 2022 NPRM, 87 FR 47838, applying this rule to all health programs and activities administered by the Department, not just those programs and activities established under title I of the Act, is the best reading of the statutory text of section 1557. The statutory language provides that section 1557's discrimination prohibitions apply to ''any program and activity that is administered by an executive agency or any entity established under this title.'' 42 U.S.C. 18116(a). As discussed in the 2022 NPRM, the operative word, ''or,'' distinguishes programs and activities operated by an executive agency from those operated by a title I entity. 87 FR 47829. To the extent there is ambiguity in the interpretation, finalizing the rule as proposed better reflects the statutory language as well as Congress's intent.[17] The application of section 1557 to every health program or activity administered by the Department ensures that nondiscrimination standards are interpreted and applied as consistently and as broadly as possible and provides for application of nondiscrimination standards to the Department consistent with the entities to which it provides Federal financial assistance.

Comment: Some commenters noted that under the most straightforward reading of section 1557, the regulatory framework should encompass all of the Department's programs and activities, not just ''health'' programs and activities, and they suggested that the Department extend the regulation's protections accordingly.

Response: We appreciate commenters' views on this issue. As we noted in the 2022 NPRM, OCR considered applying the rule to all programs and activities of the Department and sought comment on this issue. 87 FR 47838. Based on comments received and additional consideration, we are applying the final rule to the Department's health programs and activities, rather than all the Department's programs and activities, at this time. The Department may consider future rulemaking at a later date. For this final rule, however, OCR has determined that it is appropriate to apply the rule to the Department's ''health'' programs and activities given that the ACA itself is principally related to health care and the entirety of this section 1557 rulemaking seeks to regulate ''health'' programs and activities.

Comment: Commenters supported the rule's application to programs and activities administered by title I entities under § 92.2(a)(3), stating it was consistent with statutory text, Congressional intent, and the nondiscrimination purpose of section 1557 and the ACA.

Response: Proposed § 92.2(a)(3) applied section 1557 to ''every program or activity administered by a title I entity.'' In the 2022 NPRM, 87 FR 47838, OCR explained that it was unnecessary to include the modifier ''health'' to programs or activities of a title I entity because title I entities already meet the definition of ''health program or activity'' as set forth under § 92.4. While this remains true, we have reevaluated the regulatory text of § 92.2(b)(3) and determined that it should be revised to add the modifier ''health'' to a title I entity's ''program or activity'' for consistency with our interpretation that section 1557 applies to the Department's ''health'' programs or activities, as discussed in the previous comment. This technical revision does not limit or alter the scope of § 92.2(b)(3)'s application to the programs or activities of a title I entity, as we articulated in the 2022 NPRM. 87 FR 47838.

Comment: A few commenters opined that the rule should apply broadly to recipients of Federal financial assistance from any executive agency, not just the Department. These commenters noted that nothing in the statute suggests that Congress intended to limit the scope of section 1557's application in such a way.

Response: It is OCR's longstanding position that section 1557's discrimination prohibition is not limited to recipients of Federal financial assistance from the Department, but rather covers recipients' health programs or activities regardless of the executive agency providing the funding.[18] However, the final rule only applies to recipients of HHS funding, which is consistent with OCR's delegation of authority to ''develop and direct implementation of the requirements of Section 1557 . . . *as applied to* the Department and recipients of the Department's funds.'' 85 FR 37242 (emphasis added). Other Federal agencies possess section 1557 enforcement responsibility for the health programs and activities they fund and administer.

Comment: Some commenters recommended that the Department provide a model for other agencies to craft their own, more inclusive, and

[16] The application of this final rule to covered entities with conscience or religious freedom objections are discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[17] *See, e.g., Griffin* v. *Breckenridge,* 403 U.S. 88, 97 (1971) (civil rights statutes should be construed broadly); *U.S.* v. *Price,* 383 U.S. 787, 801 (1966) (same); *see also N. Haven Bd. of Educ.* v. *Bell,* 456 U.S. 512, 521 (1982) (''[I]f we are to give Title IX the scope that its origins dictate, we must accord it a sweep as broad as its language.''); S. Rep. No. 64, 100th Cong., 2d Sess. 5–7 (1988), reprinted in 1988 U.S.C.C.A.N. 3, 7–9 (statement of Sen. Humphrey stating that title VI should be interpreted as broadly as necessary to eradicate discriminatory practices in programs that Federal funds supported).

[18] *See* U.S. Health & Hum. Servs., Off. for Civil Rts., Memo. from Jocelyn Samuels, Director, to Directors of Federal Offices for Civil Rights (Nov. 5, 2015), *https://www.hhs.gov/sites/default/files/2015_11_04_fed_civil_rights_section_1557_memo_508.pdf.*

more protective rules for non-health-related programs in line with other applicable non-discrimination statutes.

Response: OCR appreciates this recommendation and reiterates its desire to work with other agencies as necessary and appropriate. OCR only has authority to apply section 1557 to HHS and recipients of Departmental Federal financial assistance. This rule does not apply to programs and activities of other agencies and OCR is unable to regulate other agencies.

Comment: A number of commenters disagreed with the non-application of the rule to employment practices under § 92.2(b). Commenters opined that the categorical exclusion of employers is inconsistent with section 1557's statutory text and creates confusion. Some commenters noted that an agency to whom a complaint is referred may not adequately address claims of discrimination, including those of dependents. Commenters further noted that other employment discrimination laws, such as title VII of the Civil Rights Act of 1964 (title VII), 42 U.S.C. 2000e *et seq.,* and the Age Discrimination in Employment Act of 1967 (ADEA), 29 U.S.C. 621–634, require a claimant to file a complaint with a Federal agency before privately enforcing their rights. Some commenters requested that OCR clarify that this provision concerns only the processing of administrative complaints by OCR and that OCR's decision not to apply this rule to employment practices does not preclude employees from vindicating their section 1557 rights in court.

Other commenters supported proposed § 92.2(b) and noted it will help prevent wasteful duplication with other Federal laws and agencies that already cover unlawful employment discrimination.

Response: The Supreme Court has recognized that section 1557 authorizes a private right of action.[19] This final rule applies only to OCR's administrative enforcement of section 1557. As discussed in the 2022 NPRM, 87 FR 47838, we believe that other Federal agencies are better equipped to review and adjudicate employee health benefits and allegations of employment discrimination given their expertise under the existing employment nondiscrimination statutes they enforce.

Comment: Some commenters noted that employers are usually the sponsors of group health plans and raised concerns that OCR could therefor find an employer liable under section 1557 for the employee benefits it provides.

Response: This rule does not apply to employers or other plan sponsors with regard to their employment practices, including the provision of employee health benefits. As stated in the preamble to the Proposed Rule, 87 FR 47838, previous rules had limited application to employment. The 2016 Rule provided that employment practices included hiring, firing, promotions, or terms and conditions of employment, and therefore the 2016 Rule did not apply to those practices. However, the 2016 Rule applied to an employer with regard to its employee health benefit programs under certain circumstances as set forth under former § 92.208. The 2020 Rule, which repealed the 2016 Rule's reference to employment practices and employee health benefit programs, reverted to enforcing the statutorily referenced nondiscrimination statutes through their existing regulations. As discussed above, the Proposed Rule proposed to exclude employment practices, which included the provision of employee health benefit programs. OCR also recognizes that other sponsors of group health plans undertake similar employment practices, such as the provision of employee health benefits. For example, a joint board of trustees for a multi-employer group health plan (also known as a Taft-Hartley plan) consists of representatives from employers and unions to sponsor a group health plan, and similarly engages in the provision of an employee health benefit like employers that sponsor a single-employer plan. To ensure consistent application of the rule to entities engaging in similar employment functions, the final rule revises § 92.2(b) to provide that the rule does not apply to any employer or other plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group, with regard to employment practices, including the provision of employee health benefits.

Group health plans, employers, and sponsors of group health plans are generally separate entities from one another that require a separate, fact-specific analysis to determine whether each entity is subject to this rule. We discuss the relationship between plan sponsors, such as employers, joint boards of trustees or similar bodies, associations, and other groups that are plan sponsors of multi-employer Taft-Hartley plans or multiple-employer welfare arrangements (MEWAs), and group health plans in more detail in the discussion of group health plans in the ''health program or activity'' definition discussion under § 92.4.

Comment: Some commenters stated that ongoing litigation surrounding section 1557 and previous iterations of OCR's section 1557 regulations, as well as agency course reversal on multiple occasions, has created confusion and compliance burden on covered entities. They urged the Department to reinforce the importance of severability under § 92.2(c) amongst the various regulatory provisions of the rule.

Response: We appreciate concerns around ongoing litigation and agency reversal, and the resulting inconsistency in requirements. OCR has attempted to answer questions and reduce confusion raised by the previous versions of the rule. While this final rule is similar to the 2016 Rule, it provides greater clarity regarding section 1557's statutory protections from discrimination along with various provisions to help alleviate burdens while providing certainty about covered entities' obligations when compared to the 2016 and 2020 Rules. We believe the final rule enhances the benefits to individuals and minimizes the burdens on covered entities.

OCR notes that § 92.2(c) provides that if any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, if a court were to invalidate the final rule's Notice of availability of language assistance services provision (Notice of Availability) at § 92.11, all other provisions of the rule would remain in effect, as those provisions ''could function sensibly without the stricken provision.'' [20] Thus, if the rule's Notice of Availability provision were invalidated, OCR would not enforce that provision. Or, for example, if a court were to invalidate the final rule's Section 1557 Coordinator requirement at § 92.7, OCR would not require covered entities to fill this position as part of their compliance with this final rule, while otherwise enforcing other administrative requirements such as the Policies and procedures requirement at § 92.8 and the Notice of nondiscrimination requirement at § 92.10.

Comment: Some commenters requested that the final rule restore the 2016 Rule clarification that any age

[19] *Cummings* v. *Premier Rehab Keller, P.L.L.C.,* 596 U.S. 212 (2022) (section 1557 provides a private right of action because the incorporated statutes do so).

[20] *MD/DC/DE Broadcasters Ass'n* v. *F.C.C.,* 253 F.3d 732, 734 (D.C. Cir. 2001) (internal quotations omitted).

distinctions exempt from the Age Act are also exempt from section 1557 enforcement.

Response: OCR appreciates commenters' request for clarity and directs commenters to § 92.101(b)(1) of this regulation, which adopts by reference the permissible uses of age located in the Department's Age Act regulations at 45 CFR part 91 (subpart B).

Comment: Some commenters argued that the Proposed Rule is inappropriate for the Indian Health Services (IHS) facilities because these are not open to members of the public but reserved for patients who are eligible beneficiaries as citizens of Tribal Nations, and as such, tribally operated IHS health facilities [21] should be exempt. These commenters stated that the 2022 NPRM failed to recognize the unique nature of the Indian Health Care System, which is the health care system for members of federally recognized Tribes in the United States. Commenters recommended that OCR acknowledge American Indian/Alaska Native (AI/AN) as a political classification, and not as a race-based classification. Commenters further opined that the 2022 NPRM failed to recognize the diplomatic, nation-to-nation relationship between Tribal Nations and the United States.

Response: OCR appreciates these comments. Similar concerns were raised during the 2022 NPRM Tribal Consultation held on August 31, 2022, pursuant to Executive Order 13175. The IHS, an agency within the Department, is responsible for providing health services to members of federally recognized tribes in 37 states, arising out of the special government-to-government relationship between the Federal Government and Indian tribes.[22]

Membership or eligibility in a federally recognized tribal entity is a political classification rather than a racial classification.[23] Preferences based upon the unique relationship between the United States and federally recognized tribal entities are distinct from the forms of discrimination prohibited by Federal civil rights laws, which aim to protect all individuals on the basis of race, color, or national origin (including AI/AN individuals, regardless of political affiliation).[24] The Department's regulations implementing title VI provide that an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals of a different race, color, or national origin. 45 CFR 80.3(d) (Indian Health and Cuban Refugee Services). IHS is mentioned in the Department's title VI regulation as an example of such a program. *Id.* In § 92.101(b), the final rule adopts this provision by reference, and OCR will fully apply it, as well as other applicable exemptions or defenses that may exist under Federal law.

Programs of the IHS are administered by IHS and tribes, including through self-determination contracts or self-governance compacts, and we intend to address any restrictions on application of the law to IHS programs in the context of individual complaints.

Comment: Some commenters requested that OCR develop an online tool that would help covered entities determine whether the final rule applies either directly or indirectly to an organization or other health program or activity.

Response: OCR provides various tools on our website to help covered entities determine their covered entity status and will continue to ascertain what tools would help the industry ensure widespread compliance. OCR notes that the Department's Office of Grants operates a website that tracks obligated Department grant funds, *https://taggs.hhs.gov/*, which allows the public to identify recipients of Department funding.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with modification. We are revising § 92.2(a)(3) to add the modifier ''health'' to ''program or activity administered by a title I entity.'' We are also revising § 92.2(b) to state that the provisions of this part shall not apply to any employer ''or other a plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group,'' with regard to its employment practices, including the provision of employee health benefits.

Treatment of the Title IX Religious Exception

In the 2022 NPRM, OCR proposed to not import the title IX religious exception into the section 1557 regulation. The title IX statute states that the nondiscrimination requirements ''shall not apply to an educational institution which is controlled by a religious organization'' to the extent that such application ''would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1681(a)(3), *as amended* Public Law 100–259, section 3(b), Mar. 22, 1988, 102 Stat. 29. The title IX statutory definition of ''program or activity'' further limits the nondiscrimination requirements, in that they do not apply to ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization.'' *Id.* at 1687(4).

In the 2022 NPRM, we said that under the most natural understanding of section 1557's text, which bans discrimination ''on the ground prohibited under . . . title IX,'' the statutory term ''ground prohibited'' is best understood as incorporating only the bases on which discrimination is prohibited in the referenced statutes (*i.e.,* ''sex'' in title IX). 87 FR 47839. Rather than import the title IX exception for ''educational institution[s]'' that are controlled by ''religious organization[s],'' OCR proposed that the best way to address religious objections to the application of this rule—and the way most consistent with section 1557's statutory text and structure—would be through the process provided in proposed § 92.302. We sought comment on this approach. We particularly invited comments from covered entities controlled by or affiliated with religious organizations, providers employed by such entities, and people who receive health care from religiously affiliated medical providers.

The comments and our responses regarding this request for comment are set forth below.

Comment: Commenters provided mixed responses to OCR's proposal not to import the title IX religious exception into this rule. Many commenters supported OCR's statutory interpretation that section 1557

[21] Titles I and V of the Indian Self-Determination and Education Assistance Act, Pub. L. 93–638, as amended, provide Tribes the option of exercising their right to self-determination by assuming control and management of programs previously administered by the Federal Government. Since 1992, the IHS has entered into agreements with tribes and tribal organizations to plan, conduct, and administer programs authorized under section 102 of the Act. Today, over sixty percent of the IHS appropriation is administered by tribes, primarily through self-determination contracts or self-governance compacts. U.S. Dep't of Health & Hum. Servs., Indian Health Servs., *IHS Profile, https://www.ihs.gov/newsroom/factsheets/ihsprofile/.*

[22] U.S. Dep't of Health & Hum. Servs., Indian Health Servs., *About IHS, https://www.ihs.gov/aboutihs/.*

[23] *See Morton* v. *Mancari,* 417 U.S. 535, 553 & n.24 (1974).

[24] *See Morton* v. *Mancari,* 417 U.S. 535, 550 (1974) (''[a] provision aimed at furthering Indian self-government by according an employment preference withing the [Bureau of Indian Affairs] for qualified members of the governed group can readily co-exist with a general rule prohibiting employment discrimination on the basis of race.'').

incorporated the title IX statute only with respect to the ground of discrimination prohibited (sex) and its enforcement mechanisms (*e.g.,* termination of Federal financial assistance and other means authorized by law). Several commenters stated that this reading is most consistent with the statutory structure, because if Congress intended for the title IX religious exception to apply, the statute would also require the importation of the other title IX exceptions, many of which are by their terms plainly inapplicable in the context of health care.

Several commenters also stated that if Congress wanted to include the title IX religious exception, it could have either explicitly referenced or listed the exception in the section 1557 statutory text. Many commenters stated that any silence regarding the title IX exceptions was not an oversight by Congress, but an intentional decision. Many commenters contended that importing the title IX religious exception is contrary to the purpose of section 1557 and the goal of the ACA: to expand access to health care coverage. Additionally, many commenters said that importing the title IX religious exception is unnecessary given the numerous other Federal laws that allow religious organizations and providers to invoke a conscience or religious objection to providing certain kinds of medical services and care.

Many other commenters disagreed with OCR's interpretation, claiming that Congress intended to incorporate the entire title IX statutory scheme by including the signal ''*et seq.*'' Several commenters also argued that title IX's prohibition on sex discrimination cannot be read separate and apart from all the exceptions included in the title IX statute, in which Congress authorized certain conduct—*i.e.,* otherwise prohibited sex discrimination. Accordingly, several commenters maintained that it is arbitrary and capricious for OCR to rely upon title IX's implementing regulations as a guide to prohibit discrimination on the basis of sex, such as those related to pregnancy-related conditions, or when distinguishing a marital, parental, and family status, while not importing the statute's religious exception.

A few commenters maintained that the differences between educational and health care institutions provide an unconvincing argument for nonimportation of the title IX religious exception because under the Title IX Common Rule of 2000 (Common Rule),[25] title IX already applies to recipients of Federal financial assistance that provide health care. Many commenters also asserted that the court in *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016), found that the decision not to import the title IX religious exception into the 2016 Rule, without explanation, was contrary to law. Several commenters also pointed to that court's determination that the Department had previously ''provide[d] that when cross-referencing the provisions of Title IX's use of 'student,' the term 'individual' should be used in the healthcare context.'' *Id.* at 691. Commenters asserted that this finding by the court undermines the Department's claim that the title IX religious exception is specific to education and cannot be adopted more broadly in the health care context.

Response: Title IX applies to ''any education program or activity'' operated by recipients of Federal financial assistance, and the statute creates an exception from coverage for the education programs and activities of ''an educational institution which is controlled by a religious organization if the application of [title IX's prohibition on sex discrimination in education programs and activities] would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1681(a)(3). In addition, the Civil Rights Restoration Act of 1987 (CRRA)[26] statutorily defined ''program or activity'' for title IX to exclude from coverage ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1687(4). The preamble to the 2020 Rule stated that section 1557 ''incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions.'' 85 FR 37208.

OCR notes that as an initial matter, the CRRA's exclusion of any operation of religiously controlled entities from the application of title IX to the extent such operation is inconsistent with the religious tenets of the organization is not incorporated into section 1557. As we explain further in the discussion of ''health program or activity,'' section 1557 includes its own coverage provision that does not incorporate the CRRA's definitions of ''program or activity.'' Moreover, unlike title VI, section 504, and the Age Act,[27] title IX modifies ''program or activity'' with ''education,'' 20 U.S.C. 1681(a), which limited title IX's prohibition on sex discrimination to the ''education'' context; the definitions of ''program or activity'' under title VI, section 504, or the Age Act do not include any comparable exclusion for the operations of religiously controlled entities.[28] Thus, the CRRA's limitation to the application of certain operations of religious entities from title IX's coverage applies only in the ''education'' context and is not part of the definition of ''program or activity'' as that term is used in civil rights statutes more generally. Further, it is inapplicable to the definition of ''health program or activity'' adopted in section 1557. As a result, the sole question is whether the exclusion in title IX, 20 U.S.C. 1681(a)(3), of certain applications of the statute to ''educational institution[s] which [are] controlled by a religious organization'' carries over into section 1557.

Although title IX's prohibition of sex discrimination applies to some health-related activities of covered education programs—such as programs training future health workers—the range of exceptions provided in section 1681(a) are plainly tied to the educational setting (*e.g.,* the membership practices of social fraternities and sororities, YMCA, Girls Scouts, Boys Scouts; voluntary youth service organizations; father-son and mother-daughter activities; and beauty pageant-based scholarships, as well as educational admissions practices). All of these exceptions have little if any application to health programs and activities. Further, exceptions listed in that subsection include limitations regarding ''educational institution[s],'' ''institution[s] of public higher education,'' or ''institution[s] of higher education.'' 20 U.S.C. 1681(a)(1)–(9).

[25] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,* 65 FR 52857 (Aug. 30, 2000) (multiagency rulemaking adopting consistent title IX implementing regulations).

[26] Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

[27] *See* 42 U.S.C. 2000d (title VI, prohibiting ''discrimination under any program or activity receiving Federal financial assistance''); 42 U.S.C. 6101 (the Age Act, prohibiting discrimination ''in programs or activities receiving Federal financial assistance''); 29 U.S.C. 794(a) (section 504 prohibiting ''discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service'').

[28] S. Rep. No. 100–64, 100th Cong., 1st Sess. (1987), *as reprinted in* 1988 U.S.C.C.A.N. 3, 6, 1987 WL 61447, at *18 (discussing ''education limitation in Title IX''); *see also id.* at *20–*21 (''[The CRRA] leaves the religious tenet exemption in Title IX intact and clarifies that the exemption is as broad as the Title IX coverage of *education programs and activities.*'' (Emphasis added)).

The language and subject matter of the exceptions suggest that Congress, in enacting title IX, did not intend those exceptions to define the statute's basis of discrimination—what section 1557 calls the ''ground prohibited''—under title IX. Title IX prohibits discrimination on the basis of sex, so the ''ground prohibited'' under that statute is sex. Congress intended these exceptions to delineate certain contexts in which otherwise prohibited sex discrimination in the educational context would be excluded from the statute's coverage. Congress could have chosen to draft section 1557 to incorporate additional elements from title IX and the other referenced civil rights statutes (*e.g.,* those statutes' applicability provisions), but did not do so, instead narrowly specifying that only the ''ground[s] prohibited'' are incorporated.

OCR further notes that the inclusion of ''*et seq.*'' is simply part of an ordinary citation to the title IX statute. Congress frequently appends ''*et seq.*'' to statutory citations as a matter of course when legislation includes a generalized reference to a previously enacted statute.[29] Including ''*et seq.*'' does not change the substantive meaning of section 1557, which incorporates only the grounds of prohibited discrimination and the enforcement mechanisms of each referenced statute. Further, section 1557 includes similar parenthetical citations with ''*et seq.*'' for the other referenced civil rights statutes in both 42 U.S.C. 18116(a) and (b). This underscores that Congress merely intended to provide the general, ordinary citation to the statutes being referenced, including title IX.

Section 1557's role as a health care statute further reinforces our reading of the statutory text and Congressional intent. Section 1557 was enacted as part of the ACA, in part, to expand access to health insurance and increase consumer protections. Title IX, as we have explained, relates specifically to education programs and activities. The title IX religious exception in that statute allows some entities to engage in certain conduct without requiring any consideration or mitigation of harm to third parties. If a similar standard were imported into this rule, it could undermine a key purpose of section 1557—ensuring access to health care. And as discussed below, unlike educational settings such as colleges and universities where there is more choice, individuals often have far fewer choices when accessing health care. In the federally funded health care context, the array of statutory conscience provisions enacted by Congress, as well as the general requirements of the First Amendment and the Religious Freedom Restoration Act (RFRA), provide a better fitting approach to addressing the relevant interests. This final rule has been revised to include regulatory text at § 92.3(c) recognizing that, insofar as the application of any rule requirement would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. Also, we have strengthened the process for raising religious freedom and conscience protections under this final rule at § 92.302.

The fact that title IX and agency implementing regulations apply to *some* health programs and activities—those that are part of educational programs and activities [30]—does not suggest that the exceptions set forth in the statute or implementing regulations apply to health programs and activities that are not a part of an educational program. Title IX's limitation to a recipient's education programs and activities has long been established.[31] For example, the Common Rule (adopted by more than 20 Federal agencies) included the statute's limitation that the prohibition on sex discrimination applied *only to the educational components* of a covered entity's program.[32] As we have explained, it is inconsistent with the text and purpose of section 1557, as well as the text and structure of title IX, to apply the title IX exceptions outside of the educational setting. Although the title IX regulations are relevant to informing what constitutes sex discrimination for purposes of this final rule—and we have looked to them for that purpose—that is because section 1557 incorporates the ''ground prohibited'' under title IX. But section 1557 does not incorporate any of the title IX exceptions. 87 FR 47839.

OCR disagrees with the *Franciscan Alliance* decision vacating portions of the 2016 Rule, and in any event, that decision does not prohibit OCR from not importing the title IX religious exception in this final rule. The promulgation of this final rule constitutes new rulemaking, and OCR has provided a detailed explanation for the decision to not import the title IX religious exception and has taken important steps to address religious freedom and conscience protections beyond those in the 2016 Rule. These steps include revisions at § 92.3(c) to recognizes that, ''[i]nsofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required,'' adoption of a voluntary assurance of exemption process based on these protections at § 92.302, and the Department's issuance of a final rule entitled *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 89 FR 2078 (Jan. 11, 2024).

OCR notes that this final rule does not alter or eliminate a recipient's ability to maintain, seek, claim, or assert a title IX religious exception under title IX if it meets the applicable criteria.[33] And to the extent the recipient is entitled to a religious exception under title IX, OCR's analysis will consider the entire statute, including title IX's specific limitation to the context of educational programs and activities.

Comment: Many commenters supported OCR's proposal not to import the title IX religious exception, highlighting what they characterized as the dangers of doing so in the context of health care and the potential consequences on people's access to health care it might have. For example, many commenters expressed concerns that providers would be able to deny essential health care services based on disapproval of a particular group, thereby putting at risk the health and well-being of already vulnerable individuals. Many commenters asserted that entities have invoked religious beliefs to deny individuals access to health care and coverage for a broad range of health care services. Commenters said that in urgent or emergency care situations, individuals may be unable to identify or use the services of an alternate provider when an institution withholds care based on religious tenets, even when the

[29] *See, e.g.,* 20 U.S.C. 1689(a)(1) (requesting a task force ''provide pertinent information . . . with respect to campus sexual violence prevention, investigations, and responses, including the creation of consistent, public complaint processes for violations of title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)[.]''); *accord id.* 1689(a)(8), (b)(1), (c).

[30] *See, e.g., Doe* v. *Mercy Cath. Med. Ctr.,* 850 F.3d 545, 555 (3d Cir. 2017) (holding that a hospital's residency program was an educational program or activity under title IX).

[31] *See O'Connor* v. *Davis,* 126 F.3d 112, 117 (2d Cir. 1997), *cert. denied,* 522 U.S. 1114 (1998) (under title IX a program or activity must be ''such that one could reasonably consider its mission to be, at least in part, educational''); *see also Jeldness* v. *Pearce,* 30 F.3d 1220, 1224–25 (9th Cir. 1994); *Klinger* v. *Dep't of Corrs.,* 107 F.3d 609, 613–16 & n.5 (8th Cir. 1997); *Roubideaux* v. *North Dakota Dep't of Corrs. & Rehab.,* 570 F.3d 966, 976–79 (8th Cir. 2009).

[32] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,* 65 FR 52858, 52868 (Aug. 30, 2000).

[33] 20 U.S.C. 1681(a)(3); 45 CFR 86.12.

individual is aware of such objections by an institution.

Many commenters highlighted the difference between education and health care. Multiple commenters stated that unlike certain health care settings, many parents have the choice to send their children to religious schools, whereas individuals often lack meaningful choices when seeking a health care provider, particularly for time-sensitive care. For example, numerous commenters stated that choice is especially limited in rural areas, and some patients may only have local access to religiously affiliated providers. Commenters worried that importing the title IX religious exception into this rule could have dire implications for health outcomes.

Response: As previously noted, this rule's application to the health care context is central to OCR's interpretation of section 1557. OCR appreciates that religiously affiliated hospitals and health care facilities play an important role in the health care system and recognizes the critical patient care needs they provide, including in underserved communities and areas which otherwise lack access to quality health care. At the same time, OCR believes that Congress chose not to import the title IX religious exception into section 1557 due to concerns about the impact such an action could have on access to health care. The importation of the title IX religious exception would raise unique concerns in the health care context that are not typically present in education programs and activities. As OCR discussed in the 2022 NPRM, health care settings differ from educational settings with respect to both the ability of affected parties to choose (or avoid) certain religiously affiliated health care institutions and the urgency of the need for services provided by the covered entities. 87 FR 47840. While students and families normally make a deliberate choice to attend a religious educational institution, in many cases specifically due to its religious character, individuals seeking health care are far more likely to be driven by other considerations such as availability, urgency, geography, insurance coverage, and other factors unrelated to whether the provider is controlled by or affiliated with a religious organization. *See id.* Rather than importing the title IX religious exception into section 1557, where Congress referenced only the ''ground prohibited under'' and the ''enforcement mechanisms provided'' for in title IX, the process set forth in § 92.302 respects religious freedom and conscience protections. As this final rule makes clear at § 92.3(c), insofar as the application of any requirement under this rule would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. Under § 92.302, recipients may rely on these protections or seek assurance of these protections from OCR, if they wish. In this process, OCR will comply with the applicable legal standards of the governing statutes, which include the protections in the ACA itself, 42 U.S.C. 18023; the Church, 42 U.S.C. 300a–7, Coats-Snowe, 42 U.S.C. 238n, and Weldon Amendments, *e.g.,* Consolidated Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, sec. 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024); the generally applicable requirements of RFRA, 42 U.S.C. 2000bb–1; and other applicable Federal laws.

Comment: Many commenters who supported OCR's proposal not to import the title IX religious exception raised concerns that its importation could discourage individuals from seeking necessary medical care. Many commenters also discussed various State laws recently enacted to further expand religious exemptions from health care requirements and how such laws have specifically affected communities with limited access to care. These commenters argued that the effects of these laws further support OCR's goal of ensuring patients have broad access to nondiscrimination protections.

Response: OCR appreciates commenters' concerns regarding the potential harms to individuals with limited or restricted access to health care. OCR appreciates that many religiously affiliated hospitals and providers are providing vital services in areas where people are in the most need and are often motivated by their faith to provide this important care. However, OCR maintains that Congress did not choose to import the title IX religious exception into section 1557. Importing the title IX exception would be inconsistent with the text, structure, and purpose of both title IX and section 1557. Rather, Congress has enacted protections for conscience in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments, among others; the generally applicable requirements of RFRA, and other applicable Federal laws as the means to protect religious freedom and conscience in this context. We are committed to affording full effect to Congress's protections of conscience and religion, as detailed in § 92.302 and the Department's issuance of its final rule, Safeguarding the Rights of Conscience as Protected by Federal Statutes. 89 FR 2078.

Comment: Multiple commenters opposed OCR's proposal not to import the title IX religious exception, stating that doing so would harm providers and hospital systems by compelling covered entities to provide abortion or other care that is contrary to their religious beliefs or that they believe will be harmful to their patients. Various commenters said that compelling such actions would turn many individuals and institutions of faith away from the medical profession.

Several commenters expressed confusion about available religious exceptions and how certain rule requirements would apply to religiously affiliated covered entities. These commenters said that including the title IX religious exception would clarify protections for religious entities.

Some commenters expressed concern that this regulation demonstrated OCR's intent to use section 1557 to force religious hospitals to dispense medication and perform procedures that are prohibited by their faith. Several commenters objected to the inclusion of cites in the 2022 NPRM that explain the increased prevalence of religiously affiliated health care systems and opined that this demonstrated hostility toward faith-based providers. According to these commenters, including these cites prejudices OCR's review of providers' religious exemption requests. Instead, these commenters urged OCR to make clear that providers will not be compelled to perform, cover, or promote procedures or medical interventions to which they have moral or religious objections.

Response: OCR appreciates commenters' concerns and respects their opposition to the proposal not to import the title IX religious exception. OCR reiterates, consistent with the 2022 NPRM, that this final rule does not promote any particular medical treatment, require provision of particular procedures, mandate coverage of any particular care, or set any standard of care; rather, the final rule implements the nondiscrimination requirements of section 1557. *See* 87 FR 47867–68. The full protections of all Federal religious freedom and conscience laws continue to apply.

Additionally, OCR makes clear that the decision not to import the title IX religious exception does not compel any individual provider or covered entity with religious or conscience-based objections to provide abortion or any other care to the extent doing so would conflict with a sincerely-held belief. The ACA itself provides that ''[n]othing in this Act shall be construed to have any

effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). As discussed further below, section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure. In addition, any recipient that believes that it is exempt from certain provisions of this rule due to the application of a Federal conscience or religious freedom law may rely on those provisions, as referenced in § 92.3(c), or choose to seek assurance of the applications of those provisions pursuant to the process provided in § 92.302.

In light of § 92.302 and 42 U.S.C. 18023(c)(2)(A) (section 1303 of the ACA), OCR maintains that although some recipient providers and hospitals may decline to participate in federally funded health programs as a result of this rule, most will choose to continue to participate. To avoid confusion, we have further clarified the process for seeking assurance of an exemption based on religious freedom and conscience laws at § 92.302 and are committed to making available trainings and other resources to assist covered entities in understanding their obligations under section 1557 and the process by which they may seek assurance of an exemption under § 92.302.

Again, OCR appreciates that religiously affiliated hospitals and health care facilities play an important role in the health care system and recognizes the critical patient care needs they provide, including in underserved communities and areas which otherwise lack access to quality health care. Any discussion relating to the prevalence of religiously affiliated care is relevant for OCR to evaluate access issues that patients seeking certain procedures or care could potentially face, although OCR does not assume that all religiously affiliated entities' refusals to provide certain forms of care would result in such access issues. As previously stated, the 2022 NPRM provided factual findings with respect to health care accessibility in the United States based upon health care capacity of providers, population demands, and geographic limitations. 87 FR 47840. A detailed discussion of these considerations can be found in the Regulatory Impact Analysis (RIA).

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the rule as proposed, without importing the title IX religious exception.

Relationship to Other Laws (§ 92.3)

In § 92.3, we provided an explanation of the relationship of the proposed regulation to existing laws. Proposed § 92.3(a) provided that neither section 1557 nor this part shall be interpreted to apply lesser standards for the protection of individuals from discrimination than the standards under title VI, title IX, section 504, the Age Act, or the regulations issued pursuant to those laws.

In § 92.3(b), we proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available under the Federal civil rights laws cited in 42 U.S.C. 18116(b) (title VI, title VII, title IX, section 504, and the Age Act), consistent with 42 U.S.C. 18116(b).

In § 92.3(c), we proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available under Federal religious freedom and conscience laws. Though not specifically referenced in the Proposed Rule, these include the protections in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws.

The comments and our responses to this provision are set forth below.

Comment: Commenters expressed a mix of viewpoints regarding the ''lesser standard'' language included in proposed § 92.3(a), concerning civil rights statutes referenced in section 1557. Some commenters recommended removing the ''lesser standard'' language because it is not included in the section 1557 statute. Commenters stated that this language ignores Congress's decision to employ a particular standard to each of the civil rights laws incorporated, such that it would allow OCR to redefine bases for discrimination and improperly preempt State law affecting such categories.

Response: In this final rule, OCR seeks to give all laws their fullest possible effect. OCR appreciates these comments but declines to remove the ''lesser standard'' language included in § 92.3(a). As the 2016 Rule recognized, 81 FR 31381, this interpretation is consistent with a natural reading of section 1557's statutory text that explicitly states that section 1557 shall not be construed to ''invalidate or limit the rights, remedies, procedures, or legal standards'' of the referenced statutes (and title VII) ''or to supersede State laws that provide additional protections against discrimination,'' 42 U.S.C. 18116(b). OCR accordingly reaffirms that the civil rights laws referenced in section 1557 establish the grounds of prohibited discrimination, and nothing in this final rule is intended to provide lesser protections than those found under title VI, title IX, section 504, or the Age Act, or their implementing regulations.

Comment: Several commenters supported the inclusion of the ''lesser standard'' language in § 92.3(a) but suggested that § 92.3(c), concerning Federal religious freedom and conscience laws, is unnecessary and, if included without any limitations, undermines this ''lesser standard'' language of § 92.3(a) and could encourage discrimination.

Response: We decline to remove § 92.3(c), concerning Federal religious freedom and conscience laws. These laws remain applicable and removing the language runs contrary to the Department and OCR's stated commitment to protect the rights of individuals and entities under Federal conscience or religion freedom laws. Indeed, the ACA itself contains a similar provision at 42 U.S.C. 18023(c)(2)(A)(i), which provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—conscience protection[.]'' As discussed later in this section, we have revised § 92.3(c) to provide additional specificity regarding the application of Federal religious freedom and conscience protections.

Comment: Some commenters suggested that OCR clarify that section 1557 does not limit the rights of individuals to any of the protections afforded under title VI, title IX, section 504, or the Age Act. These commenters suggested that section 1557 is a distinct law and, while it is intended to work in tandem with other civil rights laws, section 1557 stands on its own. Several other commenters requested that the final rule include language that clarifies that administrative exhaustion is not required to bring any claim under section 1557 in Federal court, where for example a claim may involve age as one basis of discrimination among several (*e.g.,* alleging discrimination on the bases of age, sex, and disability at the same time) but the Age Act has a

statutory requirement that claimants first exhaust their administrative remedies.

Response: Section 92.3(b) clearly states that this part does not limit or invalidate the rights, remedies, procedures, or legal standards under the statutes referenced (*i.e.,* title VI, title VII, title IX, section 504, and the Age Act), consistent with the statutory text of section 1557 at 42 U.S.C. 18116(b). In addition to incorporating the ''ground[s] prohibited'' by these other statutes, section 1557 incorporates the ''enforcement mechanisms'' of the statutes. 42 U.S.C. 18116(a). Though the section 1557 rule is informed by the title VI, title IX, Age Act, and section 504 implementing regulations, section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities that is distinct from these statutes. Section 1557's nondiscrimination requirements do not in any way limit or impact the interpretation of those statutes. *See id.* at 18116(b). Section 1557 is a distinct civil rights authority.

Courts have long recognized that section 1557 authorizes a private right of action under any of the bases for discrimination. While we appreciate concerns raised by commenters regarding the heightened risks associated with unnecessary delays in the context of health care, we decline to revise regulatory text to adopt a stance on the appropriate standards that apply to private litigants. This is an issue appropriately addressed by the Federal judicial branch and not via agency rulemaking. Comments and responses regarding OCR procedures for conducting its own administrative enforcement are provided in §§ 92.303 (Procedures for health programs and activities conducted by recipients and State Exchanges) and 92.304 (Procedures for health programs and activities administered by the Department).

Comment: Many commenters raised concerns about the potential conflicts of State and Federal laws. Some commenters expressed that any conflict between State and Federal law or policy would be inconsistent with the principles of federalism. Some commenters had specific concerns regarding the final rule's application to State laws that prohibit transgender patients from receiving certain medically necessary gender-affirming care or those that protect religious freedom and conscience. Other commenters suggested that OCR should include a subsection in the final rule that addresses the interaction between section 1557 and State or local laws, making explicit that a State may set more rigorous standards for nondiscrimination in the provision of health care but not lesser protections than those of section 1557. To the extent State or local law offers lesser protections these commenters recommended OCR make explicit that such laws are preempted by Federal law, consistent with the general preemption standard for title I of the ACA, codified at 42 U.S.C. 18041(d).

Response: OCR appreciates these comments regarding the rule's interaction with State and other Federal laws. We agree with commenters who observed that Federal laws, as a general matter, preempt conflicting State laws. *See* U.S. Const. art. 6, cl. 2. We also note that title I of the ACA itself contains a preemption provision, which courts have interpreted to preempt State laws that serve as an obstacle to or frustrate the purpose of the ACA.[34] *See* 42 U.S.C. 18041(d). Accordingly, we decline to alter the regulation to include any additional language under this provision addressing preemption. OCR recognizes that some States may have laws impacting health programs and activities that are contrary to the final rule's nondiscrimination protections, and as discussed later regarding § 92.206 (Equal program access on the basis of sex), section 1557 preempts those laws, though OCR will consider the specific facts of each case and any other relevant factors in determining whether the recipient has a legitimate, nondiscriminatory reason for taking actions that conflict with section 1557. OCR is adding § 92.3(d) regarding State and local laws to provide: ''Nothing in this part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.''

Comment: Commenters recommended that OCR include in the final rule clarification that the Emergency Medical Treatment and Labor Act (EMTALA) protects emergency care for pregnancy and related conditions, including termination of pregnancy.

Response: This rule concerns section 1557 and does not purport to interpret or enforce EMTALA—indeed, OCR does not enforce EMTALA, nor does EMTALA limit or expand the civil rights protections found in section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.3, with modifications. We are revising § 92.3(c) to provide that, insofar as the application of any requirement under the part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. For example, 42 U.S.C. 18023 provides (among other things) that, nothing in section 1557 shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. We are also adding a new § 92.3(d) to provide that nothing in the part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

Definitions (§ 92.4)

In § 92.4 of the Proposed Rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Auxiliary aids and services. The term auxiliary aids and services was defined in the 2016 Rule and has not been changed substantively. The proposed definition is consistent with the Americans with Disabilities Act (ADA) regulations at 28 CFR 35.104 and 36.303(b) and provides examples of auxiliary aids and services.

Comment: Commenters generally supported the definition of ''auxiliary aids and services.'' Some commenters recommended that the final rule clarify that ''similar services and actions'' are available for all individuals with disabilities, not just for individuals who are deaf or hard of hearing and individuals who are blind or have low vision.

Response: OCR appreciates this comment; however, effective communication requirements are addressed in § 92.202(a). As § 92.4 is simply providing a definition for the term auxiliary aids and services, which is used in § 92.202(b), we do not believe

[34] *See St. Louis Effort for AIDS* v. *Huff,* 782 F.3d 1016, 1021, 1024 (8th Cir. 2015) (partially affirming lower court preliminary injunction because Missouri law ''frustrates Congress' purpose'' and ''pose[s] an obstacle to the accomplishment and execution of the full purposes and objectives of Congress''); *Coons* v. *Lew,* 762 F.3d 891 (9th Cir. 2014), *as amended,* (Sept. 2, 2014) (''The Affordable Care Act presents a classic case of preemption by implication because the Arizona Act 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' ''), *quoting Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992).

it is appropriate to adopt language suggested by the commenters.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''auxiliary aids and services'' as proposed in § 92.4, with one technical correction in paragraph (1) to provide the correct cite for the title II definition of ''qualified interpreter'' by striking ''36.303(b)'' and replacing it with ''36.104.''

Companion. We proposed to define the ''companion'' to mean ''family member, friend, or associate of an individual seeking access to a service, program, or activity of a covered entity, who along with such individual, is an appropriate person with whom a covered entity should communicate.'' This term appeared in the 2016 Rule and has not been changed substantively.

Comment: Many commenters support the inclusion of the term ''companion'' in the definitions section of the regulation, and some highlighted that companions for persons with certain disabilities, such as brain injuries and other conditions with cognitive effects, as well as individuals with sensory disabilities, are critical to effective communication of very sensitive and important medical information. Some commenters suggested that OCR clarify that such companions should be selected by the patient and not the provider.

Response: OCR appreciates the commenters' support for inclusion of this definition. OCR declines to add additional language, as the definition of ''companion'' in this rule is consistent with the definition from 28 CFR 35.160(a)(2) under title II of the ADA, and with the proposed definition in OCR's notice of proposed rulemaking for section 504 at proposed 45 CFR 84.10.[35] We agree that the individual with a disability should be the one to determine who shall serve as their companion absent any concerns of conflict of interest or suspected abuse.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''companion'' as proposed in § 92.4, without modification.

Federal financial assistance. We proposed to define the term ''Federal financial assistance'' to include grants, loans, and other types of assistance from the Federal Government, consistent with the definition of the term in the section 504 and the Age Act implementing regulations at 45 CFR 84.3(h) and 91.4, respectively. We also proposed to specifically include credits, subsidies, and contracts of insurance, in accordance with the statutory language of section 1557. 42 U.S.C. 18116(a). Consistent with the 2016 Rule, we proposed including a clause to clarify that Federal financial assistance includes Federal financial assistance that the Department plays a role in providing or administering.

Comment: Many commenters supported the inclusion of credits, subsidies, contracts of insurance, and grants and loans in this definition. Some commenters recommended expanding the definition of ''Federal financial assistance'' to include Federal disaster relief loans and pandemic relief grants and loans.

Response: The definition of ''Federal financial assistance'' includes funds provided by the Federal Government, including grants and loans, along with Federal financial assistance that the Department plays a role in providing or administering. Because the types of funds raised by the commenters already fall under the longstanding definition of ''Federal financial assistance,'' and the inclusion of specific types of Federal financial assistance would cause unnecessary confusion and may be read as unintentionally limiting the scope of what constitutes Federal financial assistance, we decline to revise the definition.

Comment: Some commenters requested that OCR clarify whether tax-exempt status is considered Federal financial assistance.

Response: OCR appreciates commenters' request for clarity. Generally, tax benefits, tax exemptions, tax deductions, and most tax credits are not included in the statutory or regulatory definitions of Federal financial assistance. *See, e.g.,* 42 U.S.C. 2000d–1 (title VI); 28 CFR. 42.102(c) (Department of Justice Title VI Regulation). Most courts that have considered the issue have concluded that typical tax benefits are not Federal financial assistance because they are not contractual in nature.[36]

Comment: Many commenters supported the definition's inclusion of Federal financial assistance that ''the Department plays a role in providing or administering, including advance payments of the premium tax credit and cost-sharing reduction payments.'' [37] A commenter expressed support for this definition's application to funds extended via programs operated by States under section 1332 State Innovation Waivers, 42 U.S.C. 18052, which could include funds extended to issuers receiving reimbursement through reinsurance programs and entities participating in programs intended to modify or replace Exchanges that would otherwise be within the scope of section 1557.

Response: OCR appreciates these comments and believes it is important to explicitly state in regulatory text that funds that the Department plays a role in providing or administering constitute Federal financial assistance. As explained in the Proposed Rule, 87 FR 47843, this includes funds the Department administers with the Department of the Treasury under the ACA, including advance payments of the premium tax credit, cost-sharing reductions,[38] and pass-through funding available to States with approved section 1332 waivers. Thus, an issuer participating in any Exchange that receives advance payments of the premium tax credit or cost-sharing reductions on behalf of any of its enrollees is receiving Federal financial assistance from the Department.

Section 1332 of the ACA permits a State to apply for a section 1332 waiver to pursue innovative strategies for providing residents with access to high quality, affordable health insurance while retaining the basic protections of the ACA. Section 1332 waiver funds constitute Federal financial assistance and States receiving such funds are recipients. As discussed in the 2022 NPRM, section 1332 allows States to apply to HHS and the Department of the Treasury to waive certain ACA requirements in the individual and small group markets if the waiver satisfies certain statutory

[35] *See* 88 FR 63392, 63465 (Sept. 14, 2023) (proposing to define ''companion'' consistent with ADA title II regulations).

[36] *See, e.g., Paralyzed Veterans of Am.* v. *Civil Aeronautics Bd.,* 752 F.2d 694, 708–09 (D.C. Cir. 1985); *Johnny's Icehouse, Inca* v. *Amateur Hockey Ass'n of Ill., Inc.,* 134 F. Supp. 2d 965, 971–7297172 (N.D. Ill. 2001); *Chaplin* v. *Consol. Edison Co.,* 628 F. Supp. 143, 145–46 (S.D.N.Y. 1986).

[37] *See* section 1412 of the ACA, codified at 42 U.S.C. 18082 (Advance determination and payment of premium tax credits and cost-sharing reductions).

[38] The Department is not currently making cost-sharing reduction payments to issuers. *See* Memo. from Eric Hargan, Acting Sec'y, U.S. Dep't of Health & Hum. Servs., to Seema Verma, Admin'r, Ctrs. for Medicare & Medicaid Servs. (enclosing Attorney General Jeff Sessions' legal opinion, dated October 11, 2017, regarding cost-sharing reduction payments) (Oct. 12, 2017), *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.* If the Department begins making cost-sharing reduction payments in the future, such payments would be considered Federal financial assistance.

requirements.[39] 87 FR 47843. For example, under this provision, several States have utilized section 1332 waivers to introduce new or expanded plan options to consumers that lower premiums and/or expand access to coverage, or implemented reinsurance programs to lower premiums and stabilize the individual or small group market by compensating issuers for eligible high-cost claims for enrollees with significant medical costs. These State reinsurance programs use section 1332 pass-through funding to reimburse eligible issuers for high-cost enrollees. These States establish reimbursement eligibility criteria for issuers under the State's reinsurance program, which may include payments to issuers offering coverage both on and off the Exchange. Health insurance issuers receiving payments through a State's section 1332 waiver reinsurance program are subrecipients and therefore subject to section 1557. To the extent a State's waiver utilizes pass-through funding for provider reimbursement those providers would also be subrecipients and subject to section 1557; however pass-through funding received by individual consumers would not be subject to section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''Federal financial assistance'' as proposed in § 92.4, without modification.

Health program or activity. OCR proposed to adopt a definition of ''health program or activity.'' In paragraph (1), we proposed defining health program or activity to mean any project, enterprise, venture, or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage; provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; provide clinical, pharmaceutical, or medical care; engage in health research; or provide health education for health care professionals or others.

In paragraph (2), we proposed further defining ''health program or activity'' to include all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings described in paragraph (1) (''principally engaged''). We proposed that whether such entities are administered by a government or a private entity, all of their operations would be covered under this part.[40] We also invited comment on the circumstances under which a group health plan might receive funds that could be considered Federal financial assistance from the Department, including the type and prevalence of funds received that could be considered Federal financial assistance under this part.

Comment: Commenters expressed a variety of views regarding the application of the rule to health insurance issuers as health programs or activities and the rule's application to all their operations when principally engaged in any project, enterprise, venture, or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage, as set forth under paragraph (2) of the definition of ''health program or activity.''

Many commenters supported the inclusion of health insurance issuers and coverage of all their operations when so principally engaged. These commenters argued the 2020 Rule's approach, which applies to health insurance issuers only to the extent a specific plan receives Federal financial assistance, is contrary to the text of section 1557, the CRRA, and the broad remedial intent of Congress in enacting the ACA to ensure access to health insurance. Specifically, commenters argued the 2020 Rule is arbitrary and contrary to the plain language of section 1557, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance*'' (emphasis added) and specifically includes three examples of Federal financial assistance that refer to health insurance (''credits, subsidies, or contracts of insurance''). 42 U.S.C. 18116(a). This statutory language, commenters argued, affirms that Congress intended section 1557 to apply to the entire health program or activity, not just the parts that directly receive Federal financial assistance. Commenters noted that the statutory text should be construed broadly and stated that the Proposed Rule's application to health insurance will align with the application to all operations of other covered entities.

Many commenters raised objections to the 2020 Rule's provision at § 92.3(b) that covers all operations of an entity only when principally engaged ''in the business of providing *healthcare*'' (emphasis added), in combination with § 92.3(c) that specified a health insurance issuer was not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance, which resulted in the 2020 Rule not covering all operations of a recipient health insurance issuer. Commenters stated this approach was inconsistent with Congress's approach in the CRRA, which supports an expansive interpretation of section 1557's application to cover all operations of a recipient if any part of it receives Federal financial assistance. Specifically, one commenter asserted that the section 1557 statute's use of the CRRA language ''program or activity'' and ''any part of which,'' coupled with the statute's reference to title VI, title IX, section 504, and the Age Act, demonstrate Congress's intent to adopt the same broad application for section 1557. Commenters also argued the 2020 Rule's approach is inconsistent with the text of section 1557, which broadly applies to health programs or activities and is not limited to the delivery of health care. Commenters challenged the 2020 Rule's contention that health insurance is not health care, arguing that health insurance issuers are in fact engaged in the business of health care and that other parts of the ACA support this position. For example, ''health care entity'' is defined to include ''a health insurance plan'' under 42 U.S.C. 18113(b) and 42 U.S.C. 300gg–91(b)(1) defines ''health insurance coverage'' to mean benefits consisting of medical care.'' Among other things, commenters cited to section 1551 of the ACA, 42 U.S.C. 18111, which specifies that, unless otherwise indicated, the definitions in 42 U.S.C. 300gg–91 apply to title I of the ACA.

Conversely, other commenters urged the Department to retain the 2020 Rule's approach, asserting that the CRRA limits the scope of section 1557 with regard to all operations of a program or activity to only those that are ''principally engaged in the business of providing . . . *healthcare*'' (emphasis added).

Others argued that the Proposed Rule's application to health insurance is

[39] Sections 1332(a)–(b) of the ACA, codified at 42 U.S.C. 18052(a)–(b). States with approved waivers have specific terms and conditions (STCs) pursuant to which the state must also comply with all applicable Federal statutes relating to nondiscrimination, including section 1557. *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., approval of New Jersey's extension application for a section 1332 State Innovation Waiver, STC 4 (Aug. 15, 2023), *https://www.cms.gov/files/document/1332-nj-extension-approval-letter-stcs-final.pdf.*

[40] *See, e.g., Fain* v. *Crouch,* 545 F. Supp. 3d 338, 343 (S.D.W. Va. 2021), *rehearing en banc granted,* No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721) (holding that defendant health plan was, ''by virtue of its acceptance of Federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio'').

too broad and should not apply to all operations of a health insurance issuer, particularly its lines of business that do not receive Federal financial assistance. Specifically, commenters noted that because health insurance issuers participate in some types of health insurance that receive Federal financial assistance and other types that do not, the Proposed Rule would require compliance even in activities that do not benefit from Federal financial assistance. Commenters opined that this interpretation goes beyond the scope of Congressional intent, where Congress did not apply the protections to *any* entity engaging in health programs and activities, but only to those health programs and activities that specifically receive Federal financial assistance. One organization asserted that the Proposed Rule could result in health insurance issuers incurring substantial costs and declining to participate in or withdrawing from the Exchanges, the Medicaid managed care market, or the Medicare Advantage market, resulting in reduced coverage options in those markets.

Response: In re-evaluating the 2020 Rule's interpretation of ''health program or activity'' as it relates to health insurance and in deciding to add a definition of ''health program or activity,'' OCR considered a number of factors, including the plain language of section 1557, the context of its placement within the ACA, long-standing civil rights principles, and relevant case law.

The 2020 Rule does not include a definition of ''health program or activity,'' but rather addresses the term under § 92.3, the scope of application section. The 2020 Rule provides that ''health program or activity'' encompasses ''all of the operations of entities principally engaged in the business of providing *healthcare*'' (emphasis added) and specifies that a health insurance issuer is not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance. 45 CFR 92.3. The 2020 Rule further provides that for entities not principally engaged in the business of providing health care, their operations are only covered under the rule to the extent such operation is a health program or activity that receives Federal financial assistance. 45 CFR 92.3(b). Thus, the 2020 Rule limits OCR's jurisdiction over health insurance issuers to only their plans that directly receive Federal financial assistance. This is in contrast to the 2016 Rule, which defined ''health program or activity'' to include all the operations of entities principally engaged in health services, health insurance coverage, or other health-related coverage, including health insurance issuers, at former 45 CFR 92.4.

OCR agrees with commenters' assessment that the Proposed Rule's approach to the inclusion of health insurance coverage and other health-related coverage in the definition of ''health program or activity'' is most consistent with section 1557's statutory text and Congressional intent. The statutory text demonstrates Congress's clear intent to apply section 1557 to health insurance coverage and other health-related coverage. This statutory text does not support the 2020 Rule's limiting ''health program or activity'' to encompass all of the operations of only those entities principally engaged in the business of providing ''healthcare.'' Under the plain language of the statute, section 1557 applies to any ''health'' program or activity not ''healthcare'' program or activity. And the provision of health insurance coverage and other health-related coverage is plainly classified under the term ''health.'' Private health insurance issuers exercise significant control over enrollees' access to health care and play a critical role in the business of health care, as insurance is an essential component of ensuring that people receive care in the current health care system. For example, a district court opinion on this issue held that a health insurance issuer, by virtue of being the ''gatekeeper'' to the plaintiff's health services, qualified as a '' 'health program' that Congress intended to rid of discrimination.'' [41]

Further, as we discussed in the Proposed Rule, 87 FR 47845, the fact that Congress placed section 1557 in title I of the ACA, a title that predominantly regulates health insurance coverage and other health-related coverage with the purpose of increasing access to care and reducing discriminatory insurance practices, demonstrates Congress's intent for section 1557 to protect individuals from discrimination in health insurance coverage and other health-related coverage.

While not dispositive, we do appreciate commenters' thoughts on whether health insurance issuers are in fact engaged in the business of providing health care. Commenters among other things, cited to section 1551 of the ACA, which specifies that, unless otherwise indicated, the definitions in 42 U.S.C. 300gg–91 shall apply with respect to title I of the ACA. Section 300gg–91(b)(1) defines the term ''health insurance coverage'' as ''benefits consisting of *medical care (provided directly, through insurance or reimbursement,* or otherwise and including items and services paid for as medical care) . . . .'' (Emphasis added.) The 2020 Rule specifies that ''medical care'' as used in that provision is limited to the ''amounts paid for'' certain medical services and that a health insurance issuer is not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance. However, the text of section 1557 does not support the 2020 Rule's position that the rule applies only to the business of providing ''healthcare.''

OCR found commenters' concerns regarding the negative consequences that could result from the Proposed Rule's scope of application to insurance issuers unpersuasive given the lack of information provided to substantiate their concerns. For example, one commenter cited to Exchange participation statistics that indicated certain issuers have limited or no Exchange participation.[42] However, the statistics do not demonstrate the reason for such issuers' lack of participation or provide evidence that an issuer's decision not to participate in an Exchange was due to apprehension that section 1557 would apply to its activities that did not receive Federal financial assistance.

The application of civil rights laws to all operations of an entity receiving Federal financial assistance is not new and did not originate with section 1557. For more than 35 years, under the CRRA, a recipient of Federal financial assistance that accepts Federal funds in any part of its program has been required to comply with title VI, section 504, and the Age Act in ''all of the[ir] operations.'' [43] The CRRA specifies that the entire program or activity, as defined in that statute, is required to comply with title VI, section 504, and the Age Act if any part of the program or activity receives Federal financial

[41] *Fain* v. *Crouch,* 545 F. Supp. 3d 338, 342–43 (S.D.W. Va. 2021) (finding '' 'health program or activity' under Section 1557 necessarily includes health insurance issuers'' and holding that defendant health plan was, ''by virtue of its acceptance of federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio''), *rehearing en banc granted,* No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721).

[42] Mark Farrah Assocs., *http://www.markfarrah.com* (statistics compiled using data from the National Association of Insurance Commissioners, the California Department of Managed Health Care, and CMS).

[43] Public Law 100–259, 102 Stat. 29 (Mar. 1988), codified at 20 U.S.C. 1687; 29 U.S.C. 794(b); 42 U.S.C. 2000d–4(a); 6107(4).

assistance. We note that the terms ''program'' and ''program or activity'' predate the CRRA in the underlying civil rights statutes, and the legislative history of the CRRA indicates that Congress did not believe it was enacting a new definition, but rather overturning an overly narrow construction of the term by the Supreme Court and thereby restoring what Congress and the executive branch had previously understood to be a broad, institution-wide application of the term ''program.'' *See* S. Rep. No. 100–64 (1987). OCR maintains that Congress adopted a similar approach in section 1557 by specifying in the statute that section 1557 applies when ''any part of'' the health program or activity receives Federal financial assistance.[44] Entities must comply with civil rights laws just as they must comply with any other State or Federal law that is applicable to their operations.

The 2020 Rule states it was applying the CRRA's definition of ''program or activity'' to cover all operations of entities under section 1557 only when they are ''principally engaged in the business of providing healthcare.'' We received some comments in support of the approach in that rulemaking, and while we appreciate the importance of the CRRA in shaping the interpretation of the scope of Federal civil rights protections under title VI, section 504, title IX, and the Age Act, it is not applicable here. Section 1557 employs the term ''program or activity'' without adopting by reference the CRRA or any of the underlying civil rights statutes. The 2020 Rule erred in applying the CRRA to narrow the application of section 1557 by excluding a significant portion of the health insurance industry. If Congress had intended to limit section 1557 to entities principally engaged in the business of providing ''healthcare,'' it could have provided as such in the statute. Instead, the statute expressly modified ''program or activity'' with ''health,'' without requiring that that entity be ''principally engaged in the business of providing healthcare.''

While Congress did not incorporate the CRRA into section 1557 wholesale, it stated that section 1557 applies to ''any health program or activity, *any part of which* is receiving Federal financial assistance.'' 42 U.S.C. 18116(a) (emphasis added). By modifying ''program or activity'' with ''health,'' and noting a health programs or activity is covered if ''any part'' of it receives Federal financial assistance, it is reasonable to infer that Congress intended the term ''health program or activity'' to be interpreted broadly and to include all of that entity's operations, if the entity that receives Federal funding is principally engaged in the provision or administration of health insurance coverage or other health-related coverage. And because ''health program and activity'' is undefined in the section 1557 statute, it is also reasonable to infer that those health programs or activities include health-related services, health insurance coverage, or other health-related coverage.

Comment: One commenter argued that, because the CRRA delineates the scope of coverage of section 1557's underlying civil rights statutes, failing to include this limitation in the final rule would expand the notion of Federal financial assistance to ultimate beneficiaries of the funding and would have significant effect on other civil rights laws dealing with funding, including title VI, title IX, and others.

Response: The commenter's concerns regarding interference with the longstanding principle that Federal civil rights laws do not apply to direct, unconditional assistance to ultimate beneficiaries are unsupported. Ultimate beneficiaries are the intended class of private individuals receiving Federal aid,[45] a concept that is not impacted or modified under this rulemaking. In fact, the definition of ''recipient'' in the final rule at § 92.4 adopts standard language that explicitly states that the term ''does not include any ultimate beneficiary.''

Comment: OCR received comments specifically related to the rule's application to health insurance issuers' other products and lines of business that do not receive Federal financial assistance, such as health insurance coverage sold off the Exchange, excepted benefits, short-term, limited-duration insurance, and third party administrator activities.

Response: These comments are addressed in the *Scope of Application* discussion under § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage).

Comment: Some commenters, including an association representing State insurance regulators, critiqued OCR's ''fungibility of funds'' rationale for including all operations of recipients that are principally engaged in the provision or administration of health insurance coverage. These commenters argued it is inappropriate to consider funding to be fully fungible in the context of health insurance, where issuers justify their premiums based on expected costs in a particular market, not across all operations, and thus Federal financial assistance for one type of coverage does not actuarially support or subsidize an issuer's operations in other markets. Commenters noted that entities have a myriad of corporate structures, and that Federal funds received by one legal entity might not be shared with sibling entities in unrelated business ventures. Commenters pointed to the 2016 Rule's analysis regarding liability of third party administrators, where OCR discussed that a third party administrator that is legally separate from an issuer is unlikely to be covered under the rule. 81 FR 31433.

Conversely, other commenters agreed with OCR's fungibility of funds rationale, and argued that Federal financial assistance going to any part of a health program or activity necessarily benefits the entity receiving such funds as a whole. These commenters noted that a narrower construction, in which nondiscrimination rules apply only to part of a recipient, makes it easier for discriminatory actors to structure their operations to evade responsibility and frustrates the purpose of the statute.

Response: As commenters noted, OCR discussed the fungibility of funds rationale as one means of support for the interpretation that all of a health insurance issuer's operations will be covered by the final rule when the health insurance issuer receives Federal financial assistance. *See* 87 FR 47844. However, we note that reliance on this rationale is not necessary to support OCR's interpretation that this final rule applies to all of the operations of a recipient that is ''principally engaged,'' as discussed above. Under the best reading of the statutory text, where an entity receives Federal financial assistance and that entity is ''principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1)'' of the definition of ''health program or activity,'' the whole entity is defined as a health program or activity covered under section 1557 and must comply with the final rule.

We acknowledge that covered entities may structure their businesses in a variety of ways. Unless an entity that is principally engaged can demonstrate that part of their operations is truly a separate legal entity, as discussed below, a recipient that is principally engaged is liable for all its operations under the final rule.

[44] *Compare* CRRA, 20 U.S.C. 1687(4) (''any part of which is extended Federal financial assistance'') *with* section 1557, 42 U.S.C. 18116 (''any part of which is receiving Federal financial assistance'').

[45] U.S. Dep't of Justice, Title VI Legal Manual, section V.C.2.F.

Comment: One organization recommended that OCR explicitly identify patient billing and collections activities as ''health programs or activities'' by amending the definition to add a new paragraph (1)(vi) as follows: ''provide or administer billing and collections services for health-related services, including providing assistance to persons to obtain financial help or counseling.''

Response: This final rule, consistent with OCR's other civil rights implementing regulations, prohibits covered entities—directly or through contractual or other arrangements—from discriminating in patient billing and collection activities related to health programs and activities. For example, a hospital's in-house administration of billing would be covered and any contractual arrangement for collections of debt would also be covered. We decline to add the recommended language because it is unnecessary.

Comment: Many commenters strongly supported the Proposed Rule's explicit inclusion of health research in the definition of ''health program or activity.'' Some commenters recommended updating paragraph (1)(iv) to include ''clinical'' research for clarity and to update paragraph (2) to include: ''clinical trial sites including wherever potential clinical trial participants are screened or recruited'' in the list of entities considered ''principally engaged.'' In addition, other commenters recommended that OCR provide technical guidance in what ''inclusion'' in clinical research looks like and how it can be achieved through nondiscriminatory research protocols.

Response: OCR supports the request to include clinical research in the definition of ''health program and activity,'' and have revised paragraph (1)(iv) accordingly. Clinical research is the comprehensive study of the safety and effectiveness of the most promising advances in patient care, and is different from laboratory research as it involves people who volunteer to help the field better understand medicine and health.[46] However, we decline to add reference to physical sites, as the jurisdiction applies to the health program or activity regardless of where it takes place and whether it can be said to take place at a site at all. For example, if a hospital receives a grant from the National Institutes of Health to conduct a clinical study on the effects of Tuberous Sclerosis Complex, the hospital is prohibited from discriminating in its screening and recruitment activities wherever they take place, such as at the hospital itself, at community health fairs, online, or at the home of a hospital researcher who is working out of their own home.

Comment: One organizational commenter requested that OCR clarify section 1557's application to health research projects and activities to explicitly recognize that health research is conducted to answer specific questions, and that research protocols may target or exclude certain populations where nondiscriminatory justifications show that such criteria are appropriate, consistent with the 2016 Rule preamble.

Response: Consistent with the 2016 Rule, OCR does not intend the inclusion of health or clinical research within the definition of ''health program or activity'' to alter the fundamental nature in which research projects are designed, conducted, or funded. 81 FR 31385. As in the 2016 Rule, we note that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. *See* 81 FR 31385.

Comment: Some commenters recommended that OCR narrow the definition of ''health program or activity'' to exclude programs and activities unrelated to health. These commenters also requested that OCR clarify what ''any project, enterprise, venture or undertaking to provide or administer health-related services'' means. For example, these commenters were unclear whether a health-related venture may include such things as vitamin manufacturing.

Response: The final rule applies to health programs and activities that receive Federal financial assistance from the Department (or that are administered by the Department or a title I entity) and does not apply generally to programs and activities that are unrelated to health. However, where an entity is principally engaged as set forth in paragraph (2) of the definition of ''health program or activity,'' all operations of the covered entity must comply with the final rule. This applies even where the covered entities' other operations are not necessarily health-related.

Though not an exhaustive list, ''health-related service'' would include the provision of medical, dental, and pharmaceutical care; preventive health services; physical, occupational, or speech therapy; behavioral health care; clinical trials; and transportation to and from such services when necessary to facilitate access to other health-related services.[47] Should an entity engaged in commercial vitamin manufacturing receive Federal financial assistance from the Department, OCR would conduct an analysis as to whether the program or activity in question meets the definition of ''health program or activity.''

Comment: A few commenters urged the Department to expressly list Medicaid programs, Children's Health Insurance Program (CHIP), or the Basic Health Program in its definition for ''health program or activity.''

Response: The 2016 Rule included Medicaid programs, CHIP and the Basic Health Program in its definition of ''health program or activity'' at former 45 CFR 92.4. As stated in the preamble to the 2022 NPRM, these entities would be covered in their entirety as operations of State or local health agencies and we sought comment on whether such programs should be explicitly referenced in the regulatory language. 87 FR 47844. For clarity and to reduce confusion, OCR accepts the recommendation to include State Medicaid programs, CHIP, and the Basic Health Program in paragraph (2) of the definition of ''health program or activity.''

Comment: Numerous commenters objected to the 2022 NPRM's proposal to not explicitly include group health plans[48] in the list of entities considered to be principally engaged in paragraph (2) of the ''health program or activity''

[46] John Hopkins Medicine, Research, *Understanding Clinical Trials, Clinical Research: What Is It?, https://www.hopkinsmedicine.org/research/understanding-clinical-trials/clinical-research-what-is-it.html.*

[47] *See, e.g.,* 42 CFR 431.53 (requiring a state Medicaid plan to specify that the Medicaid agency will ensure ''necessary transportation for beneficiaries to and from providers'').

[48] ''Group health plan'' is defined in the Employee Retirement Income Security Act (ERISA) as an employee welfare benefit plan to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. Such term shall not include any qualified small employer health reimbursement arrangement (as defined in 26 U.S.C. 9831(d)(2)). 29 U.S.C. 1191b(a)(1); *see also* 42 U.S.C. 300gg–91(a)(1). ''Employee welfare benefit plan'' is defined in ERISA as any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services, or (B) any benefit described in 29 U.S.C. 186(c) (other than pensions on retirement or death, and insurance to provide such pensions). 29 U.S.C. 1002(1).

definition. Expressing concerns that this would result in confusion that the rule excludes group health plans, commenters urged OCR to reinstate the 2016 Rule's approach by expressly including group health plans in the definition of ''health program or activity.'' Former 45 CFR 92.4.

Commenters further suggested that the rule clarify that group health plans are covered entities when the group health plan itself receives Federal financial assistance or when the employer sponsoring the group health plan receives Federal financial assistance, such as through an Employer Group Waiver Plan (EGWP) or Retiree Drug Subsidy (RDS) plan. Some commenters argued that an employer and a group health plan should not be treated as distinct entities for purposes of section 1557 jurisdiction, and that group health plans should be considered indirect recipients of Federal financial assistance when the employer receives Federal funds.

Other commenters stated that employers are usually the sponsors of group health plans and were concerned that OCR's case-by-case analysis may find an employer liable under section 1557 based on the employee benefits it provides. Several commenters expressed concerns with OCR's proposed approach to conduct a case-by-case review to determine whether a group health plan is a covered entity and requested that OCR provide additional clarity on when employers and group health plans are liable under the rule.

Response: Commenters' concerns that group health plans would never be subject to the rule if they are not expressly included in the definition of ''health program or activity'' are unwarranted. The list of entities included as principally engaged, at paragraph (2), is not exhaustive. The fact that a group health plan is not expressly included in paragraph (2) does not affect the determination of whether a group health plan is principally engaged under this definition. As group health plans provide or administer group health coverage, they would be operating a health program or activity under the rule and would be subject to this rule if in receipt of Federal financial assistance. Further, recipient group health plans, like health insurance issuers, would be considered to be principally engaged in the provision or administration of health insurance coverage or other health-related coverage, meaning all their operations would be covered.

In the 2022 NPRM, we declined to expressly include group health plans in the definition of ''health program or activity'' in an attempt to reduce confusion because many group health plans do not receive Federal financial assistance. 87 FR 47845. It remains OCR's understanding that many group health plans do not receive Federal financial assistance, and thus we decline commenters' request to add group health plans to the non-exhaustive list of entities that are considered principally engaged that is provided in paragraph (2) of the definition of ''health program or activity.''

A group health plan that receives Federal financial assistance itself is distinct from other entities that might separately receive Federal financial assistance, such as the plan sponsor of the group health plan or the third party administrator administering the plan. As such, a group health plan does not necessarily become a covered entity under this rule by virtue of the plan sponsor or third party administrator's receipt of Federal financial assistance. Single employers that are plan sponsors of single-employer group health plans and joint boards of trustees or similar bodies, associations, and other groups that are plan sponsors of multiemployer Taft-Hartley plans or multiple employer welfare arrangements (MEWAs) do not become covered entities under the rule due to their employment practices, including the provision of employee health benefits. Later in this section, we address how OCR will determine whether related business entities are considered separate legal entities under section 1557.

When OCR receives a complaint alleging discrimination related to a group health plan, we will conduct a fact-specific analysis to determine if the group health plan is a recipient or subrecipient of Federal financial assistance. We decline to take the position that a group health plan is an indirect recipient of Federal financial assistance whenever the plan sponsor receives Federal financial assistance. Determining whether an entity is an indirect recipient requires a fact-specific inquiry.[49]

Entities that receive Federal financial assistance from the Department for an EGWP or RDS plan would be subject to this rule, though we note that employers and other plan sponsors are not subject to this rule with regard to their employment practices, pursuant to § 92.2(b). This includes when the Federal financial assistance received is for their employee health benefits. For more information about employer and plan sponsor liability, see the previous discussion under § 92.2(b).

In addition, as noted in the Proposed Rule, covered entities that contract with a group health plan could be subject to this rule themselves, regardless of the group health plan's liability. For instance, recipient health insurance issuers may be covered under this rule when offering health insurance coverage to a fully-insured group health plan or when providing third party administrator services for a self-funded group health plan.[50] We also noted in the Proposed Rule at 87 FR 47845 that even if a group health plan is not subject to section 1557, group health plans may be subject to other Federal nondiscrimination requirements.[51]

Comment: Some commenters urged OCR to expressly include pharmacy benefit managers in the definition of ''health program or activity.'' Commenters argued it was important to do so because pharmacy benefit managers play a significant role in developing and administering prescription drug benefits, and section 1557 can serve to prevent certain practices that may result in discriminatory access to medications, such as coverage criteria, utilization management practices, limitations on

[49] *See, e.g., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–CV–01031–EMC, 2022 WL 3139516, slip op. at 7, 9 (N.D. Cal. Aug. 5, 2022) (analyzing whether defendant pharmacy benefit manager is an indirect recipient of Federal financial assistance from defendant pharmacy chain and, relying on the section 1557 statute and 2020 Rule, holding that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[50] *See, e.g., Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017) (holding that a third party administrator could be liable under section 1557 for damages arising from discriminatory terms in a self-funded employer-provided health plan if the third party administrator provided the employer with a discriminatory plan document, notwithstanding the fact that the employer subsequently adopted the plan and maintained control over its terms); *C.P.* v. *Blue Cross Blue Shield of Ill.,* No. 20–cv–6145, 2022 WL 17788148, *7–9 (W.D. Wash. Dec. 19, 2022) (relying on the section 1557 statute because the ''2020 Rule is contrary to the statutory law, and the rule appears to be arbitrary, capricious and contrary to law,'' and holding that a health insurance issuer acting as a third party administrator for a self-funded employer-provided plan is a covered entity under section 1557, regardless of whether the discriminatory exclusion originated with the third party administrator, and ERISA's requirement that decisions be made in accordance with the plan documents is no defense as ERISA expressly provides that it is not to be construed to invalidate or impair Federal laws like section 1557).

[51] For example, group health plans and health insurance issuers offering group or individual health insurance coverage are generally prohibited from establishing any rule for eligibility, benefits, or premiums or contributions that discriminates based on any health factor. 26 U.S.C. 9802: 29 U.S.C. 1182; 42 U.S.C. 300gg–4; 26 CFR 54.9802–1; 29 CFR 2590.702; 45 CFR 146.121, 147.110.

where medicines can be dispensed, and high out of pocket costs.

Response: We decline to list pharmacy benefit managers expressly in paragraph (2) of the definition of ''health program or activity.'' Pharmacy benefit managers are entities that manage prescription drug benefits for issuers, group health plans, Medicare Part D drug plans, and other payers, such as State Medicaid programs (collectively known as ''payers'').[52] In their role of administering prescription drug benefits on behalf of payers, pharmacy benefit managers develop drug formularies and related policies, create pharmacy networks, reimburse pharmacies for patients' prescriptions, negotiate rebates and fees with drug manufacturers, process enrollees' claims and appeals, and review drug utilization, among other things.[53] These activities constitute the operation of health programs and activities under section 1557.

If pharmacy benefit managers receive Federal financial assistance from the Department, either directly or indirectly, they are subject to this rule. Further, if they are principally engaged under paragraph (2), all their operations are covered by the rule.

As discussed previously, the fact that a type of entity—such as a pharmacy benefit manager—is not expressly included in the definition of ''health program or activity'' does not mean that those entities are excluded from the rule or could never be subject to section 1557 jurisdiction. Even if a pharmacy benefit manager does not receive direct Federal financial assistance, we note that the three largest pharmacy benefit managers are integrated with large health insurance or pharmacy companies, and thus could be covered under the rule as part of the operations of a health program or activity receiving Federal financial assistance.[54]

Determining whether a pharmacy benefit manager is subject to the rule as part of the operations of a recipient health program or activity is a fact-specific analysis based on the corporate structure of the entity.

Comment: Commenters requested that OCR provide more clarity on how it will analyze whether corporate subsidiaries and related business entities are subject to section 1557 as part of a covered entity's operations. Specifically, some commenters were concerned about health insurance issuers that receive Federal financial assistance avoiding responsibility through use of subsidiaries in their other activities, such as third party administrators or pharmacy benefit managers. Conversely, other commenters expressed concerns that the rule would apply too broadly to an issuer's business ventures that are unrelated to their federally funded activities.

Response: As stated throughout this section, if any part of a health program or activity receives Federal financial assistance and the entity administering said health program or activity is principally engaged as provided in paragraph (2), then all the operations of the recipient are subject to the rule. If a part of a recipient's operations is determined to be a separate legal entity independent from its federally funded activities, that part would not be subject to the rule. When determining whether an entity's subsidiaries or other entities are legally separate from the federally funded activities, OCR may consider—among other things—the organizational structure and the interrelatedness between the entities, such as the degree of common ownership, management, and control between the entities, and whether the entities share centralized control of labor relations; whether the entity has some ability to accept or reject the Federal funding or exercise controlling authority over a federally funded program; [55] and whether the purpose of the legal separation was to avoid liability or avoid the application of civil rights law requirements, meaning it is intended to allow the entity to continue to discriminate.[56]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''health program or activity'' as proposed in § 92.4, with modifications. We have revised paragraph (1)(iv) to include clinical research, such that it will now read: ''Engage in health or clinical research.'' We have also revised paragraph (2) to include ''a State Medicaid program, Children's Health Insurance Program, and Basic Health Program'' as examples of entities principally engaged under this definition.

Information and communication technology (ICT). We proposed to define the term ''ICT'' to mean ''information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content.'' We also provided examples of ICT in our proposed definition.

Comment: Some commenters urged OCR to include ''electronic health records (EHRs)'' as an example within the definition of ''information and communication technology''.

Response: We appreciate that there are many different examples that can fit within the definition of ''information and communication technology''. We agree that EHRs meet the definition of ''information and communication technology''; however, we believe that it is unnecessary to specify this in the final rule.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''information and communication technology'' as proposed in § 92.4, without modification.

Language assistance services. OCR proposed to define the term ''language assistance services'' to include, but not be limited to: (1) oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for a limited English proficient individual, and the use of services of qualified bilingual or multilingual staff to communicate directly with limited English proficient

[52] Staff of H. Comm. on Oversight & Reform, 117th Cong., *A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets,* 6 (Dec. 10, 2021), *https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf*.

[53] *See, e.g.,* U.S. Gov't Accountability Off., GAO 19–19–498, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,* 14–15, 39–42 (2019), *https://www.gao.gov/assets/gao-19-498.pdf*; Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers,* pp. 3–4 (2023), *https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf*.

[54] *See Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, 2022 WL 3139516, slip op. at 7, 9 (N.D. Cal., Aug. 5, 2022) (relying on the section 1557 statute and 2020 Rule when finding that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[55] *See id. Cf. Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.,* 69 F.3d 1235, 1240–42 (2d Cir. 1995) (title VII); *Valesky* v. *Aquinas Acad.,* 2011 U.S. Dist. LEXIS 103791, No. 09–800 (W.D. Pa. Sept. 14, 2011) (title IX); *Russo* v *Diocese of Greenberg,* 2010 U.S. Dist. LEXIS 96338, No. 09–1169 (W.D. Pa. Sept. 15, 2010) (title IX, section 504); *Margeson* v. *Springfield Terminal Railway Co.,* 1993 U.S. Dist. LEXIS 12243, No. CIV.A. 91–11475–Z (D. Mass. Aug. 24, 1993) (section 504).

[56] *Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 941 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999).

individuals; (2) written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and (3) written notice of availability of language assistance services. The definitions of oral language assistance and written translation appeared in both the 2016 Rule at former § 92.4 and the 2020 Rule at § 92.101 in paragraphs (2)(i) and (iii) and have not been changed. The 2016 Rule did not explicitly include a written notice of availability of language assistance services in the definition of ''language assistance services,'' but rather included the term ''taglines,'' which was defined to mean ''short statements written in non-English languages that indicate the availability of language assistance services free of charge.''

Comment: One commenter recommended that the definition of ''language assistance services'' include assistance with form completion in another language. The commenter noted that many individuals with limited English proficiency (LEP) as well as many others (including older individuals and those with limited access to technology) have difficulty completing online forms to apply for health benefits or report life changes.

Response: OCR appreciates the suggestion and agrees it is critical for individuals with LEP to receive language assistance in completing forms. The definition of ''language assistance services'' is intended to provide a non-exhaustive list of some of the means by which a covered entity may facilitate such access—namely, oral interpretation and written translation as provided by qualified interpreters and translators, respectively. This definition works together with the requirements at § 92.201, which provide that covered entities must take reasonable steps to provide meaningful access to individuals with LEP. If an individual with LEP needs assistance with form completion in a covered health program or activity, a covered entity must provide language assistance services consistent with the requirements at § 92.201. OCR declines to modify the definition of ''language assistance services'' as suggested because the context in which services are provided is not germane to the definition.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''language assistance services'' as proposed in § 92.4, with modification. As discussed in the following summary of regulatory changes to the proposed term ''limited English proficient individual,'' we are revising the term to ''individual with limited English proficiency'' in § 92.4.

Limited English proficient individual. OCR proposed to define the term ''limited English proficient individual'' to mean ''an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.'' Further, OCR proposed that a ''limited English proficient individual'' ''may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be limited English proficient for other purposes (*e.g.,* reading or writing).'' These definitions appeared in the 2016 Rule and have not changed substantively. Former 45 CFR 92.4 (2016 Rule). OCR sought comment on whether to use the term ''limited English proficient individual'' or ''individual with limited English proficiency'' throughout the rule.

Comment: Some commenters recommended the final rule adopt the language either ''people with limited English proficiency'' or ''individual with limited English proficiency'' instead of ''limited English proficient individual.''

Response: OCR agrees with this recommendation and OCR is finalizing the rule with the term ''individual with limited English proficiency'' throughout.

Comment: Several commenters supported the proposed definition's emphasis that an individual with LEP includes those who may be competent in English for certain types of communication but still have limited English proficiency for other purposes. Commenters explained that this will ensure providers and other covered entities understand that people who have some English competency may still need translated written materials. Commenters noted this will improve language access and have far-reaching consequences for patients who both seek and receive care, which will also reduce barriers to quality health care for individuals with LEP.

Response: We appreciate the support of inclusion of additional details around what it means to be ''limited English proficient'' and are finalizing the definition as proposed.

Comment: A few commenters that agreed with the proposed definition urged that the word ''and'' be replaced with ''or'' to read ''an individual whose primary language for communication is not English *or* who has a limited ability to read, write, speak, or understand English . . .'' These commenters explained that there are many people in the United States whose primary language is English but who have a limited ability to read, write, speak, or understand English, for reasons that may or may not be related to disability, who deserve protection from discrimination.

Response: OCR appreciates the commenters' recommendation and recognizes that there are many individuals whose primary language is English but who have a limited ability to read, write, speak, or understand English. However, section 1557's language access provisions rely on the statute's prohibition on national origin discrimination.[57] For individuals with LEP, the lack of proficiency in English and the use of non-English languages is often tied to their national origin. Changing the definition to include an individual who has a limited ability to read, write, speak, or understand English, but whose primary language is English, would go beyond national origin discrimination. With respect to individuals who have a limited ability to read, write, speak, or understand English related to disability, § 92.202 addresses requirements for effective communication for individuals with disabilities, which is a long-standing requirement.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''limited English proficient individual'' as proposed in § 92.4, with modification. We are changing ''limited English proficient individual'' to ''individual with limited English proficiency'' in § 92.4 and throughout the final rule.

Machine translation. OCR proposed to define the term ''machine translation'' to mean ''automated translation, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.'' Neither the 2016 Rule nor the 2020 Rule addressed machine translation. We invited comment on the adequacy of this new definition.

Comment: We received many comments in support of the inclusion of a definition of ''machine translation''. One commenter supported the language as proposed but noted the importance of adaptability and potential for future regulation or guidance over time as

[57] *See Lau* v. *Nichols,* 414 U.S. 563, 568–69 (1974).

technology changes. For example, machine translation companies may develop technology that includes some level of human review but remains insufficient for the purposes of conforming with the intent of this rule.

Response: We appreciate commenters' support for the inclusion of this definition. The requirement to provide written translations via a qualified translator included at § 92.201(c)(2) continues to apply, regardless of whether human or machine translation is provided. Section 92.201(c)(3) requires a human translator to review machine translation under certain circumstances. The circumstances outlined in § 92.201(c)(3) set a minimum requirement for when machine translations must be reviewed by a qualified human translator—including circumstances that are critical to one's rights or benefits. Thus, any machine translation technologies that are developed must include such review if they are to meet the requirements of this rule. OCR will continue to monitor the progression of this technology and will revisit regulatory updates as well as consider issuance of future guidance as needed.

Comment: One commenter stated that the definition of ''machine translation'' should include reference to the use of software or automated tools. Specifically, the commenter recommended modifying the language to read ''machine translation is the use of automated translation software or tools, without the assistance of . . .''

Response: OCR appreciates the commenter's suggestion to explicitly refer to software or automated tools; however, the definition as proposed sufficiently accounts for translations that would be generated by software or automated tools as it refers to ''automated translation.''

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''machine translation'' as proposed in § 92.4, with modification. We are making a technical correction to change ''automated translations'' to ''automated translation.''

National Origin. We proposed to define the term ''national origin'' to mean ''a person's, or their ancestor's, place of origin or a person's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.'' This is consistent with the 2016 Rule's definition of ''national origin,'' and with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of title VII.[58]

Comment: Various commenters discussed the need to include this definition to address entrenched inequities and practices that can constitute national origin discrimination but are not always recognized. This includes the failure to take reasonable steps to provide meaningful access for individuals with LEP, even though such a failure has been long recognized as a form of national origin discrimination. Commenters added that there are also clear intersections between LEP status and race and ethnicity because the great majority of individuals with LEP are people of color; however, they noted that when individuals seek to vindicate their civil rights, they often must choose between pursuing a claim based on either their LEP status or race. Commenters also provided examples of how some people have been denied benefits they are entitled to due to national original discrimination. Several national organizations and local service providers commented that refugees, migrant workers, and other immigrants experience barriers to federally funded or provided health care due to fears related to their immigration status.

Response: OCR appreciates commenters' support for inclusion of this definition. We recognize that individuals can experience both national origin and race discrimination (or national origin discrimination and discrimination on another protected basis) and are finalizing new regulatory language that provides additional clarity and addresses such instances in which individuals may experience discrimination under multiple bases. *See* discussion regarding § 92.101.

OCR appreciates comments related to immigration status. While section 1557 does not prohibit discrimination on the basis of immigration status, we note that differential treatment such as requiring additional verification or documentation from individuals based on their appearance, name, accent, LEP, or suspected immigration status may violate section 1557 and other civil rights laws.[59]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''national origin'' as proposed in § 92.4, with modification. We are making a technical correction to change ''ancestor's'' to ''ancestors'.''

Patient care decision support tool. The Proposed Rule described but did not include a definition in § 92.4 for, the term ''clinical algorithms.'' *See* 87 FR 47880. Many commenters supported the inclusion of a provision such as proposed § 92.210, addressing nondiscrimination in the use of clinical algorithms in decision-making, but recommended OCR clarify that the provision applies to tools used to assess health status, recommend care, determine eligibility, allocate resources, conduct utilization review, and provide disease management guidance. Further, commenters requested that OCR define what tools are covered under § 92.210.

Based on comments received, we are replacing the term ''clinical algorithm'' with the more precise term ''patient care decision support tool,'' and we are adding a definition for ''patient care decision support tool'' to mean ''any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.'' The definition of ''patient care decision support tool'' reaffirms that § 92.210 applies to tools used in clinical decision-making that affect the care that patients receive. This includes tools, described in the Proposed Rule, used by covered entities such as hospitals, providers, and payers (health insurance issuers) in their health programs and activities for ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources'' as applied to the patient. 87 FR 47880. We clarify that tools used for these activities include tools used in covered entities' health programs and activities to assess health status, recommend care, provide disease management guidance, determine eligibility and conduct utilization review[60] related to patient care that is

[58] 29 CFR 1606.1; *see, also,* U.S. Equal Emp. Opportunity Comm'n, *EEOC Enforcement Guidance on National Origin Discrimination, https://www.eeoc.gov/laws/guidance/eeoc-enforcement-guidance-national-origin-discrimination#_Toc451518799.*

[59] *See, e.g.,* U.S. Dep't of Justice, *Guidance to State and Local Governments and Other Federally Assisted Recipients Engaged in Emergency Preparedness, Response, Mitigation, and Recovery Activities on Compliance with Title VI of the Civil Rights Act of 1964, Section D, https://www.justice.gov/crt/fcs/EmergenciesGuidance.*

[60] *See, e.g.,* Patrick Rucker et al., *How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them,* ProPublica (March 25, 2023), *https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims*; Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News (March 13, 2023), *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/.*

directed by a provider, among other things, all of which impact clinical decision-making. Please see our discussion regarding § 92.210, where we discuss ''patient care decision support tool'' in more detail, including examples of tools to which § 92.210 does not apply.

Summary of Regulatory Changes

Considering the comments received, we are finalizing the definition of ''patient care decision support tool'' in § 92.4 to mean ''any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.''

Qualified Bilingual/Multilingual Staff. OCR proposed to define the term ''qualified bilingual/multilingual staff'' to mean a member of a covered entity's workforce who is designated by the covered entity to provide oral language assistance directly to an individual in their primary language as part of the person's current, assigned job responsibilities and who has demonstrated to the covered entity that they are: (1) proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology, and phraseology; and (2) able to effectively, accurately, and impartially communicate directly with individuals with LEP in their primary language.

Comment: Some commenters urged that additional attention should be given to assessing qualifications for self-identified bilingual/multilingual staff abilities to provide services in languages other than English, and that policies and procedures should be developed to assess and retain their competency. Additionally, some commenters recommended establishing qualifications for bilingual/multilingual staff who may also be expected to serve as interpreters, and added that they should be compensated appropriately. Commenters stated that research has shown that bilingual staff who are not qualified interpreters often do not feel comfortable serving as interpreters. A commenter posited that bilingual/multilingual staff must be provided training and compensation opportunities to support professional development and prevent staff turnover and burnout.

Response: OCR appreciates the commenters' suggestions to establish assessment requirements for qualified bilingual/multilingual staff; however, we believe the current definition establishes sufficient requirements and guidelines regarding the necessary skills a qualified bilingual/multilingual staff member must have. The definition sets forth a two-prong definition to ensure proficiency, effectiveness, and impartiality in direct communications with individuals with LEP in their primary languages, including any necessary specialized vocabulary, terminology, and phraseology. Similar to the rule's definitions for qualified interpreters and qualified translators, OCR has established the necessary skills that must be held to meet the definition, while providing covered entities the flexibility by which to have these skills assessed. We note that an individual's self-identification as bilingual or multilingual alone is insufficient to determine whether they meet this definition, and covered entities should determine processes by which they will independently determine and periodically assess an individual's qualifications.

While qualified bilingual/multilingual employees may also be qualified interpreters, the ability to interpret is a separate skill. Anyone whom a covered entity allows to serve as an interpreter must be qualified to do so, consistent with the definition of ''qualified interpreter for an individual with limited English proficiency'' in this section, independent of whether they have been identified as a qualified bilingual/multilingual staff member. OCR will consider developing guidance and providing technical assistance for covered entities on mechanisms for covered entities to assess if staff members meet the requirements.

Consistent with the Department's approach on language access, OCR encourages covered entities to provide training and compensation opportunities to support professional development for bilingual/multilingual staff.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified bilingual/multilingual staff'' as proposed in § 92.4, with modification. As discussed in the summary of regulatory changes to the proposed term ''limited English proficient individual,'' we are revising the term to ''individual with limited English proficiency'' in § 92.4.

Qualified interpreter for an individual with a disability. We proposed to define the term ''qualified interpreter for an individual with a disability'' to mean ''an interpreter who . . . is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary.'' Such an interpreter may interpret via a video remote interpreting service (VRI) or in person. We also provided a non-exhaustive list of examples of qualified interpreters, to include sign language interpreters, oral transliterators, and cued-language transliterators.

Comment: Most of the commenters recommended that OCR amend this definition to include the three (3) parts of the definition of ''qualified interpreter for an individual with limited English proficiency'', which requires that the qualified interpreter: (1) has demonstrated proficiency, (2) is able to interpret effectively, accurately, and impartially, (3) and adheres to generally accepted interpreter ethics principles. Commenters noted that these revisions would provide alignment between the different types of interpreters and recognize that similar standards should apply regardless of whether an interpreter is interpreting for an individual with LEP or a person with a disability.

Commenters recommended that the definition include that a qualified interpreter for a person with a disability demonstrate proficiency. For sign language interpreters, this should include proficiency in speaking or communicating in and understanding both English and a relevant sign language, noting that not all individuals who are deaf or hard of hearing are signers of American Sign Language (ASL). Some commenters also recommended that in order to be proficient, Certified Deaf Interpreters (CDI) must have specialized training in Deaf interpreting in addition to the basic CDI training. For transliterators, these commenters recommended that the rule require proficiency in the relevant alternative communication modality, such as cued speech or oral transliteration.

Commenters further stated that an interpreter for an individual with a disability should communicate ''without changes, omissions, or additions while preserving the tone, sentiment, and emotional level of the original statement.''

Finally, commenters stated that an interpreter for an individual with a disability must also adhere to the principles contained in recognized standards of practice and professional codes of ethics for health care interpreters, such as those of the National Council on Interpreting in Health Care and the Registry of Interpreters for the Deaf.

Response: We appreciate commenters' recommendation to revise the definition

of ''qualified interpreter for an individual with a disability'' to align more closely with the definition of ''qualified interpreter for an individual with limited English proficiency''. While the proposed definition is consistent with the ADA, we agree that the standards for a qualified interpreter should be equivalent regardless of whether an individual has LEP or has a disability. We have revised the definition for consistency among the standards, which is also consistent with the 2016 Rule's definition at former 45 CFR 92.4.

Comment: Some commenters recommended aligning the two qualified interpreter definitions but recommended that a revised definition be expanded to recognize qualified interpreters who have demonstrated proficiency in speaking and understanding two non-English languages. These commenters noted that not all interpreters for people with disabilities are interpreting between English and another language. For example, these commenters noted that a CDI may be interpreting between an individual who is deaf and uses a unique version of ASL and a non-American sign language, or home signs unfamiliar to the medical interpreter. Commenters were concerned that a definition that specified interpretation ''between English and non-English language'' would exclude CDIs and cued-language transliterators. These commenters recommended a multi-pronged definition where several contexts are taken into consideration and is inclusive of ASL-to-English interpretation, ASL-to-ASL CDI interpretation, and cued-language transliteration.

Response: As proposed, the definition of ''qualified interpreter for an individual with a disability'' does not reference ''English'' or a ''non-English language,'' but rather included a non-exhaustive list of examples of qualified interpreters inclusive of sign language interpreters, oral transliterators, and cued-language transliterators. However, as previously discussed, we have revised the definition of ''qualified interpreter for an individual with a disability'' to be more aligned with the definition of ''qualified interpreter for an individual with limited English proficiency.'' The revised definition includes language that is inclusive of different types of interpretation and also includes the non-exhaustive list of examples from the proposed definition.

Comment: Some commenters noted that a covered entity must not use the services of staff who use sign language or another communication modality to act as interpreters and relay information to individuals with disabilities unless they meet the definition of a ''qualified interpreter for an individual with a disability'' found within this section, and they meet the unique needs of the individual for whom the services of an interpreter is being provided.

Response: The definition of a ''qualified interpreter for an individual with a disability'' addresses these concerns; and anyone designated by a covered entity to serve as an interpreter for an individual with a disability must be qualified to do so.

Comment: Some commenters recommended that the definition of ''qualified interpreter for a person with a disability'' take into consideration applicable State law governing licensure of interpreters if any are available in the State where the covered entity provides services. These commenters noted that the process of who can serve as a qualified interpreter differs from State to State, and OCR should adopt language that reflects the minimum standards of State laws governing qualifications of sign language interpreters, if any.

Response: OCR understands and appreciates commenters raised concerns. Covered entities may use adherence to State law governing licensure as a means by which to demonstrate compliance with this definition, provided licensure demonstrates the individual possesses the requirements provided in the definition. OCR declines to adopt language that incorporates any State law licensure requirements as a minimum standard of compliance with this rule.

Comment: Some commenters raised concerns over the qualifications of interpreters. Commenters recommended that the definition include the requirement that an interpreter be certified or assessed by a formal process that objectively measures the competency of the individual. Other commenters recommended that health care entities include a screening system to ensure quality assurance of the abilities of the sign language interpreters to meet the needs of the patients.

Response: OCR appreciates the commenters' recommendations to require certification for qualified interpreters and agrees that covered entities should ensure that the use of interpreter services provides for effective communication. OCR will take into account certification in assessing compliance with this regulation; however, as we will discuss below in the response for certification of qualified interpreter for an individual with LEP in § 92.201, we decline to require certification in the definition of ''qualified interpreter for an individual with a disability.''

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified interpreter for an individual with a disability'' in § 92.4, to more closely align with the definition of ''qualified interpreter for an individual with limited English proficiency,'' such that it now means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance: (1) has demonstrated proficiency in communicating in, and understanding: (i) both English and a non-English language (including American Sign Language, other sign languages); or (ii) another communication modality (such as cued-language transliterators or oral transliteration); (2) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement; and (3) adheres to generally accepted interpreter ethics principles including client confidentiality. Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for a limited English proficient individual. OCR proposed to define the term ''qualified interpreter for a limited English proficient individual'' to mean an interpreter who via a remote interpreting service or an on-site appearance: (1) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; (2) is able to interpret effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement; and (3) adheres to generally accepted interpreter ethics principles, including client confidentiality. This definition is consistent with both the 2016 Rule at former § 92.4 and the 2020 Rule at § 92.101(b)(3)(i).

Comment: Some commenters who otherwise supported this definition expressed concern that, as written, it may inadvertently create difficulties for interpreting in certain languages, especially indigenous languages of Central and South America. These

commenters recommended that the definition be amended to allow for the use of services of relay interpreters, such as those who are proficient in an indigenous language and another language such as Spanish. Commenters explained that these interpreters may not be fluent in spoken English or trained to interpret to and from spoken English, and that those who are qualified to interpret between two non-English languages are critical in providing meaningful access for many isolated and marginalized communities. Furthermore, a few of these commenters recommended the inclusion of the following definition for relay interpreting: ''relay interpreting means a form of simultaneous interpreting when the speech is rendered from an intermediate language rather than directly from the source language.''

One commenter recommended adding ''and dialect'' after ''spoken language'' under paragraph (1) to acknowledge that speakers of a language may not always be qualified to interpret for a person who speaks a variation in that language and adding ''understanding and'' before ''using necessary specialized vocabulary or terms'' under paragraph (2) to indicate that providing effective interpretation for complex situations, such as communicating a treatment regimen, requires understanding of the terminology being used, particularly given the consequences of a miscommunication.

Response: OCR appreciates and understands concerns that the proposed definition may inadvertently create obstacles for meaningful access in certain languages. For example, if a Zapotec-speaking patient with LEP attended a medical appointment and the hospital could not find an individual qualified to interpret between Zapotec and English after reasonable efforts, the hospital could utilize the services of two qualified interpreters that could perform relay interpretation between Zapotec and Spanish and Spanish and English. While relay interpretation may introduce challenges related to accuracy, it may be necessary to afford meaningful access for individuals who speak languages, dialects, or variants not common to the area where they are receiving services.

For this reason, we are revising the definition of a ''qualified interpreter for an individual with limited English proficiency'' to provide that the qualified interpreter (1) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language (qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages); and (2) is able to interpret effectively, accurately, and impartially to and from such language(s) and English (or between two non-English languages for relay interpretation), using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement. This provision makes clear that specialized skills and vocabulary may be needed for less commonly spoken languages as well as dialects.

In light of these modifications to the definition of ''qualified interpreter for an individual with limited English proficiency'', we are also adding and finalizing a definition of ''relay interpretation'' to mean interpreting from one language to another through an intermediate language. This mode of interpretation is often used for monolingual speakers of languages of limited diffusion, including select indigenous languages. In relay interpreting, the first interpreter listens to the speaker and renders the message into the intermediate language. The second interpreter receives the message in the intermediate language and interprets it into a third language for the speaker who speaks neither the first nor the second language.

Lastly, OCR appreciates the commenter's suggestion to add ''understanding and'' before ''using necessary specialized vocabulary or terms'' under paragraph (2). However, the interpreter themself does not need to *understand* complex medical concepts behind medical terms but rather must be able to interpret said terms effectively and accurately. OCR is of the view that the interpretation should directly convey the provider and patient's words and phrases in order to avoid the risk that the individual's message was not accurately communicated. Further, paragraph (1) already requires that the interpreter have ''proficiency in speaking *and understanding*'' the languages at issue (emphasis added).

Comment: A few commenters recommended the definition address how an individual would demonstrate proficiency in English and another language (*i.e.,* through use of an established standard for describing language ability, such as the Common European Framework of Reference of Languages [61]). Some commenters recommended implementing a certification requirement and suggested implementing a national credential requirement that establishes interpretation proficiency for enforcement purposes. Some commenters requested that OCR lay out examples of when it would be appropriate to require qualified interpreters to obtain certification in order to comply with section 1557. Commenters expressed their belief that the proposed definition could be easily misinterpreted and result in assigning the least skilled interpreter for a medical encounter.

Response: OCR appreciates the commenters' suggestions to establish certification requirements for qualified interpreters; however, there are currently no consistent certification standards and there is also a lack of certification available for a significant number of languages. The requirements in this definition provide sufficient standards for determining interpreter qualifications. Individuals that hold a certification will still need to meet the standards provided in this definition. For covered entities seeking information on certification, we encourage covered entities to review the Department of Justice's (DOJ) resource regarding what it means to be a certified linguist.[62]

Comment: One commenter encouraged OCR to include ''via a video remote interpreting service'' to the definition because telehealth can be an important tool for expanding access to interpretation for individuals with LEP.

Response: The definition as proposed and finalized includes interpreter services provided via remote interpreting services and is therefore inclusive of video remote interpreting as drafted.

Comment: One commenter noted that we use the phrase ''use an interpreter'' in our text. They recommended we use the wording ''utilize the services of an interpreter'' instead.

Response: OCR agrees that we are referring to the utilization of interpreter services and have adjusted the use of this phrase accordingly.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments we received, we are revising the definition for a ''qualified interpreter for an individual with limited English proficiency'' as proposed in § 92.4, with modifications. To account for concerns related to relay

[61] Council of Europe, *Common European Framework of Reference for Languages (CEFR), https://www.coe.int/en/web/common-european-framework-reference-languages/introduction-and-context.*

[62] U.S. Dep't of Justice, Fed. Coordination & Compliance Section, *What Does It Mean to Be a Certified Linguist* (2014), *https://www.justice.gov/crt/page/file/1255916/download.*

interpreting, we are revising paragraph (1) to add ''(qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages).'' As discussed in the summary of regulatory changes to the proposed term ''limited English proficient individual'' we are revising the term to ''individual with limited English proficiency'' in § 92.4. We are also adding a definition of ''relay interpretation'' to § 92.4 to mean interpreting from one language to another through an intermediate language. This mode of interpretation is often used for monolingual speakers of languages of limited diffusion, including select indigenous languages. In relay interpreting, the first interpreter listens to the speaker and renders the message into the intermediate language. The second interpreter receives the message in the intermediate language and interprets it into a third language for the speaker who speaks neither the first nor the second language.

Qualified Reader. We proposed to define the term ''qualified reader'' to mean ''a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary,'' which comes from the ADA title II regulation at 28 CFR 35.160 through 35.164. This definition, which did not appear in the 2016 or 2020 Rules, was included to provide clarity to both covered entities and protected individuals about the necessary qualifications of a reader when required under this regulation.

Comment: Commenters supported the addition of ''qualified reader'' to the proposed list of definitions.

Response: OCR appreciates the commenters support for adding the definition of ''qualified reader'' to the proposed list of definitions.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments we received, we are finalizing the definition of ''qualified reader'' as proposed in § 92.4, without modification.

Qualified Translator. OCR proposed to define the term ''qualified translator'' to mean a translator who: (1) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; (2) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original written statement; and (3) adheres to generally accepted translator ethics principles, including client confidentiality. This definition of ''qualified translator'' appeared in the 2016 Rule at § 92.4 and appears in the 2020 Rule at § 92.102(b)(2)(ii) and has not been changed.

Comment: One commenter recommended that the definition of a ''qualified translator'' include the requirement that such individuals, for purposes of providing translation services, be certified or assessed by a formal process that objectively measures the competency of the individual. A number of commenters stated that high quality translation is essential to providing equal access to health care and health services. Some added that oral interpretation is critical to ensuring understanding of written translations, some of which have been inaccurate or insufficient to convey the complicated medical and technical terms translated in the communications.

Response: OCR appreciates the commenter's suggestion to require that a qualified translator be certified or objectively assessed to verify competency in translating. For the reasons we provided when declining to require certification of qualified interpreters for individuals with LEP, we decline to specify the means by which a covered entity may determine that an individual meets the definition of ''qualified translator''. In order to be qualified, translators must meet the definition provided in the rule. OCR also notes that reasonable steps to provide meaningful access may require the provision of both written translation and oral interpreting, and thus utilizing the services of both a qualified translator and a qualified interpreter may be necessary under certain circumstances.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified translator'' as proposed in § 92.4, without modification.

State. The 2022 NPRM did not propose a definition of the term ''State.'' However, based on comments received, we became aware that there may be some confusion as to what encompasses ''State'' for purposes of this final rule. We therefore have decided to include a definition of ''State.''

Summary of Regulatory Changes

Considering the comments received, we are finalizing a definition of ''State'' in § 92.4 to mean ''each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, the Trust Territory of the Pacific Islands, and the Commonwealth of the Northern Mariana Islands.'' This definition is consistent with the ADA regulations at 28 CFR 35.104.

Telehealth. The 2022 NPRM did not propose a definition of the term ''telehealth.'' However, based on comments received, we became aware that there may be some confusion as to what encompasses ''telehealth'' for purposes of this final rule. We therefore have decided to include a definition of ''telehealth.''

Summary of Regulatory Changes

Considering the comments received, we are finalizing a definition of ''telehealth'' in § 92.4 to mean the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications. This definition is consistent with the Health Resources and Services Administration and the Office of the National Coordinator for Health Information Technology definitions referenced in the 2022 NPRM, 87 FR 47884.

Assurances Required (§ 92.5)

In § 92.5 of the 2022 NPRM, we proposed retaining the requirement of the 2016 and 2020 Rules, at former § 92.5 and current § 92.4 respectively, for recipients to submit assurances of compliance to OCR. In paragraph (a), we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in an Exchange, and each State seeking approval to operate a State Exchange is required to submit an assurance that its health programs and activities will be operated in compliance with section 1557 and this part, consistent with similar requirements found in the implementing regulations for title VI, title IX, section 504, and the Age Act. The duration of obligation (proposed paragraph (b)), and covenants language (proposed paragraph (c)) adopt the corresponding requirements found in the section 504 regulation at 45 CFR 84.5.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Commenters expressed support for the assurances provision included in the 2022 NPRM because it

is consistent with other Federal civil rights regulations and the 2016 and 2020 Rules, and it is reasonable for OCR to require recipients of Federal financial assistance to comply with section 1557 as a condition of receiving that funding. One organizational commenter recommended revising this requirement to conditioning prospective recipients' receipt of Department Federal financial assistance on recipients': (1) collection of demographic data such as race, ethnicity, spoken and written language, disability status, age, sex, gender identity, sex characteristics, and sexual orientation; and (2) submission of a written proposal (including through written policies and procedures) about how they intend to provide language assistance services, auxiliary aids and services, and whether an entity's proposed budget includes funding to meet these identified needs.

Response: We appreciate the suggestion to include a data collection requirement in this provision, but do not believe such a requirement is appropriate, as this language is longstanding and consistent across civil rights regulations. We address data collection in further detail later in this preamble, when discussing responses to our request for comment on the issue.

We also decline to revise § 92.5 to require Federal financial assistance applicants to provide OCR with budget information and a written proposal about how they intend to provide language assistance services and auxiliary aids and services as a condition of receiving Federal financial assistance. The combined requirements at §§ 92.8 (Policies and procedures), 92.201 (Meaningful access for individuals with LEP), 92.202 (Effective communication for individuals with disabilities), and 92.205 (Requirement to make reasonable modifications) address the commenter's concerns regarding a recipient's obligation and ability to provide language assistance services and auxiliary aids and services.

Comment: One commenter raised concerns that proposed § 92.5's requirement that recipients make assurances to comply with all provisions of the rule does not take into account situations where a third party administrator could otherwise lawfully administer a plan sponsored by a religious employer that does not conform to OCR's current interpretation of section 1557 with regard to the prohibition on sex discrimination. Specifically, the commenter suggested that a third party administrator may be inhibited from submitting an assurance required by § 92.5 because (1) of the Employee Retirement Security Act of 1974 (ERISA), 29 U.S.C. 1104(a)(1)(D), which for example, obligates such a third party administrator to administer the religious employer's self-insured health plan in accordance with terms that may conflict with section 1557's prohibition of sex discrimination; and (2) there are injunctions that currently prohibit OCR from enforcing prohibitions on sex discrimination against religious employers and those acting in concert with them.[63]

Response: OCR complies with court orders, including court-ordered injunctions. If a recipient third party administrator is covered by any current court order or court-ordered injunction, OCR would not find the third party administrator to be in violation of section 1557 or this rule for its activities that are covered by the injunction, and such an entity would not need to provide an assurance under § 92.5 to the extent it conflicts with a current court order or court-ordered injunction by which they are covered.

Regarding the commenter's point that third party administrators are required under ERISA to administer plans consistent with the plan's terms, OCR addresses this issue in detail under the *third party administrator* section of § 92.207. In short, while we acknowledge that ERISA requires plans to be administered consistent with the documents and instruments governing the plan,[64] ERISA further provides that it is not to be construed to impair or supersede other Federal laws, including regulations issued under such laws.[65] Courts have held that ERISA's requirement to comply with the terms of the plan must not be construed to invalidate or impair section 1557.[66]

[63] *Franciscan All.,* 553 F. Supp. 3d at 378.

[64] 29 U.S.C. 1104(a)(1)(D) (''[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.'').

[65] 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.'').

[66] *See, e.g., C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8, 10 (W.D. Wash. Dec. 19, 2022) (holding that ERISA's requirement at 29 U.S.C. 1104(a)(1)(D) to administer a plan's terms as written ''is subservient to Section 1557, outlawing discrimination, which is dominant''); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (''The Court will not construe ERISA to impair Section 1557. Nothing in Section 1557, explicitly or implicitly, suggests that TPAs are exempt from the statute's nondiscrimination requirements.'').

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.5, without modification.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, OCR proposed to include requirements regarding remedial and voluntary action, which would reinstate former § 92.6 in the 2016 Rule and is consistent with parallel requirements in the implementing regulations for section 504, title IX, and the Age Act. The 2020 Rule does not include a similar provision. In § 92.6(a)(1) of the 2022 NPRM, we proposed requiring recipients or State Exchanges that have been found by the Director to have engaged in discriminatory conduct in their health programs and activities in violation of this part to take voluntary actions to remediate the effects of such discriminatory conduct. Similarly, we proposed that under § 92.6(a)(2), where a recipient exercises control over another recipient that has discriminated, the Director may require either or both entities to take remedial action. Under proposed § 92.6(a)(3), a recipient or State Exchange must take remedial action if OCR requires such action to redress the harm experienced by an individual who was subjected to prohibited discrimination. Under proposed § 92.6(b), a covered entity may voluntarily take nondiscriminatory steps to overcome the effects of the conditions that limited an individual's ability to participate in a health program or activity based on their race, color, national origin, sex, age, or disability.

The comments and our responses regarding § 92.6 are set forth below.

Comment: Commenters generally supported the requirement that a recipient remedy instances of confirmed discrimination and the voluntary action provision that allows for covered entities to address effects of past discrimination.

One commenter recommended that we limit the application of this provision to avoid exposing recipients to unfair and specious claims of discrimination. Specifically, the commenter suggested that the remedial action be limited to: (1) individuals who applied to participate in a health program or activity but were unable to participate due to alleged discrimination; or (2) individuals who had been participants in a health program or activity but are no longer participants due to alleged discrimination.

Response: This provision is an essential tool in remediating findings of discrimination and encouraging recipients to take voluntary actions to overcome potential discrimination. The suggested revisions to § 92.6 are unnecessary, as they generally request implementing conditions that are already present. For example, § 92.6(a)(1) requires remedial action by a recipient or State Exchange only *after* a finding of discrimination. Section 92.6(a)(3) limits any required remedial action in the spirit of the commenter's recommendation, namely providing that recipients and State Exchanges take remedial action with respect to individuals who were or would have been participants in the health program or activity had the discrimination not occurred.

Covered entities are prohibited from discriminating and as such should take steps to ensure nondiscrimination, even in the absence of a finding of discrimination by OCR. Where a covered entity has identified conditions that currently or in the past had resulted in limited participation in their health programs and activities by individuals protected by this rule, they are encouraged to take the voluntary action contemplated in § 92.6(b).

We also note that regulations for section 504, title IX, and the Age Act require recipients to take remedial action, and recipients have complied with the remedial action provisions in those civil rights statutes for more than 40 years.[67] For example, where there is a finding that a recipient engaged in disability discrimination, the recipient's remedial action to overcome the effects of the disability discrimination would likely satisfy this provision's remedial action requirement as well as section 504's remedial action requirement at 45 CFR 84.6(a).

Comment: Another commenter expressed concern about the obligation this provision places on a recipient that exercises control over another recipient that is found to have engaged in discrimination prohibited by section 1557. The commenter recommended that OCR revise the provision so that only the recipient that OCR found to have engaged in unlawful discrimination (and not the controlling entity) take remedial action and that OCR enumerate specific remedial actions OCR may require and the circumstances under which OCR may require them.

Response: The word ''control'' has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. As we explained in the preamble for the 2016 Rule, OCR's experience and the longstanding approach for controlling entities to secure appropriate action from discriminating entities over which they have control has played an important role in remedying discrimination. 81 FR 31393. Given that nothing has changed in OCR's experience in the intervening years regarding the principles of ''control'' as applied here, we decline to define the term ''control.''

While we appreciate the commenter's request to list the remedial actions OCR may require of a recipient or State Exchange found in violation of this part, the remedial actions that a recipient or State Exchange must take to address confirmed discrimination will be subject to the facts involved in a particular case. A review of past resolution agreements provides useful, though not exhaustive, examples of the variety of means by which OCR achieves corrective action.[68]

Comment: One commenter recommended that OCR revise § 92.6 to require a recipient or State Exchange to notify participants, enrollees, and beneficiaries of any finding of discrimination by the Director and the remedial action the recipient has taken or will take to address the confirmed discrimination.

Response: We recognize the benefit that notice of confirmed discrimination and the steps a recipient or State Exchange will take to remedy the discrimination can provide to participants, enrollees, and beneficiaries. While we encourage recipients and State Exchanges to provide notice to participants, we decline to require they do so. Current Federal civil rights regulations with similar remedial and voluntary action provisions do not include a notice requirement, and we do not believe imposing such a requirement on recipients and State Exchanges is warranted at this time. We note, however, it is OCR's practice to notify the public via a press release or posting on our website when a violation has been found or a resolution has been reached.[69] Additionally, OCR has established a Civil Rights listserv to inform the public about civil rights settlement and enforcement activities, press releases, FAQs, guidance, and technical assistance materials. To subscribe to OCR's Civil Rights listserv, please visit *https://list.nih.gov/cgi-bin/wa.exe?SUBED1=OCR-CIVILRIGHTS-LIST&A=1*.

Comment: One commenter recommended that, for § 92.6(b) (voluntary action), we replace ''may'' with ''must'' to require covered entities to take nondiscriminatory steps to overcome effects that result or resulted in limiting participants ability to participate in the covered entity's health program or activities based on the participants' race, color, national origin, sex, age, or disability.

Response: Such a revision would alter the voluntary nature of the provision, which encourages covered entities to take nondiscriminatory steps on their own accord to make their programs more inclusive absent a finding of discrimination. We note that, when there is a finding that prohibited discrimination occurred, § 92.6(a) mandates the offending recipient or State Exchange to take action to remedy such discrimination.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.6, without modification.

Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)

In proposed § 92.7(a), OCR proposed requiring covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator (''Coordinator'') to coordinate their efforts to comply with and carry out the covered entity's responsibilities under section 1557 and the part. OCR also proposed to permit covered entities to, as appropriate, assign one or more designees to carry out some of the responsibilities of the Coordinator.

In § 92.7(b), we proposed a list of responsibilities of the Coordinator. We invited comment on this requirement, including whether OCR should require covered entities with fewer than 15 employees to designate a Coordinator and, if so, whether there should be a requisite number of employees or whether all covered entities should be required to designate a Coordinator. We further sought comment on whether the enumeration of responsibilities of the Coordinator is beneficial and sufficiently comprehensive. We also requested comment on how the

[67] *See* 45 CFR 84.6(a) and (b) (section 504); 86.3(a) and (b) (title IX); and 91.48 (Age Act).

[68] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Recent Civil Rights Resolution Agreements & Compliance Reviews, https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/index.html*.

[69] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Civil Rights News Releases & Bulletins, https://www.hhs.gov/civil-rights/newsroom/index.html*.

Department can support Coordinators, including through the provision of training, so that they understand their duties, the protections afforded by section 1557, and the rationales for both.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Commenters on this provision overwhelmingly supported the Coordinator requirement at § 92.7. A number of supportive commenters indicated that civil rights violations often occur due to ignorance, neglect, and administrative indifference, and Coordinators will equip providers with critical civil rights knowledge and the ability to recognize and adequately care for patients at risk for poor health outcomes. Other commenters similarly emphasized that the Coordinator requirement will equip covered entities with an internal resource dedicated to section 1557 implementation and compliance, and that this is especially critical for small covered entities and covered entities in rural communities. Commenters cited a number of other reasons for their support of the Coordinator requirement, including that having a Coordinator will help covered entities proactively protect civil rights; will provide central points of contact for language access; and will allow covered entities and OCR to better identify patterns or practices of discrimination, which will aid covered entities in delivering effective and efficient care.

One commenter expressed concern about the possibility that Coordinators evolve and become ineffective by privileging the institutions they serve rather than appropriately conducting thorough investigations of grievances. Relatedly, another commenter recommended that OCR revise § 92.7 to require covered entities' Coordinators to be independently minded or independent from the covered entity to ensure impartiality and transparency and to require that Coordinators be able to work independently.

Many of these commenters cited the COVID–19 Public Health Emergency as a reason for their support of the Coordinator requirement. Specifically, they stated that the health outcomes resulting from the COVID–19 pandemic highlighted covered entities' ignorance of civil rights regulations with respect to individuals from marginalized communities.

Response: We agree with commenters regarding the myriad benefits of the Coordinator requirement, particularly with regard to increasing covered entities' ability to proactively prevent discrimination before it happens and hopefully more thoroughly address it when it does. Coordinators are expected to perform their impartially, which will also benefit covered entities through ensuring compliance with section 1557.

OCR appreciates commenters' concerns that Coordinators be sufficiently independent from a covered entity to ensure impartiality and transparency. We note that a covered entity may run the risk of noncompliance with section 1557 if an investigation reveals that its Coordinator did not carry out their obligations under section 1557 in an impartial manner. By having a Coordinator, with specific compliance responsibilities, OCR expects that covered entities will be cognizant of the importance of compliance with civil rights requirements, including in times of public health emergencies or other crises.

Comment: Other commenters opposed the Coordinator requirement, contending that it will increase the burdens covered entities will face.

One commenter reiterated the 2020 Rule's reasoning for eliminating the Coordinator requirement by stating that regulations for underlying civil rights statutes requiring coordinators is sufficient for section 1557 enforcement. Another commenter stated covered entities can meet section 1557 compliance obligations without a Coordinator. Yet another commenter recommended that OCR instead encourage practices to adopt a collaborative approach where all staff take an active role in ensuring nondiscrimination.

Response: The role of the Coordinator is to promote effective and efficient implementation of section 1557 and the part, and in so doing decrease compliance inefficiencies and promote meaningful investigations of allegations of potential civil rights violations.

OCR remains confident that the benefits to a covered entity and the public of the Coordinator requirement outweigh any potential burdens. Time spent coordinating a covered entity's section 1557 compliance program is an investment that will likely result in improved, nondiscriminatory health care delivery and saving resources otherwise spent responding to potential OCR investigations and private litigation. Even if a covered entity is subject to a civil rights complaint or litigation, its Coordinator's presence and active coordination efforts may enable the covered entity to more quickly resolve a complaint or litigation.

This rule addresses the confusion that the 2020 Rule creates surrounding the extent to which covered entities were required to maintain a Coordinator for purposes of section 1557 compliance. The 2020 Rule does not clarify, for example, whether a covered entity's existing section 504 coordinator—whose role relates to ensuring a recipient's efforts to comply section 504 alone, per 45 CFR 84.7—must also ensure the covered entity's compliance with section 1557's prohibition of discrimination based on race, color, national origin, age, or sex. OCR is providing for a specific Section 1557 Coordinator, rather than relying on the requirements found in the implementing regulations for the referenced statutes, to resolve any confusion as to covered entities' responsibilities.

Comment: Some commenters requested that OCR clarify that Coordinators are responsible for covered entities' internal section 1557 oversight and that covered entities may have other staff members implement various Coordinator activities. These commenters recommended that OCR revise § 92.7(b) to add ''or designee'' after ''Section 1557 Coordinator'' to confirm that one or more staff can assist the Coordinator with the enumerated Coordinator responsibilities. Some commenters requested clarity about whether a covered entity's Coordinator can also serve in other capacities within the covered entity's organization, and whether the Coordinator requirement obligates covered entities to hire a new employee to serve as a Coordinator, and if so, whether the job description must list all of the Coordinator responsibilities enumerated at § 92.7(b).

Response: Section 92.7(a) expressly states that a covered entity may assign one or more designees to assist the Coordinator in carrying out their responsibilities. However, the Coordinator must retain ultimate oversight for ensuring the covered entity's compliance with this part. In general, it is the covered entity's prerogative to designate any qualified individual to serve as its Coordinator. A covered entity does not need to hire a new employee for the role, and the Coordinator may serve in other capacities and have responsibilities in addition to their Coordinator responsibilities at § 92.7(b); so long as those responsibilities do not create a conflict of interest or otherwise prevent the Coordinator from effectively carrying out their responsibilities.

Comment: Some commenters recommended that OCR not require covered entities to list a Coordinator's name and contact information in their publicly available Notice of Nondiscrimination because of the constant need to update Coordinators'

names and contact information due to turnover and to avoid potential harassment from section 1557 opponents. Instead, these commenters requested that OCR allow covered entities to list the Section 1557 Coordinator job title instead of an individual's name.

Response: OCR appreciates the challenges associated with updating specific contact information; for this reason, nothing in § 92.8 (Policies and procedures) or § 92.10 (Notice of nondiscrimination) require covered entities to include a Coordinator's name. As proposed, and finalized, §§ 92.8(b) and 92.10(a)(1)(v) both require ''contact information'' for the Coordinator; providing the job title rather than an individual's name is sufficient to meet this requirement. However, contact information in the form of a phone number, email address, and mailing address must also be provided. A covered entity may establish a general phone number, email address, and/or mailing address to meet this requirement. Absent this information, individuals who need to reach the Coordinator will have no knowledge of how to do so.

While this rule does not apply to employment practices, as discussed in § 92.2(b), employees of covered entities remain protected against retaliation as provided in §§ 92.303 and 92.304. If a covered entity's staff is harassing the Coordinator because of the Coordinator's job responsibilities, the covered entity should take appropriate measures to address the harassment, and, if the harassment is based on one or more characteristics protected by the Federal laws enforced by the EEOC, the Coordinator may file a charge of discrimination with the EEOC at *https://www.eeoc.gov/filing-charge-discrimination*.[70] If staff, including a covered entity's Coordinator, are being threatened by other covered entity staff or by individuals external to the covered entity, we strongly encourage reporting these threats to the FBI at 1–800–225–5324 or via *www.fbi.gov/tips*.

Comment: One commenter requested that OCR clarify whether a large health system made up of several covered entities can have a single Coordinator for the entire health system or whether each covered entity needs to have its own Coordinator. Another commenter stated that it is impossible for one Coordinator to oversee section 1557 compliance for an entire large health care system, with another suggesting that there should be at least one Coordinator for every 250 employees for covered entities with 500 or more employees.

Response: In order to provide covered entities with flexibility, OCR clarifies that large health systems may customize their Coordinator and designee configurations as long as each individual covered entity has either a Coordinator or designee responsible for section 1557 compliance. Because a covered entity is better positioned to determine how to ensure that the coordinator(s) can effectively perform all of their duties, we decline to revise the Coordinator requirement so that a covered entity is required to designate one Coordinator for every 250 employees.

Comment: A significant number of commenters recommended that all covered entities, regardless of size, have a Coordinator because ensuring section 1557 compliance is integral to providing nondiscriminatory health care services. Another commenter noted that the requirement aligns with the Joint Commission's recent standards requiring accredited hospitals and similar facilities to designate an individual to lead activities to reduce health disparities.

Several commenters stated that the 15-employee threshold is arbitrary, arcane, and inconsistent with protecting civil rights to the maximum extent possible. Others stated the position is critical for smaller covered entities that provide services to individuals with disabilities, particularly in rural and low-income communities, and for covered entities that provide long-term services and supports to older adults and people with disabilities who use home and community-based services. Others referenced that smaller covered entities include mental health providers, social workers, psychologists, counselors, and family and marriage therapists.

One commenter suggested that covered entities with fewer than 15 employees could still voluntarily designate a Coordinator.

Response: OCR appreciates comments received regarding the application of the Coordinator provision. While all covered entities, regardless of size, would benefit from having a dedicated Coordinator on staff, we decline to extend the requirement to all covered entities beyond those with 15 or more employees, in an effort to reduce unnecessary or counterproductive administrative obligations on small providers. OCR does not find this limitation to be arbitrary, as it is consistent with section 504's coordinator requirement, 45 CFR 84.7(a), and was also included in the 2016 Rule at former § 92.7. We note that covered entities with fewer than 15 employees retain the option of designating a Coordinator.

Comment: Other commenters thought the 15-employee threshold was appropriate, and that applying the requirement to smaller entities would result in burdens and costs for small and solo practices. Another commenter recommended increasing the employee threshold so that only covered entities with 50 or more employees be required to designate a Coordinator. Another commenter recommended that covered entities that fall within the Small Business Association's (SBA) classification[71] of a small business not be required to designate a Coordinator. Another commenter recommended that the Coordinator requirement be removed altogether.

Response: The Coordinator requirement is a vital step in encouraging proactive civil rights compliance; therefore, OCR declines to remove this provision. We also decline to increase the employee threshold for the Coordinator requirement to 50 or more employees. Though the coordinator requirement in title II of the ADA is limited to public entities with 50 or more employees, 28 CFR 35.107, the 15-employee threshold in section 504 is more appropriate for section 1557. Section 504 covered entities are more analogous to section 1557 covered entities given that they are recipients of Federal financial assistance of all sizes; ADA title II covered entities, however, are all State or local governments. For similar reasons, we believe that that the SBA classification of a small business—which was set in a very different context serving very different purposes—is inappropriate for this rule.

Comment: Some commenters requested additional clarity about the 15-employee threshold. For example, commenters asked whether part-time, contractor, and sub-contractor employees would count toward a covered entity's employee total or if

[70] The EEOC is responsible for enforcing Federal laws that make it illegal to discriminate against an employee because of the person's race, color, religion, sex (including pregnancy, childbirth or related medical conditions, gender identity, and sexual orientation), national origin, age (40 or older), disability or genetic information. *See* U.S. Equal Emp. Opportunity Comm'n, *Overview, https://www.eeoc.gov/overview*.

[71] U.S. Small Business Ass'n, *Basic Requirements: Meet Size Standards, https://www.sba.gov/federal-contracting/contracting-guide/basic-requirements#section-header-6* (The SBA assigns a size standard to each NAICS code. Most manufacturing companies with 500 employees or fewer, and most non-manufacturing businesses with average annual receipts under $7.5 million, will qualify as a small business.).

only full-time employees would count. One commenter suggested that, without this clarification, some covered entities will engage in hiring and human resources practices that undermine and abuse the 15-employee threshold. Another commenter also sought to clarify whether only clinical staff should count toward the 15-employee threshold and whether administrative staff should count as well.

Response: With respect to the employees who will count towards the 15 or more-employee threshold, OCR will consider the total number of individuals employed by a covered entity. This includes full-time and part-time employees and independent contractors. All employees, regardless of job classification (*e.g.,* clinical versus clerical), will count toward the threshold. We intend for this clarification to reduce concerns that the 15-employee threshold may lead to questionable employment practices.

Comment: One commenter indicated that the Coordinator requirement implicates religiously affiliated covered entities' authority to hire people who share their religious beliefs because requiring religiously affiliated covered entities to have a Coordinator may compromise the religiously affiliated covered entity's religious beliefs if its Coordinator has fundamentally different beliefs or viewpoints.

Response: Nothing in the regulatory text requires a covered entity to designate a Coordinator with a particular viewpoint or particular beliefs. No part of this final rule prevents a religiously affiliated recipient from designating or hiring an employee who shares the entity's religious beliefs as its Coordinator, provided that the individual is qualified to effectively and impartially perform the role required by the regulation. In addition, where title VII applies to a recipient's employment and hiring decisions, section 1557 does not interfere or otherwise conflict with requirements or protections afforded under title VII.

Comment: Several commenters supported the 2022 NPRM's inclusion of an enumerated list of Coordinator responsibilities at § 92.7(b). Many of these commenters appreciate the flexibility for covered entities to spread or delegate responsibilities to one or more designees within a covered entity's organization. Some commenters requested that OCR consider revising § 92.7(b) to add an additional responsibility that Coordinators coordinate with other covered entities, as necessary, to ensure that individuals who are interacting with multiple entities receive the required language assistance services and/or auxiliary aids and services. A different commenter felt that the enumerated list of Coordinator responsibilities at § 92.7(b) is too prescriptive and recommended that OCR allow each covered entity the opportunity to determine their Coordinator's responsibilities.

Response: The responsibilities enumerated at § 92.7(b) provide a baseline for expected duties while allowing covered entities the flexibility, discretion, and ability to structure responsibility for such duties to their Coordinator(s) or designee(s). A covered entity may assign duties beyond those enumerated at § 92.7(b), at its discretion.

With respect to situations where two covered entities are interacting with the same individual with LEP, individual with a disability, or individual with a disability with LEP, both covered entities are responsible for ensuring that individuals receive the appropriate language assistance services and/or auxiliary aids and services required by this rule under §§ 92.201 and 92.202. Some agencies may find that coordination between their Section 1557 Coordinators will help to more effectively meet the needs of these individuals, but OCR declines to implement a requirement to this effect as each covered entity has an obligation under this part regardless of what services they believe another covered entity may be providing.

Comment: Another commenter recommended that a covered entity's Coordinator not handle section 1557 grievances given that a covered entity may have an existing grievance collection point, which allows it to quickly address grievances through existing structures. A different commenter recommended that OCR clarify that a covered entity can assign Coordinator responsibilities to a group or division instead of one or more specific individuals because organizations may already have individuals specifically trained and responsible for ensuring nondiscrimination.

Response: These regulations do not prohibit a Coordinator from working within existing organizational structures that receive and investigate grievances or perform other Coordinator responsibilities identified in § 92.7(b). As discussed above, this provision provides a covered entity wide latitude to designate one or more Coordinator(s) and to assign one or more designee(s) to assist the Coordinator with their responsibilities, including collecting and addressing grievances. A covered entity may also assign Coordinator responsibilities to a group or division, provided that the covered entity identifies an individual Coordinator who retains ultimate oversight for coordinating section 1557 compliance.

Comment: One commenter recommended that OCR make clear that, when performing their grievance responsibilities, the Coordinator is required to collect specific data, including: alleged basis or bases of discrimination; the date the grievance was filed; the date of the alleged discriminatory action; and the grievance resolution. This commenter indicated that this data should not include individually identifying information and indicated that the covered entity, through the Coordinator, should be responsible for the privacy of the data that they collect while fulfilling their coordinator role. A different commenter recommended that OCR require Coordinators to review grievance data in order to identify potential and actual discriminatory trends.

Response: OCR appreciates the commenter's suggestion regarding the data that must be retained for each grievance. However, we decline to include these details here as the data points the commenter suggested are already in § 92.8(c)(2), which discusses the information that must be retained in grievance records. Although this final rule does not require covered entities to collect data on trends across the organization, we highly encourage all Coordinators to review grievance data to identify and address any potential and actual discriminatory trends revealed in such data. We discuss this in greater detail at § 92.8(c) (grievance procedure).

Comment: Multiple commenters requested that OCR provide training and other resources to help covered entities implement the Coordinator requirement. Some commenters requested that OCR provide (1) training for people who are new to the Coordinator role and for providers who are updating the role; (2) facts sheets to introduce section 1557 to the Coordinator and other staff throughout the organization; and (3) checklists that can be consulted and used to confirm the Coordinator's responsibilities. One commenter requested that OCR training for Coordinators include civil rights, cultural, and implicit bias training.

Response: OCR commits to serve as a resource and partner with covered entities that need help regarding their Coordinator obligations. As discussed in further detail at § 92.8 (Policies and procedures), we plan to make various resources available to assist Coordinators with their responsibilities.

Comment: One commenter asked how OCR will audit covered entities'

compliance with the Coordinator requirement and whether the Coordinator post will be eligible for the Federal matching rate as an administrative activity under section 1903(a)(7) of the Social Security Act.

Response: Consistent with current practice, OCR will determine a covered entity's compliance with the Coordinator requirement during complaint investigations and affirmative compliance reviews. With regard to the commenter's inquiry regarding the availability of Federal financial participation under section 1903(a)(7) of the Social Security Act, 42 U.S.C. 1396b(a)(7), OCR does not administer Medicaid and therefore this comment is outside of the scope of this rulemaking.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7, without modification.

Policies and Procedures (§ 92.8)

At § 92.8 of the 2022 NPRM, OCR proposed requiring covered entities to develop and implement written policies and procedures that are designed to facilitate compliance with the requirements of the part. We proposed requiring each covered entity, in its health programs and activities, to adopt and implement a nondiscrimination policy, grievance procedures (for covered entities employing 15 or more persons), language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities (collectively, ''Section 1557 Policies and Procedures'').

In § 92.8(a), we proposed a general requirement for covered entities to implement written Section 1557 Policies and Procedures. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with the part.

In § 92.8(b), we proposed requiring each covered entity to implement a written nondiscrimination policy that, at minimum, provides the contact information for the Section 1557 Coordinator (if applicable) and states that the covered entity in its health programs and activities: is prohibited from unlawfully discriminating on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, or disability; and provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or the part.

In § 92.8(c), we proposed addressing the requirements for covered entities with 15 or more employees with regard to grievance procedures and recordkeeping in their health programs and activities, including ensuring that the grievance procedure is accessible to individuals with LEP and individuals with disabilities.

In § 92.8(c)(1), we proposed requiring that covered entities with 15 or more employees establish written civil rights grievance procedures.

In § 92.8(c)(2), we proposed that a covered entity must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability in its health programs and activities for no less than three (3) years from the date of the filing of the grievance.

In § 92.8(c)(3), we proposed that a covered entity keep confidential the identity of an individual who has filed a grievance, except as required by law or to the extent necessary to carry out the purposes of this proposed regulation, including the conduct of any investigation.

We invited comment on the record retention requirement, particularly with regard to patient privacy concerns or concerns regarding potentially unauthorized use of information included in such records. We also sought comment on best practices for record retention of grievance procedures, including strategies for ensuring patient privacy.

In § 92.8(d), we proposed requiring covered entities to develop and implement written language access procedures to support compliance with requirements to take reasonable steps to provide meaningful access to individuals with LEP in their health programs and activities under proposed § 92.201.

In § 92.8(e), we proposed requiring covered entities to develop and implement written effective communication procedures to support compliance with requirements to take appropriate steps to ensure that communications in their health programs and activities with individuals with disabilities are as effective as communications with individuals without disabilities under proposed § 92.202.

In § 92.8(f), we proposed requiring covered entities to develop and implement written procedures for making reasonable modifications to their policies, practices, or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities as required under proposed § 92.205.

In § 92.8(g), we proposed that a covered entity may combine the content of the policies and procedures required by this provision with any policies and procedures pursuant to other civil rights statutory protections if they clearly comply with section 1557 and the provisions in the part.

We sought comment on this proposed provision and whether there may be alternative measures that OCR should consider to proactively prevent discrimination, and whether they would be more or less burdensome than what was proposed. We also invited comment from all covered entities that had previously implemented or were currently implementing any of the proposed procedures; consumers who interact with covered health programs and activities; and community-based organizations that work with individuals with LEP and individuals with disabilities. We also requested comment on whether covered entities employing fewer than 15 people should be required to have a grievance procedure, including the benefits of a less formal resolution process.

The comments and our responses regarding § 92.8 are set forth below.

General Comments

Comment: Many commenters expressed support for the Section 1557 Policies and Procedures requirement at § 92.8, noting that, in their view, it will help prevent discrimination and health disparities; requires providers to proactively engage in the process of avoiding discrimination; elevates covered entities and their employees' knowledge about their section 1557 obligations; and alleviates the burden on patients to file complaints in order to trigger section 1557 compliance and enforcement. Some commenters supported the requirement because the 2020 Rule leaves requirements for policies and procedures disjointed, confusing, and ineffective.

Some commenters recommended that OCR strengthen this requirement by requiring covered entities to evaluate the effectiveness of their Section 1557 Policies and Procedures and update them when necessary to ensure consistency.

Response: Covered entities' Section 1557 Policies and Procedures should be dynamic and updated to ensure covered entities comply with changes in the law

and meet their section 1557 obligations. In addition, when covered entities' operations change, this may necessitate revising Section 1557 Policies and Procedures to maintain section 1557 compliance.

Accordingly, we have added § 92.8(h) to address when it is required and permissible for a covered entity to revise their Section 1557 Policies and Procedures. Section 92.8(h)(1) explains that a covered entity must review and revise its policies and procedures, as necessary, to ensure they are current and in compliance with section 1557 and this rule. Section 92.8(h)(2) states that a covered entity may change its policies and procedures at any time, provided that the changed policies comply with section 1557 and the part.

Comment: Some commenters who opposed this requirement cited covered entities' existing compliance burdens and the resources needed to draft Section 1557 Policies and Procedures. Some commenters requested that, if OCR maintains the requirement in the final rule, OCR make template Section 1557 Policies and Procedures available for covered entities to use and tailor to their organizations as far in advance of the final rule's effective date as possible.

One commenter stated that existing Federal and State regulations prevent covered entities from focusing on high-quality care, and that this requirement is an unfunded mandate. One commenter recommended that OCR should continue previously permitted flexibility and allow covered entities to develop Section 1557 Policies and Procedures voluntarily.

Response: To assist covered entities' compliance with this requirement, OCR has developed Section 1557 Policies and Procedures templates that are available on OCR's website at *www.hhs.gov/1557*, which are designed to assist covered entities in tailoring their own Section 1557 Policies and Procedures. We reiterate the requirement that a covered entity's Section 1557 Policies and Procedures must be reasonably designed, take into account a covered entity's size, complexity, and the type of health programs or activities provided. A covered entity should view these templates as a starting point for adopting and implementing Section 1557 Policies and Procedures that are specific to their health programs and activities. The templates provided may be insufficient for large covered entities given the range in complexity and structure of those entities, and entities must ensure that their Section 1557 Policies and Procedures reflect the appropriate scope.

Comment: Some commenters recommended that OCR not require covered entities to identify the names of their respective Coordinators in their Section 1557 Policies and Procedures required by § 92.8(b), (d), (e), and (f) because high employee turnover may make coordinators' names obsolete and require constant changes.

Response: OCR notes that nothing in § 92.8 requires a covered entity to identify the Coordinator by name; rather, § 92.8(b), (d), (e), and (f) require the Coordinator's current contact information. The referenced provisions require sufficient information for an individual who needs assistance in implementing the procedures to reach the Coordinator. Thus, a covered entity could choose to list the position title with a phone number, email address, and mailing address.

Comment: One commenter requested that OCR clarify, especially with respect to large health systems (such as hospitals, clinics, home care entities, and home medical equipment retail settings), the regulatory language related to scalability.

Response: OCR recognizes that covered entities—including not only recipients, but also the Department and title I entities—need flexibility when developing and implementing their Section 1557 Policies and Procedures. A covered entity should consider its size, capabilities, the costs of specific measures, the operational impact, and the composition of the patient populations they serve in deciding the appropriate scale of their Section 1557 Policies and Procedures. Thus, OCR expects the scope and detail of a covered entity's Section 1557 Policies and Procedures to vary accordingly.

Comment: Some commenters requested that OCR include additional required policies and procedures, such as policies and procedures regarding service animals, protecting civil rights in public health emergencies, assessing the competency of bilingual/multilingual staff, and telehealth. Specifically, one commenter recommended requiring a telehealth procedure designed to assist covered entity employees communicate with patients before, during, and after telehealth visits, and that this telehealth procedure could address pre-appointment telehealth screenings to ensure that patients have the necessary equipment or technology for their appointments and to determine whether the patient has the requisite technological skills to participate in a telehealth session. The proposed telehealth procedure would require covered entities to provide telehealth training resources for patients who lack skills or familiarity with telehealth prior to their appointments. Other commenters recommended that covered entities' procedures ensure accessibility for individuals with physical and/or behavioral health disabilities and specifically comply with the U.S. Access Board's Standards for Accessible Medical Diagnostic Equipment. 82 FR 2810 (Jan. 9, 2017).

Response: OCR recognizes the benefit of policies and procedures to support civil rights compliance. However, we recognize that developing and implementing such policies and procedures is not without an initial burden on the covered entities, and the continued—though much diminished—effort of maintaining the procedures and employee familiarity with such procedures. For that reason, we decline to require additional policies and procedures at this time. However, covered entities are encouraged to develop and implement policies and procedures related to service animals, protecting civil rights during public health emergencies, assessing bilingual and multilingual staff members' competency, nondiscriminatory provision of telehealth,[72] accessible medical equipment, or any other situation they choose in order to ensure compliance with section 1557. For more about section 1557's accessibility requirements, please refer to our discussion for § 92.204, which requires covered entities to make their buildings and facilities accessible to individuals with disabilities. In addition, please see the discussion of medical diagnostic equipment under § 92.207. Please also see the discussion of § 92.211 related to nondiscrimination in the delivery of health programs and activities through telehealth services.

Summary of UUegulatory changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the policies and procedures requirement provision at § 92.8 as proposed, with modifications. We have added a paragraph (h) that explains that a covered entity must review and revise its policies and procedures, as necessary, to ensure they are current and in compliance with section 1557 and this rule and that a covered entity

[72] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts.; U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons, https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf.*

may change its policies and procedures at any time, provided that the changed policies comply with section 1557 and this rule.

Nondiscrimination Policy

Comment: Many commenters supported the Nondiscrimination Policy at proposed § 92.8(b). Some commenters recommended that OCR revise the language in this Policy so that the description of prohibited sex discrimination is consistent with the description of sex discrimination included in § 92.101 (*i.e.,* revise to include sex stereotypes and pregnancy or related conditions). Some of these commenters further recommended that OCR also specify that ''pregnancy or related conditions'' includes termination of pregnancy. Other commenters requested that OCR further revise § 92.8(b)'s reference to sex discrimination and make a corresponding revision to § 92.101(a)(2) by adding ''transgender status'' to the description of sex discrimination for both provisions.

Response: OCR appreciates the need for consistency across the regulation, and to ensure that the public is aware of the various types of discrimination included under the umbrella of sex discrimination. We clarify that a Nondiscrimination Policy's prohibition of sex discrimination encompasses protections afforded for various types of sex discrimination such as pregnancy, including termination of pregnancy or related conditions, and we have revised the parenthetical in § 92.8(b) to explain that this provision's reference to sex discrimination is consistent with the various types of sex discrimination described at § 92.101(a)(2), which includes ''gender identity.'' We decline to add ''transgender status'' to the regulatory text, as the term ''gender identity'' necessarily encompasses ''transgender status'' and these terms are often used interchangeably.[73]

At the same time, we want to emphasize that the ACA itself provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). HHS will comply with this provision.[74] For further discussion regarding what constitutes sex discrimination, including the application of religious freedom and conscience protections in this context, please see the discussion at § 92.101(a)(2).

Comment: One commenter expressed opposition to § 92.8(b) because it would increase paperwork without benefiting or improving the quality of care.

Response: As we noted above, many commenters, some of which are providers and professional medical associations, support the requirement to have a Nondiscrimination Policy. Peer-reviewed medical publications acknowledge that a health care organization's written policies and procedures can improve quality of care and mitigate the legal risk of causing patient harm.[75] Indeed, research suggests that the mere existence of policies that prohibit discrimination helps reduce health and other inequities.[76] Thus, we disagree with the commenter's contention that § 92.8(b) increases paperwork without benefitting or improving quality of care particularly for individuals who belong to communities with a history of experiencing discrimination in health care settings.

Comment: A few commenters expressed First Amendment concerns related to the overarching Section 1557 Policies and Procedures requirement, particularly the Nondiscrimination Policy requirement. One of these commenters recommended that, with respect to the Section 1557 Policy and Procedures requirement, OCR should clarify that covered entities retain free speech protections to the extent that sex discrimination does not result if a covered entity acknowledges a patient's sex assigned at birth. An organizational commenter stated that the Nondiscrimination Policy is problematic under the First Amendment because requiring a covered entity to state that it does not discriminate on the bases of pregnancy, sexual orientation, gender identity, and sex characteristics constrains freedom of speech and freedom of association.

Response: OCR acknowledges the comments regarding protections on the basis of sex, particularly as they relate to nondiscrimination on the basis of pregnancy or related conditions, sexual orientation, and gender identity. As noted above, we have revised § 92.8(b) by removing descriptions of sex discrimination and by cross-referencing § 92.101(a)(2) and that provision's description of sex discrimination. Thus, a covered entity's Nondiscrimination Policy need not explicitly include the various forms of prohibited sex discrimination to address any potential First Amendment concern. However, we emphasize that these concerns do not negate a covered entity's obligation to implement Section 1557 Policies and Procedures.

We also note here that we have amended the regulatory text to add, as a best practice towards compliance, that a recipient's Nondiscrimination Policy reflect assurance of exemptions that have been triggered or that have been granted to that recipient under § 92.302.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Nondiscrimination Policy requirement at § 92.8(b) as proposed, with modifications. We are revising § 92.8(b)(1) to adjust the explanatory parenthetical for sex in the Nondiscrimination Policy to state ''consistent with the scope of sex discrimination described at § 92.101(a)(2).'' We are revising § 92.8(b) to add paragraph (b)(2) that states, ''OCR considers it a best practice toward achieving compliance for a covered

[73] *See, e.g., Bostock* v. *Clayton Cnty., Georgia,* 590 U.S. 644, 658–59 (2020); *Doe* v. *Mass. Dep't of Correction,* No. CV 17–12255–RGS, 2018 WL 2994403 (D. Mass. June 14, 2018); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017).

[74] The application of this final rule to covered entities with religious freedom or conscience objections is discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[75] *See* James O'Donnell et al., *Policies and Procedures: Enhancing Pharmacy Practice and Limiting Risk,* 37 Health Care & L. 341 (2012), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411206/*; Savithiri Ratnapalan et al., *Organizational Learning in Health Care Organizations,* 2 Systems 24–33 (2014), *https://www.mdpi.com/2079-8954/2/1/24.*

[76] *See generally* Douglas Almond & Kenneth Chay, *Civil Rights, The War on Poverty, and Black-White Convergence in Infant Mortality in the Rural South and Mississippi,* Mass. Inst. of Tech., Dep't of Economics, Working Paper Series, SSRN, (2007), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=961021*; Doughlas Almond & Kenneth Chay, *The Long-Run and Intergenerational Impact of Poor Infant Health: Evidence from Cohorts Born During the Civil Rights Era,* Nat'l Bureau of Econ. Rsch (2006), *https://users.nber.org/~almond/chay_npc_paper.pdf*; Nancy Krieger et al., *The Unique Impact of Abolition of Jim Crow Laws on Reducing Inequities in Infant Death Rates and Implications for Choice of Comparison Groups in Analyzing Societal Determinants of Health,* 103 a.m. J. of Pub. Health, 2234 (2013), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3828968/*; John J. Donahue III & James Heckman, *Continuous Versus Episodic Change: The Impact of Civil Rights Policy on the Economic Status of Blacks,* NBER Working Papers Series, SSRN, (2007), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=474003*; David Card & Alan Krueger, *Trends in Relative Black-White Earnings Revisited,* 83 The Am. Econ. Rev. 85–91 (1993), *https://www.jstor.org/stable/2117645#:~:text=For%20both%20of%20these%20cohorts,1939%20cohort%20is%20especially%20noteworthy.*

entity to provide information that it has been granted a temporary exemption or granted an assurance of exemption under § 92.302(b) in the nondiscrimination policy required by paragraph (b)(1) of this section.''

Grievance Procedures

Comment: In general, commenters supported the grievance procedures requirement at § 92.8(c), including because allowing patients to voice concerns to providers builds trust between patients and providers.

Response: OCR's enforcement experience reveals that grievance procedures help covered entities lower compliance costs and provide covered entities the opportunity to resolve grievances—through direct communication with the individual raising the grievance—in the quickest possible manner without OCR's involvement.

Comment: Some commenters recommended that OCR require covered entities to adjudicate grievances quickly, and some of these commenters specifically requested that OCR add timeframes by which section 1557 grievances must be both acknowledged and resolved because covered entities may either belatedly or never acknowledge a complaint or take longer than perceived as necessary to resolve grievances. Others requested that OCR define ''prompt and equitable'' resolution, with one stating that ''equitable'' is a subjective construct and suggested that OCR consider requiring covered entities to resolve grievances by affording the aggrieved individual appropriate access to the health program or activity at issue. Relatedly, another commenter asked that OCR consider differentiating between pretreatment grievances and other grievances, because denials of care and coverage can result in the postponement or foregoing of care altogether and can require patients to wait for the resolution of a grievance before seeking care from an alternate provider.

Response: We appreciate these commenters' desire for additional specificity regarding what is meant by ''prompt and equitable'' resolution of a grievance. This terminology is consistent with grievance procedures requirements found in the Department's section 504 and title IX regulations at 45 CFR 84.7(b) and 86.8(b), respectively.

Imposing a single timeframe by which a covered entity must resolve a grievance does not account for the fact that covered entities vary in size, resources, and capabilities, and so one timeframe may not be appropriate for all entities. Multiple factors may impact the length of time required to evaluate and resolve a particular grievance and to ensure a fair process and reliable outcome, including the nature of the grievance. This is balanced by the fact that prompt resolution of complaints is necessary to further section 1557's nondiscrimination objective. We encourage individuals to file complaints with OCR if they have filed a grievance that they do not believe has been resolved in a prompt and equitable manner. OCR's investigation of such a complaint may determine whether a covered entity's grievances procedures truly provide for prompt and equitable resolutions, and if they do not, OCR may seek corrective actions from the covered entity. For these reasons, we decline to add timeframes within which covered entities are required to address grievances, and we decline to define the term ''prompt and equitable.''

Comment: Some commenters recommended that OCR require covered entities to notify individuals of the ability to file a grievance. Other commenters requested that OCR revise § 92.8(c) to require a covered entity's process for filing grievances be simple, not burdensome, and accessible to individuals with LEP and individuals with disabilities.

Response: To the extent covered entities are required to have grievance procedures, covered entities are also required to include information about the availability of their grievance procedures and how to file a grievance in their Notice of Nondiscrimination, per § 92.10(a)(1)(vi). All covered entities, regardless of size, must also include information in the Notice of Nondiscrimination on how to file a discrimination complaint with OCR, per § 92.10(a)(1)(vii).

In addition, the grievance process must be accessible to individuals with LEP and individuals with disabilities, consistent with section 1557 and this regulation. If an individual finds that a covered entity's grievance process is generally overly burdensome to the point it is ineffective or nonexistent and thus hindering the prompt and equitable resolution of grievances, we recommend the individual file a complaint with OCR.

Comment: Many commenters on this provision recommended that OCR require all covered entities (not just those with 15 or more employees) to have grievance procedures, while others either requested that OCR maintain the 15-employee threshold or eliminate the requirement altogether.

Commenters in support of eliminating the 15-employee threshold contended that a covered entity's size does not protect patients from discrimination and the threshold is inequitable because it deprives patients of smaller covered entities the opportunity to directly engage with the covered entity to address alleged discrimination. According to commenters, individuals with disabilities face significant barriers to care when seeking and receiving services from smaller covered entities, and the 15-employee threshold unjustly deprives individuals with disabilities of the opportunity to address these barriers through grievances.

Further, commenters remarked that regulatory carve outs and distinctions are confusing and difficult for both covered entities and patients when determining applicable requirements and protections. Commenters expressed concern that individuals from marginalized communities would be confused about why they could not submit a grievance with a covered entity with fewer than 15 employees simply due to the size of the covered entity, when other requirements in the rule apply regardless of covered entity size.

Commenters also raised the following issues countering inclusion of a 15-employee threshold: the statutory text of section 1557 is not so limited; the limitation is inconsistent with expanding section 1557's application; an individual should have the ability to address discrimination in the first instance directly to the covered entity; and a covered entity with fewer than 15 employees that has grievance procedures will be able to resolve discrimination complaints more promptly at an earlier stage without formal OCR investigation.

Citing the burden on smaller covered entities, some commenters requested that OCR maintain the grievance procedures requirement only for covered entities with at least 15 employees, eliminate the procedures altogether or utilize the SBA's definition of small business.

Response: We appreciate commenters' concerns about the 15-employee threshold and recognize that individuals are not immune from experiencing discrimination when interacting with smaller covered entities. However, OCR declines to apply this requirement to all covered entities and note that this approach is consistent with OCR's section 504 regulation, which similarly limits the grievance procedure requirement. *See* 45 CFR 84.7(a). Individuals remain able to file complaints with OCR when they experience discrimination in health programs and activities and may also raise concerns to smaller covered

entities outside of a formal grievance process.

Given the benefits of having grievance procedures, we encourage smaller covered entities to voluntarily implement such procedures, which may help them more meaningfully engage with all individuals, including members of underserved communities, and better identify potential barriers to accessing their health programs and activities.

Comment: Some commenters pointed to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as precedent and demonstrable evidence that the Department believes providers of all sizes have the ability to comply with a Federal requirement to implement a process for handling complaints. These commenters suggested that all HIPAA-covered entities, including those with fewer than 15 employees, have experience implementing a process for receiving, handling, and investigating privacy complaints, which these covered entities can modify or replicate, if necessary, to include section 1557 discrimination grievances.

Response: OCR appreciates commenters' observation that HIPAA-covered entities of all sizes have experience implementing a complaint process. However, we are unpersuaded that the potential burden to smaller covered entities with existing HIPAA complaint processes would be minimal because these entities would need to revise their existing policies, train relevant staff, and process civil rights-related grievances in addition to processing HIPAA-related complaints. This is similar to our position in response to comments received in response to the 2015 NPRM. 81 FR 31395. Nothing in this rule prohibits entities of fewer than 15 employees from voluntarily creating a grievance process.

Comment: In support of requiring all covered entities to have grievance procedures, commenters suggested that covered entities could have less extensive or detailed grievance procedures, and that such a procedure would not need to involve significant staff or resources. These commenters recommended that OCR develop model grievance procedures for smaller covered entities to help them comply with the grievance procedures requirement.

Response: To assist all covered entities—including those with fewer than 15 employees that may wish to voluntarily implement a grievance procedure—we have made available sample grievance procedures on OCR's website at *www.hhs.gov/1557*. We note that the sample grievance procedure available on OCR's website is more appropriate for smaller covered entities, and we remind covered entities that the rule's general Section 1557 Policies and Procedures requirement is founded on the principle of scalability. Accordingly, the sample grievance procedure on our website may not be adequate for a larger covered entity or health system made up of several covered entities.

Comment: Many commenters supported the record retention requirement at § 92.8(c)(2). Under this provision, we proposed that covered entities must retain records for a minimum of three (3) calendar years, and each record must include the name and contact information of the complainant, the alleged discriminatory action and alleged basis or bases of discrimination, the date the grievance was filed, the grievance resolution, and any pertinent information.

Some commenters expressed that this requirement will help covered entities identify potential patterns and practices of discrimination of which they may not have otherwise been aware. Other commenters who supported this requirement expressed concern about patient privacy and recommended that OCR require covered entities to deidentify information related to the grievance during the retention period.

Response: We appreciate commenters' support for this new provision and recognize the importance of ensuring patient privacy related to recordkeeping. Section 92.8(c)(3) requires covered entities to keep confidential the identity of the individual who submits a grievance, subject to limited exceptions. We decline to revise the records retention requirement to require covered entities to deidentify that information related to the grievance.

Many section 1557 covered entities must also comply with the HIPAA Privacy and Security Rules, which requires HIPAA covered entities to protect and secure all protected health information that a covered entity or business associate creates, receives, maintains, or transmits. If a covered entity discloses an individual's protected health information in violation of the HIPAA Rules, then the covered entity is subject to OCR's HIPAA enforcement measures.[77] If a section 1557 covered entity maintains grievance records beyond three (3) calendar years, the covered entity may deidentify the information after the records retention period has elapsed. Even where a section 1557 covered entity is not subject to HIPAA, that section 1557 entity must still comply with all applicable Federal and State privacy laws.

Comment: One commenter requested that OCR revise § 92.8(c)(2) so that a covered entity be required to retain only ''actionable'' grievances because large, covered entities may receive grievances that are not related to section 1557's protections. This commenter gave an example that a complaint may be employment-related, and therefore § 92.8(c)(2) should not require a covered entity to retain such a grievance.

Another commenter raised a similar concern and recommended that OCR completely eliminate any record retention requirement as they relate to grievances because it is difficult to know when a grievance triggers the retention requirement. This commenter requested that, if OCR retains the grievance records retention requirement, that it only apply to covered entities with 15 or more employees.

Response: Section 92.8(c)(2) applies only to covered entities that are required to have grievance procedures (*i.e.,* those with 15 or more employees), and this provision expressly specifies that covered entities retain grievances it receives pursuant to the grievance procedures requirement at § 92.8(c)(1) that allege discrimination on the basis of race, color, national origin, sex, age, or disability in the covered entity's health programs or activities. Thus, covered entities need not retain records pertaining to employment-related grievances or grievances that do not allege discrimination based on race, color, national origin, sex, age, or disability in the covered entity's health programs or activities. If a covered entity cannot determine whether a complaint relates to section 1557, the covered entity should contact the complainant to obtain sufficient information to either investigate the grievance or determine if the complaint should be handled under a different process. We note that a covered entity's dismissal of a grievance constitutes its resolution of the grievance.

Comment: One commenter who expressed support for the retention requirement opined that the proposed three-year retention period is less burdensome than the seven-year retention requirement applicable to most records for hospice and palliative care. Another commenter recommended that covered entities be required to retain grievance-related records permanently due to the low costs associated with maintaining these records electronically, and a covered entity could find older records useful in

[77] *See* 45 CFR 160.312 and 160.400 through 160.414.

litigation. Another commenter recommended that OCR adopt a four-year retention period to match section 1557's four-year statute of limitations [78] because a retention period shorter than section 1557's statute of limitations would prevent private litigants from obtaining grievance-related evidence relevant to a section 1557 claim. One commenter also recommended that OCR revise § 92.8(c)(2) so that the timeframe for covered entities to retain grievance records starts once the covered entity resolves the grievance rather than when the covered entity receives it.

Response: OCR has determined that the three-year record retention requirement strikes the appropriate balance between covered entities' burden concerns and the need for OCR to access this vital information in the course of a complaint investigation or compliance review. As stated in the 2022 NPRM, we understand that many covered entities already have a practice of retaining grievance records, and nothing in this rule prevents a covered entity from retaining records longer if they so choose. 87 FR 47849.

We appreciate commenters' recommendation that OCR specify that the retention obligation starts on the date that the covered entity resolves the grievance rather than on the date that the complainant filed the grievance, and we are revising § 92.8(c)(2) to reflect this change. Grievances take varying amounts of time to resolve, and starting the retention obligation on the date of receipt could potentially result in a covered entity disposing of records pertaining to a grievance prior to the resolution of the grievance. This change necessitates that we further revise § 92.8(c)(2) to require a covered entity's grievance records also include the date that the covered entity resolved a grievance.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Grievance Procedure requirement provision at § 92.8(c) as proposed, with modifications. We are revising § 92.8(c)(2) to explain that the grievances that a covered entity must retain are those filed pursuant to its grievance procedures required by § 92.8(c)(1) that allege discrimination based on race, color, national origin, sex, age, and disability in a covered entity's health programs or activities, and that the records include the date the grievance was resolved. We are also clarifying at § 92.8(c)(2) that the retention period for grievance procedures starts on the date the covered entity resolves the grievance.

Language Access Procedures

Comment: Most commenters on this provision expressed support for the proposed language access procedures requirement at proposed § 92.8(d). Some commenters recommended that OCR revise § 92.8(d) to make clear that a covered entity's language access obligations extend to companions of patients, beneficiaries, enrollees, and applicants.

Response: It has been OCR's practice to require covered entities to provide language assistance services for LEP companions of patients, beneficiaries, enrollees, and applicants when necessary. Rather than revising § 92.8(d), we are revising § 92.201 (Meaningful access for individuals with LEP) to codify this requirement. We discuss this further when addressing comments related to § 92.201. Because the language access procedures are intended to assist covered entities in complying with their language access obligations under § 92.201, they should ensure that companions are included.

Comment: One commenter recommended that OCR allow covered entities the flexibility to identify the process and business rules that they currently use to identify individuals with LEP, how to provide language assistance services, and how to create and store translated materials and resources. This commenter suggested that § 92.8(d) reads as if it is intended for smaller covered entities that provide language assistance services in an ad hoc manner.

Response: Section 92.8(d) applies to covered entities of all sizes, allowing flexibility for covered entities to scale their language assistance services procedures as needed. Section 92.8(d) does not restrict the manner in which a covered entity implements its language access procedures, which may include the use of pre-existing business tools that meet the necessary requirements. For example, § 92.8(d) does not dictate how covered entities' employees identify individuals with LEP or how covered entities obtain language assistance services from qualified interpreters and translators (*i.e.,* through contract interpreters, in-house interpreters, etc.).

Comment: Some commenters indicated that often patients with LEP have to repeat a language access intake process with every visit to a covered entity, even when they have already gone through such a process and their language access needs have been previously identified by the covered entity. To avoid this situation, commenters recommended that OCR require covered entities to note in a patient's records whether the patient needs language assistance services, and if so, the specific language and services needed.

Response: OCR understands that repeatedly having to request necessary language assistance services from the same covered entity can be frustrating and may result in wasted time or the cancellation of an appointment if the needed services are unavailable. While the commenters' suggestion for covered entities to document the specific language assistance services needs in the patient with LEP's record is a best practice that we encourage for inclusion in a covered entities' language access procedures, OCR declines to revise § 92.8(d). As drafted, the provision allows covered entities the flexibility needed to comply.

Comment: Some commenters requested that OCR revise § 92.8(d) with text: (1) directly from § 92.201 related to covered entities' obligation to provide each individual with LEP with meaningful access; and (2) that aligns with Executive Order 13166 (''Improving Access to Services for Persons with Limited English Proficiency''); [79] title VI*;* Medicaid's commitment to enhancing access through culturally competent care as defined in 42 CFR 440.262; and the Agency for Healthcare Research and Quality's ''Improving Patient Safety Systems for Patients with Limited English Proficiency'' guide.[80]

Response: Section 92.8(d) already references covered entities' obligations under § 92.201, so it is unnecessary to restate that language here. We decline to modify the provision to add language from the suggested requirements and resources, as this provision relates to covered entities' obligation under section 1557.

Comment: Many commenters sought clarity about whether the language

[78] *See, e.g., Tomei* v. *Parkwest Med. Ctr.,* 24 F.4th 508, 515 (6th Cir. 2022) (holding the catchall Federal statute of limitations at 28 U.S.C. 1658(a) applies to claims under section 1557 because section 1557 lacks an express statute of limitations); *but see Solis* v. *Our Lady of the Lake Ascension Cmty. Hosp., Inc.,* No. CV 18–56–SDD–RLB, 2020 WL 2754917, at *4 (M.D. La. May 27, 2020) (applying the Rehabilitation Act statute of limitations to a section 1557 claim of disability discrimination).

[79] E.O. 13166, 65 FR 50121 (Aug. 11, 2000).

[80] U.S. Dep't of Health & Hum. Servs., Agency for Healthcare Rsch. and Quality, *Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals* (2012), *https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

access ''procedures'' required by § 92.8(d) differ from documents commonly referred to as language access ''plans.'' Noting OCR's longstanding recognition of the benefits of having a language access plan, as expressed in the Department's ''2003 Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (HHS LEP Guidance), 68 FR 47311 (Aug. 8, 2003), many commenters recommended that OCR modify § 92.8(d) to clarify that covered entities must develop and implement a language access plan before developing language access procedures because developing effective policies and procedures require such advance planning and give covered entities clear policies to follow when seeing patients with LEP.

According to these commenters, formal language access plans require a covered entity to consider and evaluate the needs of a service area, providing a better understanding of populations, prevalence of specific language groups, language access needs, and scope of services needed to provide meaningful access. Commenters highlighted the rapid growth of pockets of individuals with LEP with distinct language and cultural conventions, including indigenous immigrant populations from Central and South America, and the changing language needs for recent arrival of refugees from Afghanistan, Ukraine, Russia, and other non-English speaking countries.

In contrast, one commenter appreciated that the Proposed Rule did not require covered entities to implement language access plans and noted that small, covered entities lack resources, including time, administrative effort, and financial resources to implement a language access plan. Citing the 2015 NPRM, the commenter stated the cost to develop a language access plan at $1,135 per small, covered entity,[81] and recommended that OCR finalize the rule without requiring covered entities to develop and implement a language access plan.

Response: OCR appreciates commenters' emphasis on the value of language access plans, which as commenters noted, are distinct from the language access procedures required under this section. Covered entities are not explicitly required to analyze the specific populations with LEP in their service areas. However, in order to develop effective language access procedures and ensure compliance with the obligations at § 92.201, a covered entity will need to engage in some form of analysis to identify the language access needs in their service area.

For example, when finalizing a list of preferred language assistance services providers, a covered entity will need to determine which providers are most capable of meeting the language needs of the individuals with LEP within the service area. To best inform its decision-making process, a covered entity may first attempt to identify the non-English languages most spoken in the relevant service area and confirm that interpreter and translation service providers can accommodate those languages. The HHS LEP Guidance, cited by commenters, is still instructive and relevant and provides helpful information in how to develop a strategy for delivery of language assistance services. *See* 68 FR 47313–22. Covered entities are also encouraged to use the language access planning resources provided at *https://www.lep.gov/language-access-planning* or reference HHS's 2023 Language Access Plan for guidance at *https://www.hhs.gov/sites/default/files/Language-Access-Plan-2023_0.pdf*.

Covered entities with language access plans are often better prepared to provide individuals with LEP with meaningful access to their health programs and activities. For covered entities that have developed, implemented, and maintained language access plans, we highly encourage those covered entities to sustain that practice and to consider modifying their plans to include the elements required by § 92.8(d), to the extent it is not already included. To the extent a covered entity's language access plan meets the requirements of § 92.8(d), a separate procedures document will not be required regardless of whether the document is referred to as a ''plan'' or ''procedures.''

Comment: Some commenters recommended that OCR delete the requirement in § 92.8(d) for covered entities to identify the names of qualified bilingual/multilingual staff members due to employee turnover, with one commenter also requesting that OCR eliminate the requirement to maintain a list and location of electronic and written translated materials because such a requirement would be an onerous, inefficient use of time due to frequent changes to translated materials. Another commenter indicated that these requirements are especially difficult for large, covered entities, and that health insurance issuers in particular should have the option to provide business rules and rationale with respect to how and where they store documents rather than create a duplicative process. This commenter also recommended that OCR allow covered entities to articulate the process for accessing language services and contact information for the covered entity's department or functional group responsible for translations.

Response: OCR acknowledges that covered entities may need to periodically revise their language access procedures to reflect changes to qualified bilingual/multilingual staff; however, these staff members play a critical role in the delivery of timely language assistance services and therefore it is imperative that employees be able to identify qualified bilingual/multilingual staff members as quickly as possible through the use of a current directory. We decline to remove the requirement that language access procedures include a current list of qualified bilingual/multilingual staff members.

Timely and effective language assistance services are also best served by maintaining a current list of translated materials. OCR notes commenters' concerns regarding the practicality and burden of maintaining a list of the physical location of all written translated materials. For this reason, we are revising the requirement to no longer require the location of written translated materials, but only how to access electronic translated materials (*i.e.,* their location on a covered entity's network, intranet, or external-facing website).

Section 92.8(d) requires covered entities to include contact information for their Coordinator and how employees obtain services of qualified interpreters, translators, and multilingual/bilingual staff. This allows for covered entities to articulate the process for accessing language services; if this function has been delegated to a department or functional group, contact information for that department or functional group should be included in the language access procedures.

Comment: Some commenters recommended that the Department secure resources for small, covered entities to support their provision of language assistance services. For example, one commenter recommended that OCR contract with a telephonic interpretation service and allow small, covered entities to opt-in to using that service. Another commenter suggested that OCR partner with the U.S. Department of Education to invest in medical interpreter training for smaller language communities because investing in these communities would

[81] The $1,135 figure is derived from the 2015 NPRM for section 1557 on ''training costs'' for small entities. *See* 80 FR 54213.

result in higher quality health care. Another commenter requested that OCR make available sample policies and procedures; best practices for working with language assistance companies, identifying qualified (and unqualified) interpreters, and producing accurate and quality translations; and training videos.

Response: OCR appreciates these commenters' suggestions for providing resources to assist small, covered entities and, we are committed to making sample language access procedures available on our website at *www.hhs.gov/1557*. However, it is not appropriate for OCR, as a Federal agency, to endorse private interpreter or translator service providers. We are also unable to provide a telephonic interpretation contract into which small, covered entities could voluntarily participate.

OCR also appreciates the importance of interpreter training for less frequently encountered languages and is committed to developing a robust health care work force. To illustrate this commitment, the Department announced a ''Promoting Equitable Access to Language Services in Health and Human Services'' initiative in Fall 2022, for which grants were awarded to 11 organizations to develop and test methods of informing individuals with LEP about the availability of language assistance services in health care settings.[82]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Language Access procedures requirement provision at § 92.8(d) as proposed, with modifications. We are revising § 92.8(d) to require language access procedures to strike the requirement to include the location of any written or electronic materials and adding a requirement to include ''how to access electronic translations.'' We replaced ''publication date'' with ''date of issuance'' to better account for translated materials that may be in hard copy or electronic format. We are also making one technical revision. We are replacing ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

[82] U.S. Dep't of Health & Hum. Servs., Off. of Minority Health, *FY 2022 Grants Awards: Promoting Equitable Access to Language Services in Health and Human Services* (October 11, 2022), *https://minorityhealth.hhs.gov/fy-2022-grant-awards#:~:text=Grant%20period%3A%20 2022%2D2025,in%20health%20care%2D related%20settings.*

Effective Communication Procedures

Comment: Comments related to proposed § 92.8(e), regarding effective communication procedures, were similar to the language access procedures comments. Many commenters requested that OCR require covered entities to develop and implement a broad ''communication access plan,'' which would address effective communication and accessibility for individuals with disabilities, including individuals with disabilities who also have LEP. Commenters recommended that covered entities be required to develop communication access plans prior to developing their effective communication procedures. Some commenters suggested that a covered entity's effective communication procedures should also include how to determine the sign language an individual with a communication disability uses and whether the individual needs the services of an interpreter team, such as a certified deaf interpreter and an American Sign Language interpreter. One commenter recommended that we add a requirement for covered entities to create section 1557, ADA, and section 504 communication access plans along with the effective communication procedures requirement.

Response: Advance planning is an essential component of developing and implementing effective procedures that will ensure compliance with the obligations at § 92.202, which necessitate consideration of the various aids and services that may be required to deliver effective communication. Thus, while covered entities are not explicitly required to engage in advance planning, their ability to comply with § 92.202 will be best supported though robust procedures that are developed though a thoughtful and thorough process.

Covered entities may include more information in their respective effective communication procedures than § 92.8(e) requires, and we encourage covered entities that are already implementing communication access plans to maintain that practice. Covered entities with active communication access plans are permitted to modify such plans to include the information required by § 92.8(e); to the extent a covered entity's communication access plan meets the requirements of § 92.8(e), a separate procedures document will not be required regardless of whether the document is referred to as a ''communication access plan'' or ''effective communication procedures.'' While OCR appreciates the similarities between section 1557, section 504, and ADA's effective communication requirement, section 1557 is a distinct statute and imposing requirements for a similar procedure under the ADA and section 504 is outside the authority of this rulemaking.

Comment: One commenter requested that OCR make clear in the final rule that covered entities must implement effective communication and language access requirements in a well-coordinated, comprehensive, seamless, and equally effective manner such as through a standard operating procedure. This commenter also recommended that we inform covered entities that effective communication and language access requirements are of equal, paramount importance and closely interdependent with each other, and the commenter suggested that we issue guidance recommending effective communication and language access coordination.

Response: We agree with the commenter that effective communication and language access requirements are equally important, and effective communication and language access requirements can be interdependent, particularly when communicating with individuals with disabilities who have LEP. Though covered entities would ideally implement their effective communication and language access requirements in a well-coordinated, comprehensive, seamless, and equally effective manner, we decline to revise either paragraph (d) or (e) of § 92.8 or include any additional regulatory provisions imposing such standards on covered entities, in part, because such standards would be difficult to objectively measure.

Comment: Another commenter recommended that we revise § 92.8(e) to require covered entities' effective communication procedures include information about how covered entities will assess staff members' competency as qualified interpreters or qualified readers.

Response: We discuss assessment of interpreters at § 92.4; because of the flexibility allowed by the definition regarding how a covered entity chooses to assess the qualifications of interpreters (and readers), we decline to require this information be included in the procedures.

Comment: Some commenters recommended that OCR clarify that a covered entity's effective communication procedures apply to individuals with any disability that affects an individual's ability to communicate. Further, these

commenters also requested that we clarify that a covered entity's auxiliary aids and services options are not limited to qualified interpreters. Another commenter recommended that we include examples of accommodations, assistance, and opportunities for individuals with speech-related disabilities in the preamble and accompanying guiding documents.

Response: Covered entities' effective communication responsibilities, further discussed at § 92.202, apply to communication with all people with disabilities and a covered entity's effective communication procedures must equip employees with the information and tools necessary to meet the needs of individuals with many different types of disabilities. These may include, but are not limited to, sensory, manual, or speaking disabilities. Covered entities' obligations to provide auxiliary aids and services extend beyond qualified interpreters. A non-exhaustive list of auxiliary aids and services can be found in the definition of ''auxiliary aids and services'' in § 92.4.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Effective Communication Procedures requirement provision at § 92.8(e) as proposed, without modifications.

Reasonable Modification Procedures

Comment: Many commenters supported the reasonable modification procedures requirement under proposed § 92.8(f), with some noting that many covered entities, particularly smaller covered entities, are unaware of their obligation to reasonably modify their policies and procedures when necessary to avoid discrimination on the basis of disability. Some commenters recommended that OCR proactively provide examples of the types of reasonable modifications that covered entities should consider as a means of increasing the likelihood that a covered entity's reasonable modifications procedures are adequate. One commenter urged OCR to include a statement in the final rule's preamble or guidance that a reasonable modification can include communicating in a more accessible modality (*e.g.,* via email), if the patient requests it.

Response: It is OCR's intent that requiring a reasonable modification procedure will address the lack of knowledge on behalf of covered entities that commenters raised, and will increase covered entities' ability to respond appropriately to requests. OCR believes this will raise overall compliance with the requirement at § 92.205 to provide reasonable modifications, and will benefit both covered entities and individuals seeking access to health programs or activities.

The vast range of potential reasonable modifications available or necessary do not lend themselves to an exhaustive list and so we are not able to include such a list here. However, many reasonable modifications involve reasonable changes in the way that an entity does something or permits an individual to do something. For example, a covered entity that generally communicates with patients via phone but receives a request from an individual with a disability to receive communication via email as a modification should generally grant that request, unless the covered entity can demonstrate that doing so would fundamentally alter the nature of the health program or activity. Other examples include allowing an individual with a disability whose disability makes attending morning appointments difficult to schedule afternoon appointments when appointments may not generally be available at that time, or allowing an individual with a disability to attend appointments via telehealth instead of in person when such modification does not fundamentally alter the nature of the service being provided. To be clear, there is no exhaustive list of what constitutes a reasonable modification, nor must covered entities develop one. Rather, covered entities are required to implement written procedures describing their process by which an individual with a disability may request a reasonable modification and how a covered entity processes and responds to such requests.

Comment: One commenter stated that a covered entity must provide reasonable modifications to an individual with a disability in the absence of an affirmative request for the modification if the covered entity had knowledge of the individual's disability or when the individual's disability is obvious. Relatedly, another commenter requested that OCR revise § 92.8(f) to reflect that an individual's failure to request a reasonable modification does not always excuse the covered entity from providing a reasonable modification if the modification does not result in a fundamental alteration.

Response: Section 92.8(f) is an administrative requirement to implement a procedure by which a reasonable modification can be requested, evaluated, and granted. However, as noted in the 2022 NPRM, failure to request a reasonable modification does not always excuse the covered entity from providing a reasonable modification to avoid discrimination on the basis of disability, as long as the modification would not result in a fundamental alteration of the health program or activity. 87 FR 47850. For example, when a covered entity has knowledge of an individual's disability and needs, or when an individual's disability and needs are obvious, a covered entity must provide modifications in the absence of a request.[83]

Comment: Some commenters noted a common occurrence where patients with disabilities must repeatedly request the same reasonable modifications or auxiliary aids and services from the same covered entity for each visit. These commenters urged OCR to include additional language in the final rule preamble and guidance for covered entities to minimize patients' burdens of having to repeatedly notify, request, monitor, and enforce the covered entity's obligation to remove access barriers.

Response: These commenters' recommendations mirror similar comments related to experiences of patients with LEP who must repeatedly request the same language assistance services from the same covered entity. Such a practice may be inefficient and may violate the requirements of this part if they result in the delay or denial of access to a health program or activity. *See* discussion of § 92.201. While we strongly recommend that covered entities engage in the best practice of documenting in patients' medical records the specific reasonable modifications requested by patients with disabilities, in an effort to avoid overly prescriptive requirements we decline to revise § 92.8(f).

Comment: Commenters recommended that OCR require covered entities to appoint an individual to ensure compliance with the reasonable modification requirement. This person would: inquire whether patients need communications-related modifications; ensure such modifications are provided promptly; and monitor the patient's stay

[83] *See, e.g., Greer* v. *Richardson Indep. Sch. Dist.,* 472 F. App'x 287, 296 (5th Cir. 2012) (holding that a ''failure to expressly 'request' an accommodation is not fatal to an ADA claim where the defendant otherwise had knowledge of the individual's disability and needs but took no action''); *Duvall* v. *Cnty. of Kitsap,* 260 F.3d 1124, 1139 (9th Cir. 2001) (''When the plaintiff has alerted the public entity to his need for accommodation (or where the need for accommodation is obvious . . .), the public entity is on notice that an accommodation is required . . .'').

to ensure the modification is provided through the duration of the entire stay. This person would also be responsible for ensuring the covered entity is otherwise complying with the requirement to provide auxiliary aids and services.

Response: This rule, at § 92.7, requires designation of a Section 1557 Coordinator by covered entities that employ 15 or more persons. The Coordinator is responsible for ensuring compliance with section 1557's requirements, including the requirement to provide auxiliary aids and services at § 92.202 and to make reasonable modifications at § 92.205. A covered entity may delegate responsibility for the actual provision of auxiliary aids and reasonable modifications, and implementation of the corresponding procedures, to an individual other than the Coordinator, such as a designee; however, we decline to require the designation of an additional employee to implement these requirements.

Comment: One commenter recommended that OCR revise the regulatory text for § 92.8(f) to substitute the modifier ''reasonable'' with ''reasonable and appropriate.''

Response: We decline to adopt the commenter's suggested regulatory revision because ''reasonable modification'' is a term of art with a long history of enforcement in the disability context. We note that, consistent with similar longstanding disability rights law enforcement, we use ''appropriate'' in §§ 92.8(e) and 92.202(b) when describing the auxiliary aids and services that a covered entity must use to effectively communicate with individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Reasonable Modification Procedures requirement provision at § 92.8(f) as proposed, without modifications.

Training (§ 92.9)

In § 92.9, we proposed requiring covered entities to train relevant employees in their health programs and activities on their Section 1557 Policies and Procedures.

In § 92.9(a), we proposed a general requirement that covered entities train relevant employees of their health programs and activities on the Section 1557 Policies and Procedures required by proposed § 92.8.

In § 92.9(b), we specified when covered entities must train relevant employees on their Section 1557 Policies and Procedures.

In § 92.9(b)(1), we proposed that covered entities would be required to train existing relevant employees on their Section 1557 Policies and Procedures as soon as practicable, but no later than one (1) year after the effective date of the final rule.

In § 92.9(b)(2), we proposed that covered entities train new relevant employees within a reasonable period of time after they join a covered entity's workforce.

In § 92.9(b)(3), we proposed requiring covered entities to train relevant employees whose roles are affected by material changes to the covered entity's Section 1557 Policies and Procedures and any other civil rights policies or procedures the covered entity has implemented.

In § 92.9(c), we proposed requiring covered entities to contemporaneously document their employees' completion of the training required by this section in written or electronic form and maintain said documentation for no less than three (3) calendar years.

We invited comment on the experiences of covered entities in implementing training such as that required by proposed § 92.9, examples of where training made a difference in compliance, the timing of required training, whether covered entities would like the flexibility to include this required training as part of their existing annual compliance training, what types of changes would constitute a material change such that a covered entity would need to retrain staff, and how long training records must be retained. We also sought general comment on this proposal, including the effectiveness of civil rights training programs, the benefits experienced by covered entity staff and the people they serve, as well as the costs associated with the proposed training requirements. We further requested comment on whether the Section 1557 Policies and Procedures requirements and training requirements may increase the likelihood of compliance with the substantive legal requirements of section 1557.

The comments and our responses regarding § 92.9 are set forth below.

Comment: Many commenters on this provision expressed support for the training requirement and provided a range of reasons, including because the training is intended to impart knowledge and awareness of civil rights requirements and responsibilities; it will serve as an additional safeguard against discrimination and help reduce health disparities; and it will help providers connect patients to the services they need.

Commenters believed that a covered entity's staff need to understand section 1557 requirements, especially considering increased instances of employee turnover. One commenter also encouraged OCR to repeat the language in the Proposed Rule and remind covered entities that ''the more thoroughly a covered entity trains its staff on its Section 1557 Policies and Procedures, the more likely it is that the covered entity will successfully provide services to individuals in a nondiscriminatory manner.'' 87 FR 47850.

Some commenters said that civil rights violations occur due to lack of awareness and that training on covered entities' Section 1557 Policies and Procedures will help eliminate discrimination in health care because it promotes knowledge about how to deliver and administer health programs and activities to all patients, including patients who are members of communities that have experienced discrimination in health care services.

Some commenters suggested that OCR provide additional detail regarding the contents and delivery of the training, including by being more explicit about the nature and standards for determining adequacy of training. Conversely, one commenter recommended that OCR not make the training requirement overly prescriptive, and another asked OCR to give covered entities the authority to determine the training elements that best fit covered entities' operations.

Some commenters opposed the training requirement, referencing existing compliance burdens for providers, particularly small providers. Some commenters requested that OCR abandon the training requirement in the final rule because the requirement lacks specificity, is weak, vague, difficult to enforce, ineffective, will require more paperwork, and will confuse specialty clinics like dental offices; one commenter requested that OCR specifically exempt dermatology practices from the training requirement.

Many of the commenters that opposed the training requirement added that, if the rule is finalized as proposed, OCR should develop and provide educational materials and training resources, including materials to test trained employees' understanding of the new requirements.

Response: Section 92.9 requires covered entities to train relevant employees on their tailored Section 1557 Policies and Procedures, which will serve as a proactive safeguard against discrimination. Given this benefit, we decline to remove this

provision or exempt specific fields of practice from compliance with this requirement.

Recognizing the resources needed to comply with the training requirement, § 92.9 allows covered entities flexibility in designing the training they provide. However, the efficacy of the training—and its civil rights compliance benefit—will depend on a covered entity's effort in developing and conducting the training. OCR's experience with enforcing HIPAA's training requirement, 45 CFR 164.530(b), has found that employee-related violations are more limited where the required HIPAA training is routinely provided compared to where it is not. We anticipate that the section 1557 training requirement will similarly result in covered entities' employees being more aware of section 1557's discrimination prohibitions and establish a foundation by which covered entities' employees more consistently comply with nondiscrimination requirements.

With respect to the commenters' view that the training requirement will be difficult to enforce, the document retention requirement in § 92.9(c) is designed to assist with this. Moreover, OCR has been successfully enforcing HIPAA covered entities' compliance with HIPAA training requirements for more than 20 years. Through investigations, OCR evaluates covered entities' compliance with training requirements, and, when necessary, OCR ensures that a covered entity takes corrective actions to comply with said requirement.

To support compliance with this rule, OCR has made materials available on our website at *www.hhs.gov/1557*; however, the training required under § 92.9 must be based on the covered entity's own policies and procedures. Thus, while OCR is providing general resources on section 1557 requirements, they must be supplemented by the covered entity to include information regarding their specific Section 1557 Policies and Procedures.

Comment: Several commenters asked OCR to clarify whether covered entities could incorporate training on their Section 1557 Policies and Procedures with existing employee and annual compliance training instead of mandating a stand-alone training. One commenter recommended that covered entities train their employees on their respective Section 1557 Policies and Procedures separately because combining this training can result in information overload if employees are trained on multiple issues at the same training.

Response: This rule does not require or prohibit covered entities from incorporating the training required under § 92.9 with pre-existing employee or annual compliance trainings. We encourage covered entities to regularly train employees on their Section 1557 Policies and Procedures, possibly alongside other annual compliance trainings, and we recommend that covered entities offer section 1557 trainings in a manner that will result in maximum knowledge retention. While the rule does not specify the frequency with which trainings must be provided, covered entities should keep in mind that they must train new employees within a reasonable period of time after the employee joins a covered entity's workforce.

Comment: We received several comments recommending that OCR clarify the term ''relevant employees'' who must be trained under § 92.9. Many commenters recommended that we define ''relevant employees'' in the final rule's definitions section at § 92.4 or within § 92.9 itself. Some commenters suggested that ''relevant employees'' should include: employees whose roles and responsibilities require interfacing with patients and the public; employees who make decisions about patient care and covered entity operations that impact patient care; employees in leadership and supervisory roles who make decisions that affect nondiscrimination; and employees, including C-suite leadership (*i.e.,* the chief executive officer, chief financial officer, chief operating officer, and chief information officer), who are responsible for executing and making decisions regarding financial assistance, patient billing, and collections. Citing the importance of interactions between covered entities and patients in the long-term services and supports context, one commenter recommended that ''relevant employees'' should include temporary staff who interact with the public or clients.

Response: We appreciate commenters' recommendations to define ''relevant employee.'' Though we described a covered entity's relevant staff who must receive the training required in the 2022 NPRM, 87 FR 47851, based on comments received, we agree that including more specificity in the final rule text will add additional clarity for covered entities. We have provided a description of ''relevant employee(s)'' in new § 92.9(b)(4), which that, for purposes of the section, ''relevant employees'' includes employees whose roles and responsibilities entail interacting with patients and members of the public; making decisions that directly or indirectly affect patients' health care, including the covered entity's executive leadership team and legal counsel; and performing tasks and making decisions that directly or indirectly affect patients' financial obligations, including billing and collections. Below, we specify that relevant employees may include temporary employees in addition to permanent employees and have revised the regulatory text accordingly.

Comment: Other commenters recommended that OCR require covered entities to train all of their employees on the covered entities' Section 1557 Policies and Procedures because all employees may encounter a patient at any time, and they should understand basic section 1557 concepts. One commenter suggested that if OCR does not require covered entities to train all of their employees, then we should broaden who we consider to be ''relevant employees'' because employees who do not have direct patient interaction or policy-making roles may still have section 1557 responsibilities, and many of these employees are likely to engage in incidental patient interaction during the course of their work.

Response: A covered entity has the discretion to train all of its employees to eliminate the burden of determining who the covered entity believes is and is not a relevant employee. OCR notes that an employee who makes decisions that indirectly affect patients' health care or financial obligations meets the definition for ''relevant employee'' at § 92.9(b)(4), and therefore a covered entity would need to train such an employee pursuant to this provision. However, given the diversity of covered entities under this rule, we decline to mandate training for all staff. For example, to do so may cause confusion for covered entities that operate a health program that is part of a larger operation (*e.g.,* a retail grocery store that also operates a covered pharmacy).

Comment: Some commenters recommended that, due to high staff turnover and the common practice of hiring temporary, contract, or travel staff, OCR should consider allowing temporary staff to transfer prior, completed training from one facility to another to limit burden and redundancy. These commenters also asked OCR to permit training completion documentation from one covered entity to meet the documentation requirement for another covered entity as a means to limit burden and redundancy.

Response: Section 92.9 requires a covered entity to train employees on its

specifically tailored Section 1557 Policies and Procedures. Thus, Covered Entity A's Section 1557 Policies and Procedures will be different from Covered Entity B's Section 1557 Policies and Procedures, and therefore a temporary employee's training on Covered Entity A's policies and procedures will not be transferable to Covered Entity B. Though temporary, contractor, and travel employees may be with an entity for a limited amount of time, that does not minimize the likelihood that these employees may still encounter an individual with LEP or an individual with a disability who may need language assistance services, effective communication, or a reasonable modification. Covered entities that hire temporary, contract, and travel employees will still need to train these employees, document such training, and maintain that documentation for the requisite amount of time. We note that this approach is consistent with OCR's enforcement of the HIPAA training requirement.

Comment: Several commenters requested that OCR require covered entities to train their employees beyond their respective Section 1557 Policies and Procedures. For example, commenters suggested that OCR require covered entities to train their employees on a variety of issues including: how to work with interpreters (in person, over the telephone, and via remote video); cultural competence, including how employees should address stigma experienced by individuals with LEP and individuals with disabilities; interacting with people with disabilities (including individuals who are deaf, hard of hearing, deafblind, and deaf-disabled); and how to competently address transgender and nonbinary patients.

Some commenters recommended that covered entities invite individuals with disabilities and other diverse backgrounds to help conduct required training because learning from people with lived experiences will help covered entities achieve effective communication and reduce biases. Another commenter recommended that OCR work with stakeholders to develop appropriate training materials.

Response: We encourage covered entities to consider investing in their workforces by providing employees additional civil rights and nondiscrimination training beyond what § 92.9 requires. For example, covered entities may deploy interactive civil rights trainings that involve questions and answers and that more actively engages participants rather than the use of training formats like pre-recorded sessions to maximize comprehension of complex civil rights concepts. OCR also acknowledges that hiring, collaborating with, or otherwise engaging individuals with disabilities and other individuals from underserved communities to provide input on training (and the underlying Section 1557 Policies and Procedures) is a best practice. Further, engaging with these same groups to provide training regarding best practices and other civil rights-related issues will give a covered entity's employees valuable perspective about the importance of delivering compassionate, inclusive, and responsive health care.

However, we decline to expand the scope of the training requirement at this time. It is our position that the training on the Section 1557 Policies and Procedures required in § 92.9 strikes the appropriate balance between covered entities' burden concerns and the need for awareness of this vital information. We note that OCR has provided a general resource on section 1557 requirements that can supplement covered entities' Section 1557 Policies and Procedures training, available at *www.hhs.gov/1557*.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 92.9 as proposed, with modifications. We are revising § 92.9(b)(1) to specify that a covered entity must begin training its relevant employees no later than 30 days after a covered entity implements its policies and procedures required by § 92.8 and no later than 300 days after the effective date of the part. We are including a definition of ''relevant employee(s),'' for purposes of the section only, at § 92.9(b)(4) to provide: ''for the purposes of this section 'relevant employees' includes permanent and temporary employees . . . .'' Lastly, we are modifying § 92.9(c) to clarify that covered entities are required to retain (rather than ''maintain'') training documentation for the requisite time period.

Notice of Nondiscrimination (§ 92.10)

In § 92.10(a), we proposed requiring covered entities to provide a notice of nondiscrimination, relating to their health programs and activities, to participants, beneficiaries, enrollees, and applicants of their health programs and activities, and to members of the public (''Notice of Nondiscrimination''). Section 92.10(a)(1) proposed the required contents of the Notice of Nondiscrimination. Section 92.10(a)(2) proposed when and where covered entities must provide the Notice of Nondiscrimination.

In § 92.10(b), we proposed that a covered entity may combine the content of the notice required by § 92.10(a) of this section with the notices required by title VI, section 504, title IX, and the Age Act implementing regulations [84] if the combined notice clearly informs individuals of their civil rights under section 1557 and the part and meets the requirements outlined in proposed § 92.10(a)(1).

We invited comment on whether the Notice of Nondiscrimination requirement as proposed is practical, likely to be effective, and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the contents of the notice and requirements regarding when and where covered entities must provide this notice. We sought comment on the best ways to provide an accessible notice to individuals with disabilities who may require auxiliary aids and services and the best way in which to provide the notice in a manner accessible to individuals with LEP.

The comments and our responses regarding § 92.10 are set forth below.

Comment: Many commenters strongly support the notice requirements set forth in §§ 92.10 and 92.11 (Notice of Availability), stating that such notices are needed to help people know their rights and will reduce health disparities, especially for persons with LEP and persons with disabilities. Some organizational commenters added that when the 2016 Rule's notice requirement, former 45 CFR 92.8, was removed by the 2020 Rule, many people did not know their rights, how to access interpreters or auxiliary aids and services, or how to file a grievance. Several commenters added that a clear explanation of rights and contact information for the Section 1557 Coordinator, as set forth in § 92.10(a)(1)(v), is crucial. Some disability rights groups commented that not only should the Section 1557 Coordinator's contact information be included, but also that of the ADA Coordinator.

Response: The Notice of Nondiscrimination is a critical means by which to inform individuals of their civil rights, which is part of a proactive civil rights compliance structure that functions—in part—through grievances and complaints raised by individuals. We decline to require inclusion of contact information for an ADA

[84] 45 CFR 80.6(d) (title VI); 84.8 (section 504, federally assisted); 85.12 (section 504, federally conducted); 86.9 (title IX); 91.32 (Age Act).

Coordinator as this regulation is limited to section 1557; further, not all covered entities under this rule are subject to the ADA.

Comment: Various covered entities commented that the burden of the notice provisions is compounded by the complexity of having two separate notices (*i.e.,* the Notice of Nondiscrimination and the Notice of Availability) and the requirements to provide information in 15 languages.

Response: OCR takes seriously the concerns raised by some commenters regarding burden. In crafting the two distinct notice requirements, OCR considered comments received in response to the 2015 and 2019 NPRMs regarding the burden of a notice requirement. The provisions in the final rule reflect careful consideration of what must be included in each notice, and they include substantially more clarity regarding when and where each notice must be provided compared to the 2016 Rule.

We note that there is not a requirement that ''all information'' be provided in multiple languages; the requirement is that the Notice of Availability required by § 91.11 be provided in 15 non-English languages to inform individuals of the availability of language assistance services and auxiliary aids and services. Further discussion of this requirement can be found in our discussion related to the Notice of Availability (§ 92.11).

Comment: Many commenters noted that the parenthetical for sex discrimination included in proposed § 92.10(a)(1)(i) differs from the language of § 92.101(a)(2) and that it should be consistent, such that it should include sexual orientation and gender identity as well as pregnancy-related conditions.

Response: OCR appreciates the need for consistency across the regulation, and to ensure that the public is aware of the various bases for discrimination included under the umbrella of sex discrimination. As such, OCR has revised the parenthetical in § 92.10(a)(1)(i) to directly cite to § 92.101(a)(2), rather than listing examples of discrimination on the basis of sex. This is consistent with edits made to the Nondiscrimination Policy required by § 92.8(b).

Comment: Various commenters requested that OCR require any entity receiving a religious exemption to include notice of the exemption in the Notice of Nondiscrimination; they said it would be misleading to have a notice stating that the entity does not discriminate if it has been granted permission to do so in certain circumstances. They stated that the information is needed for LGBTQI+ persons seeking health care.

Response: OCR appreciates these comments. OCR declines to revise § 92.10 to impose an affirmative obligation on a recipient to identify any exemptions it has received under applicable Federal religious freedom and conscience laws. OCR additionally notes that it is a best practice for a recipient to include in its Notice of Nondiscrimination language when it has received a temporary exemption or an assurance of exemption. OCR is also subject to the Freedom of Information Act (FOIA), and information may be released to a requestor or made available for public inspection consistent with the agency's obligations under that statute and its implementing regulations.

Comment: Several commenters stated that the Notice of Nondiscrimination should be provided in the same non-English languages required by § 92.11 (Notice of Availability). Several commenters urged OCR to create a model Notice of Nondiscrimination, and to issue translations of this notice.

Response: The Notice of Nondiscrimination is among the materials that must be accompanied by a Notice of Availability, per § 92.11(c)(5)(i), which must be provided in multiple languages. While we have declined to require translation of the Notice of Nondiscrimination into a set number of languages, covered entities may still be required to provide translations when necessary to ensure meaningful access as required under § 92.201. OCR will provide a sample Notice of Nondiscrimination and may provide translations of the sample Notice of Nondiscrimination.[85]

Comment: Some commenters argued that the requirement for when and where the Notice of Nondiscrimination must be provided, § 92.10(a)(2), is too burdensome; others commented that it eases financial burdens compared to the 2016 Rule requirements, while also ensuring that people receive information about the covered entities' civil rights obligations. Some commenters supported the requirement of prominent posting on websites, including because of the low cost, while another commenter observed that poor and rural areas sometimes cannot be reached by internet and described the need to reach historically underserved and marginalized populations.

Various commenters agreed with the proposal to provide the Notice of Nondiscrimination annually and upon request as opposed to the 2016 Rule's ''significant communications'' [86] requirement, including because the current proposal is clearer than the 2016 Rule requirement. Others stated that OCR should require the Notice of Nondiscrimination in all significant communications, such as Explanations of Benefits and patient intake forms. Some opposed annual notices as costly and annoying to patients, recommending that notice instead be upon enrollment, upon request, and prominently in health care plan documents. Others argued for using the HIPAA model, which requires notice at first point of service and then upon request only.

Response: In developing the points of contact at which a Notice of Nondiscrimination must be provided, OCR considered the concerns raised by covered entities regarding burden, consumer fatigue, and lack of clarity and specificity in prior requirements. However, we also considered comments that stated the Notice of Nondiscrimination is important to ensure that persons are informed of their civil rights and without this knowledge, including the right to language assistance services and effective communication, health disparities may continue to increase as they did during the COVID–19 pandemic. The provision is a reasonable and balanced approach that reduces the number of communications in which this essential notification is required compared to the 2016 Rule requirements,[87] while preserving its necessary function.

While OCR appreciates that many individuals lack internet access, we note that the regulation as drafted requires posting in physical locations, as well as being provided upon request, § 92.10(a)(2)(ii) and (iv); therefore, access to the Notice of Nondiscrimination is not dependent on internet access.

Comment: Various commenters recommended that the Notice of Nondiscrimination be posted prominently where frontline employees can see it, and that it be in large sans serif font (at least 18-point font).

Response: OCR appreciates these comments and the importance of ensuring that the Notice of Nondiscrimination posted in physical

[85] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Translated Resources for Covered Entities, https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html* (translated Notice of Nondiscrimination. Statement of Nondiscrimination, and Taglines required by the 2016 Rule).

[86] 87 FR 47852–53 (discussion in 2022 NPRM); 85 FR 37161–62, 37175 (discussion in 2020 Final Rule).

[87] *Id.*

locations can be seen and is accessible to individuals who may have low vision. For this reason, we are finalizing § 92.10(a)(2)(iv) to require that posted notices be in a sans serif font, no smaller than 20-point font.[88]

Comment: Several commenters argued that the Notice of Nondiscrimination and Notice of Availability must be provided together, because they are so intertwined, adding that this may also reduce the burden for covered entities.

Response: OCR appreciates this comment and directs commenters to the requirement at § 92.11(c)(5)(i), which requires that the Notice of Availability be provided with the Notice of Nondiscrimination. Covered entities may choose to integrate the Notice of Availability into its Notice of Nondiscrimination.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.10, with modifications. OCR is revising the explanatory parenthetical for sex at § 92.10(a)(1)(i) to read ''consistent with the scope of sex discrimination described at § 92.101(a)(2).'' We are also providing a technical revision to § 92.10(a)(1)(iii) to replace ''necessary'' with ''a reasonable step'' for consistency with the standard articulated in § 92.201(a), that ''[a] covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency (including companions with limited English proficiency) eligible to be served or likely to be directly affected by its health programs and activities.'' We are revising § 92.10(a)(2)(iv) to require that posted notices be provided ''in no smaller than 20-point sans serif font.'' Finally, we are making a technical revision to replace ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

In § 92.11, we proposed requiring covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities (''Notice of Availability'').

In § 92.11(a), we proposed requiring a covered entity to provide a notice that, at minimum, states that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge in its health programs and activities, when necessary for compliance with section 1557 or the part. This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity's health program or activity, and members of the public.

In § 92.11(b), we proposed requiring the Notice of Availability to be provided in English and at least the 15 most common languages spoken by individuals with LEP of the relevant State or States, and in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

In § 92.11(c), we proposed requiring the notice be provided on an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants, and upon request at any time; we also proposed that the notice be provided online (when applicable) and in a clear and prominent physical location where it is reasonable to expect individuals seeking services from the health program or activity to be able to read or hear the notice. In § 92.11(c)(5), we proposed a list of specific electronic and written communications that the Notice of Availability must accompany. We invited comment as to whether requiring a Notice of Availability for all Explanation of Benefit (EOB) documents is the most appropriate approach, balancing the burden of providing Notices of Availability with all EOBs against the burdens associated with determining which EOBs must include the notice.

In § 92.11(d), we proposed alternative, optional methods by which a covered entity may be deemed in compliance with proposed § 92.11(a).

We sought comment on whether the Notice of Availability requirement as proposed is practical and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the content of the Notice of Availability and requirements for when and where covered entities must provide the notice. We also invited comment as to whether the proposed requirements adequately address the specific concerns raised regarding the burdens associated with the 2016 Rule requirements by providing a list of specific documents with which the Notice of Availability must be provided. Additionally, we invited comment on how to best provide the Notice of Availability to individuals with disabilities to ensure they know how to request and receive relevant materials and documents in formats that meet their disability-related needs, and whether covered entities should be required to provide the Notice of Availability in sign language. Similarly, we sought comment on how to best provide the Notice of Availability to individuals with LEP, including individuals with LEP with disabilities, to ensure they know how to request and receive language assistance services and auxiliary aids and services to provide meaningful access to relevant materials and documents. We also sought comment on whether the proposed list of electronic and written communications that the Notice of Availability must accompany adequately captures the documents for which individuals with LEP and individuals with disabilities should receive the Notice of Availability. We further invited comment on the anticipated costs to covered entities of various sizes to comply with the proposed requirements.

The comments and our responses regarding § 92.11 are set forth below.

Comment: Many commenters stated that the Notice of Availability is needed because people are unaware of their rights to language assistance and auxiliary aids and services, leaving them unable to advocate for themselves and leading to health disparities. Commenters agreed that the 2019 NPRM and 2020 Rule fail to address the costs borne by participants, beneficiaries, and enrollees in the absence of notice, and the additional costs to the health care system that could result. 87 FR 47853. Many commenters provided examples of how individuals with LEP experience disparities in health care, including poor care and outcomes; higher uninsured status; lower health literacy; longer hospital stays; greater difficulty understanding health instructions; and general health care underuse. The commenters emphasized that providing Notice of Availability is the most essential element to decreasing language barriers and that with proper notice of their rights, health disparities for individuals with LEP would be reduced.

Response: OCR appreciates commenters highlighting the importance of providing individuals with LEP notice of their right to receive language assistance services, and the negative consequences of failure to do so. As discussed, OCR considered the concerns raised in response to the 2019 NPRM and 2020 Rule's failure to include a similar notice provision, as well as concerns raised in response to the 2016 Rule's notice provision. As proposed and finalized, § 92.11 provides

[88] *See* Am. Council of the Blind, *Best Practices and Guidelines for Large Print Documents Used by the Low Vision Community* (2011), *https://archive.org/details/bestpracticesgui00coun.*

an appropriate balance between the approaches of these prior rules and is an important tool for combatting and preventing health disparities based on communication barriers.

Comment: Numerous commenters stated that the requirement to provide the Notice of Availability in 15 non-English languages was too many, providing examples of places in which they believe fewer languages were needed. For example, one provider commented that in California, 95 percent of their communications were requested in the top five languages in the State, therefore translations into the top five languages would be sufficient. Other commenters noted that smaller entities would be particularly burdened by the proposed standards. One commenter stated that requiring pediatric dental offices to offer the Notice of Availability as proposed would be burdensome and cause confusion.

Conversely, many other commenters stated that 15 languages is too few and that, under the proposed requirements, the Notice of Availability would not reach enough individuals with LEP, giving examples of language populations that would not be reached. Some commenters expressed a belief that covered entities should ensure each individual with LEP receives information about their rights in their preferred language, and that a 15-language requirement would not adequately provide that assurance. Some commenters stated that the identification of languages required should not be determined at the State level but should instead be based on the covered entity's entire program area in various states. On the other hand, some commenters expressed that the required languages should always be determined at the State level only, rather than ''State or States.''

Commenters said that because OCR will provide model notices translated into the required languages, and because of the need for meaningful notice of auxiliary aids and language assistance services, the burden for providing notices in the top 15 languages per State is lessened and reasonable. A few local government commenters stated that their jurisdiction currently requires translation in more than 100 languages and recommended that this rule incorporate State and local norms.

Response: In determining the formula for the Notice of Availability translation requirement, OCR considered the 2016 Rule requirement, evaluated national- and State-level language proficiency data issued by the U.S. Census Bureau (Census), as well as potential the costs and burdens for covered entities.

The need to provide individuals with LEP notice of the availability of language assistance services remains clear and there is ample evidence that failure to provide meaningful language access in a health care setting can lead to higher costs to the health care system and have grave consequences to individuals with LEP. 87 FR 47853–54. Since the ACA was enacted, the percentage of the U.S. population with LEP (defined as those who speak English less than ''very well,'' as collected by the Census) has remained at roughly 10 percent.[89]

OCR has received complaints and entities have sued the Department for rescinding the 2016 Rule's notice requirements.[90] Litigants in *Chinatown Services Center* v. *U.S. Department of Health & Human Services* raised specific concerns that older members of the Asian American, Native Hawaiian, and Pacific Islander community, who have high rates of limited English proficiency, experienced disparities because they are not aware of their right to receive language assistance services or how to raise a concern when such services are not provided.[91] Although one Federal court ultimately held that a plaintiff health system was not likely to prevail on the merits of its Administrative Procedure Act challenge to the 2020 Rule's repeal of the 2016 Rule's notice requirements, the court notably acknowledged that a consequence of the 2020 Rule was that the plaintiff health system provided ''costlier and more difficult treatment'' because patients with LEP likely received inadequate health care elsewhere and arrived to their system sicker than they otherwise may have.[92]

OCR appreciates concerns regarding proposed § 92.11, which would require a covered entity operating in all 50 States to aggregate the populations with LEP across those States to determine the top 15 languages spoken by individuals with LEP in its service area. While this may result in a failure to reach some in-State LEP populations due to geographical variances, no single formula, including a State-level formula, will cover all individuals with LEP. However, this formula would cover a significant majority (over 93 percent) of individuals with LEP, even for covered entities that operate on a national level.[93]

Thus, while OCR appreciates the request to increase the number of languages into which the Notice of Availability must be translated, we have determined that this would likely increase burdens while yielding additional coverage of marginally few individuals with LEP. However, covered entities are reminded that they must still take reasonable steps to provide meaningful access to *all* individuals with LEP, regardless of whether the individual's primary language is one of the 15 most frequently spoken non-English languages in their State or States, per § 92.201. Further, nothing in this rule prevents jurisdictions from requiring that the Notice of Availability be translated into more languages; covered entities wishing to provide more languages may also do so.

OCR recognizes concerns raised in the comments regarding the potential cost of translating the Notice of Availability into the required languages. To offset this concern, OCR has provided translations of the model Notice of Availability in the top 15 languages in each State, at *www.hhs.gov/1557*. Additionally, § 92.11(c) reduces the number of documents for which provision of the translated notices is required from the 2016 Rule, and § 92.11(d) provides two options for how a covered entity may otherwise meet the requirements of this provision. OCR anticipates that efficiencies created by this formula—complemented by the availability of OCR-translated Notices of Availability—will benefit covered entities and the communities they serve. These benefits will reduce harmful impacts of the failure to take reasonable steps to provide meaningful access—such as unnecessary hospital readmissions, lower rates of outpatient follow up, limited use of preventive services, poor medication adherence, and lack of understanding of discharge

[89] U.S. Bureau of Census, Sandy Dietrich & Erik Hernandez, *Language Use In the United States: 2019, Am. Community Survey Reports,* p. 4 (2022), *https://www.census.gov/content/dam/Census/library/publications/2022/acs/acs-50.pdf.*

[90] *See* Compl., *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 1:21–cv–00331 (D.D.C. Feb. 25, 2021), Compl., *Whitman-Walker Clinic* v. *U.S. Dep't of Health Hum. Servs.,* No. 1:20–cv–01630 (D.D.C. June 22, 2020) and *see* 87 FR 47853–54.

[91] Compl., *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 1:21–cv–00331, 22–35 (D.D.C. Feb. 25, 2021).

[92] *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Hum. Servs.,* 485 F. Supp. 3d 1, 30 (D.D.C. 2020).

[93] U.S. Census Bureau, *Am. Community Survey 5-Year Estimates Public Use Microdata Sample 2020 for the 50 States and DC* (2000), ACS 5-Year Estimates Public Use Microdata Sample 50 States & DC; *https://data.census.gov/mdat/#/search?ds=ACSPUMS5Y2020&cv=ENG&rv=ucgid,LANP&wt=PWGTP&g=0400000US01,02,04,05,06,08,09,10,11,12,13,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,44,45,46,47,48,49,50,51,53,54,55,56.*

instructions [94]—thereby alleviating burdens on community organizations that have been providing notice of language access as well as providers who have seen negative impacts such as increased costs and sicker patients since the repeal of the 2016 Rule's notice requirements. *See* 87 FR 47853–54. Given these efforts, the requirement of providing notice of language access rights is not overly burdensome when balanced with the need to provide notice of the availability of language assistance services to individuals with LEP.

Comment: A few commenters suggested that a hybrid method should be used to calculate which languages are required for translation under this provision, such as the higher or lower of a percentage or absolute number (for example, a threshold of five percent or 1,000 individuals with LEP, whichever is lower). Some commenters recommended OCR adopt the standard found in Tri-Departmental regulations at 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e), which applies a county-level formula and is applicable to the internal claims and appeals and external review processes for group health plans and health insurance issuers in the group and individual health insurance markets, to decrease costs and avoid confusion. Some added that a hybrid method, such as allowing for calculations at the county- instead of State-level, is especially critical for small practices operating at only the county level. They stated these practices may not have resources to translate the Notice of Availability into the top 15 languages spoken in the State and may serve language communities that are different from those represented by the top 15 languages at the State-level.

Response: OCR appreciates these suggestions but, as we discussed in the Proposed Rule, OCR declined to adopt a population threshold due to variances among urban and rural communities. 87 FR 47855. We are concerned about similar results if a percentage threshold is used, and we decline to adopt this approach.

While OCR appreciates that some covered entities will have to comply with both OCR and Tri-Departmental regulations, we decline to adopt the county-level formula found in the referenced Tri-Departmental regulations, 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e), which provides that a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as section 1557 applies to a wider range of covered entities, communications, and individuals with LEP. We will continue to monitor issues related to this area and work with CMS as appropriate in the future to ensure compliance.

Comment: Some commenters suggested that OCR work with covered entities and community groups to develop additional effective ways to inform individuals with LEP about their language access rights. A health insurance entity suggested convening a stakeholder process to develop and test a pilot with easy-to-understand, universal language access symbols to connect persons with LEP to language assistance services.

Response: OCR appreciates this recommendation and welcomes the opportunity to collaborate with covered entities and community groups to develop effective means for informing individuals with LEP of their language access rights.

Comment: Many commenters supported the list of documents requiring a Notice of Availability in § 92.11(c), emphasizing the critical importance of clear communications in health care settings. Some commenters noted the provision fills information gaps and that receiving information multiple times is sometimes needed for effective notice, particularly for older adults. Others expressed support for the balanced approach of including opt-out provisions so that covered entities are not overly burdened, but participants and beneficiaries know their rights. Several commenters urged OCR to add medical bills to the list, providing examples of negative impacts of bills being sent without notice of how to access effective communication.

Many other commenters expressed concerns about administrative burdens and costs of notice in relation to the number of communications in which the Notice of Availability would be required under § 92.11(c), while others pointed out that the list is effectively shorter than in the past.

Several commenters wrote generally about language assistance services and auxiliary aids and services, with some asking for flexibility in the language access rules to allow for translation of the most important documents with the provision of oral interpretation for other information. Another argued that translation and interpretation as well as auxiliary aids and services rules should not apply to physician practices or health centers. Others requested that health insurance issuers or the Federal Government reimburse providers for disseminating these items.

Response: We appreciate the comments and believe that the list of documents identified in § 92.11(c), which provides clarity and prioritizes inclusion of the Notice of Availability in critical health care documents, strikes the appropriate balance between potential burdens to covered entities and the benefits to individuals with LEP and individuals with disabilities. OCR appreciates commenters raising concerns regarding the accessibility of medical billing, which can have long-term negative financial impacts on patients.[95] Similarly, accessible notices of expected costs and benefits, such as the good faith estimate, can help patients make informed, cost-conscious decisions about their care and reduce the risk of unexpected medical bills.[96] The potential financial impact of making these estimates accessible is particularly significant for individuals with LEP and individuals with disabilities who are uninsured (or self-pay), because these individuals have the right to dispute medical bills that are substantially in excess of the expected charges on their good faith estimate [97] and exercise of this right depends on the ability of such individuals to understand both their good faith estimates and their medical bills. For these reasons, we are adding § 92.11(c)(5)(ix), which requires a covered entity to provide its Notice of Availability along with billing-related documents and reads: ''Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B–6 of the Public Health Service Act.''

Comment: Regarding an alternative, optional means of compliance at § 92.11(d), one covered entity commenter requested that OCR specify that entities in compliance with other

[94] *See* Neelam H. Ahmed et al., *Moderation of the Association Between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022), *https://www.mdpi.com/1660-4601/19/13/7750.*

[95] *See* NPR, Lauren Weber & Hannah Recht, *Medical Bills Remain Inaccessible for Many Visually Impaired Americans,* Health, Inc. (Dec. 1, 2022), *https://www.npr.org/sections/health-shots/2022/12/01/1139730806/blind-disability-accessibility-medical-bills* (discussing an investigative news report and including an OCR investigation).

[96] Internal Revenue Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), as added by section 111 of title I of division BB of the Consolidated Appropriations Act, 2021 (CAA); PHS Act section 2799B–7, as added by section 112 of title I of division BB of the CAA; 45 CFR 149.610.

[97] PHS Act section 2799B–6, as added by section 112 of title I of division BB of the CAA; 45 CFR 149.620.

Department requirements related to language access and auxiliary aids are deemed to have complied with section 1557. One commenter stated that the Notice of Availability should be combined with the Notice of Nondiscrimination, as well as HIPAA notices; another suggested OCR work with CMS and other HHS agencies to leverage existing practices and make these requirements technically operational.

Response: As discussed elsewhere, OCR appreciates that covered entities may have compliance requirements under other Department regulations similar to those found in this provision. However, given the range of health programs and activities to which section 1557 and the part apply—including those where inaccessible communication can have life-or-death consequences—it is imperative to have an independent requirement. Covered entities' compliance with § 92.11(b) will increase the likelihood of compliance with similar Department translation requirements. While we appreciate commenters' suggestion to combine the Notice of Availability with the Notice of Nondiscrimination and the HIPAA notices, § 92.11(c)(5) requires the Notice of Availability to additionally be included with a list of important health care documents because the ability of patients to avail themselves of language access services is foundational to improving health outcomes for individuals with LEP. OCR will therefore maintain this requirement under § 92.11(c)(5) for covered entities.

Comment: Various commenters expressed support for the alternate compliance provisions found in § 92.11(d). One group raised the idea of an ''opt-in'' provision, in which individuals with LEP would have to state that they want Notice of Availability, in lieu of the proposed opt-out provision, and sought clarification about whether the opt-out provision can be combined with Notice of Availability.

Some commenters argued that the alternate compliance options could be difficult to implement and lead to additional costs, cause confusion, or be generally burdensome, with one commenter stating they would be more burdensome than the 2016 Rule requirements because they require customizing documents. One commenter requested OCR delay implementation of the opt-out provision until 2024; other commenters suggested replacing the option with a less burdensome approach, asking that it be only electronic.

On the other hand, commenters stated that the opt-out provision strikes a reasonable balance that is effectively narrower than the 2016 Rule's ''significant communications'' requirement. Another commenter agreed, commenting that the proposal could be both more consumer friendly and helpful, as well as less duplicative and costly than the 2016 Rule. One commenter encouraged OCR to provide robust oversight of opt-out processes in order to protect civil rights.

Response: OCR appreciates the range of comments received on this new provision. We emphasize that the options included in § 92.11(d) are options, and not requirements. Thus, we appreciate that covered entities may wish to have a delayed applicability date, to pursue these options only through electronic means, or not pursue them at all. OCR is not requiring any actions under § 92.11(d) be taken; rather, OCR is providing alternate means to satisfy the requirements of § 92.11 without including the full Notice of Availability with all communications listed at § 92.11(c).

OCR declines to make further changes clarifying that a person should only be asked about their language needs once, because § 92.11(d)(1) permits this if the individual exercises the option to opt-out. Moreover, § 92.11(d)(2) allows a covered entity to document an individual's primary language, any appropriate auxiliary aids and services, and to communicate with them in that manner.

OCR intends to provide robust review of opt-outs, as well as technical assistance, to ensure that covered entities that choose to exercise this option do so in a manner consistent with the requirements at § 92.11(d).

Comment: Many commenters submitted recommendations to increase guarantees of accessibility of the Notice of Availability for individuals with disabilities, such as requiring that: (1) notices be provided in large sans serif print, at a minimum of 18-point font; (2) notices be on the first page or otherwise at the beginning of documents or publications; (3) the needs of persons who are illiterate be taken into account through provision of audio or video notices; (4) all written notices be in plain language (fourth grade reading level), accompanied by visual aids when practicable; and (5) notice should be provided via audio, video, and American Sign Language. A coalition also discussed recommendations to ensure effective communication. Other accommodations recommended included: (1) screen readers and audio/video accessibility; (2) alternatives to braille (*e.g.,* large print, qualified reader) because braille may not be economically feasible for all entities; (3) accessible tagline requirements or cross-references to language access rights; and (4) ''Easy Read'' text, images, brief sentences, large and simple fonts, and location on the first page.

Many also commented that the Notice of Availability should be posted where frontline employees can readily see it, that employees should be trained to provide it, and that it be available upon request. Various commenters urged that covered entities must proactively ask people if they have communications barriers. Further, commenters stated that primary consideration should be given to what a person with a disability asks for in terms of auxiliary aids or services. Another commenter added that provision of the notice should be clarified so it applies to listening devices and the other range of auxiliary aids.

Response: OCR appreciates all the suggestions and reminds commenters and others that the meaningful access and effective communication requirements (§§ 92.201 and 92.202, respectively) regarding the provision of language access and auxiliary aids apply to the Notice of Availability. Covered entities have existing effective communication obligations under section 504 and section 1557, which may include providing the notice in an alternate format or providing another auxiliary aid or service. Thus, if an individual is in need of the notice in an alternate format or through another auxiliary aid or service, that would likely already be required when it is necessary to ensure effective communication. We decline to affirmatively require the notice be provided in any additional formats at this time. However, OCR agrees that larger print should be required to ensure the accessibility of the Notice of Availability when posted in physical locations, and that this requirement is relatively straightforward to implement; accordingly, § 92.11(c)(4) has been amended to require print no smaller than 20-point in a sans serif font.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.11, with modifications. We are revising § 92.11(b) to clarify the relevant State or States are those ''in which a covered entity operates.'' We are modifying § 92.11(c)(4) to clarify that posted notices be provided ''in no smaller than 20-point sans serif font.'' We are adding

§ 92.11(c)(5)(ix) to read: ''Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B–6 of the Public Health Service Act.'' We are also making technical revisions, including replacing ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

Data Collection

We solicited comments on requiring covered entities to collect additional data, beyond those required by the referenced statutes and their regulations, on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age, to inform a final rule and OCR's overall civil rights work.

We also sought comment on whether covered entities are already collecting disaggregated demographic data in their health programs and activities and, if so, for which categories of data, through what systems, and at what cost. We also invited comment on how a section 1557 civil rights data collection requirement could impact current data collection efforts, either positively or negatively. We also requested comment on whether the adoption of a regulatory standard for a recurring civil rights data collection would benefit civil rights enforcement, as well as how frequently the data should be submitted to OCR. We also sought comment on whether the data collection requirements should vary by type of entity, as recipients of Federal financial assistance include a variety of entities, including State and local agencies, health insurance issuers, providers, health care facilities and clinics, hospitals, Federally Qualified Health Centers, and health-related educational and training programs. Accordingly, we invited comment on which types of recipients (if any) should be covered; if recipients under a certain size should be exempt from the data collection requirement, and if so, whether that exemption should be based on employee number, the number of beds (if relevant), or some other metric; what types of data should be collected; what definitions should be used; the potential costs associated with such a requirement; and the potential benefits of such a requirement.

The comments and our responses regarding data collection are set forth below.

Comment: Some commenters recommended that OCR not mandate the collection of data, with some strongly suggesting that we minimize provider burden and utilize existing data collection systems.

Response: OCR is not including a data collection requirement in the final rule. OCR has the authority independent of this rulemaking to conduct data calls to ensure recipient compliance with Federal civil rights laws.[98] OCR is actively engaged with other agencies within the Department and throughout the Federal Government related to responsible data collection and recognizes the importance of data collection to meet its mission. We will continue to work with covered entities and beneficiaries to determine whether an additional data collection requirement is needed in a future rulemaking.

Comment: Some commenters recommended that OCR adopt data collection standards. They noted that with any demographic data collection requirement, OCR must provide appropriate training and technical assistance resources to programs and grantees and make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups.

Response: OCR appreciates the comments regarding standards and safeguards to ensure that programs and grantees have the appropriate training. OCR also understands the concerns that some commenters have regarding data being used for adverse actions. While OCR is not including a data collection requirement in the final rule, OCR will continue to research the benefits of civil rights data collection and how to mitigate potential negative impacts.

Comment: Some commenters urged OCR to require covered entities to collect data regarding a core set of disaggregated categories to include race, ethnicity, language, sex, gender, gender identity, sexual orientation, pregnancy status, sex characteristics, disability, and age from patients and providers. Commenters stated that data are essential to identify and address unmet needs, and for many populations data remain largely uncollected. Some commenters also noted that collecting disaggregated data could allow OCR to distinguish the impact of intersectional discrimination on those seeking access to health care. Some commenters also urged that if individuals volunteer such information, it should be self-reported to ensure accuracy and privacy.

Response: OCR agrees that better standards and practices for collecting data can have a positive impact on reducing disparities. OCR will continue to work to ensure that any civil rights data collection yields accurate data that adequately protects the privacy of individuals.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the rule without a data collection provision.

Subpart B—Nondiscrimination Provisions

In subpart B, OCR proposed provisions related to the prohibition of discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs and activities.

Discrimination Prohibited (§ 92.101)

In § 92.101(a), we proposed a general prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which section 1557 or the part applies and provided additional detail regarding what constitutes discrimination on the basis of sex.

In § 92.101(a)(1), we proposed general prohibitions on discrimination under section 1557 by restating the core objective of section 1557. In § 92.101(a)(2), we clarified that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.

In § 92.101(b), we identified several specific forms of prohibited discrimination under section 1557. Proposed § 92.101(b)(1)(i) specifically referred to recipients of Federal financial assistance and State Exchanges; proposed § 92.101(b)(1)(ii) referred to the Department's health programs and activities, including Federally-facilitated Exchanges.

In § 92.101(b)(2), we proposed that the enumeration of specific forms of discrimination in 92.101(b) does not limit the general application of the prohibition in proposed § 92.101(a).

The comments and our responses regarding § 92.101 are set forth below.

Comment: Numerous commenters supported the Proposed Rule's nondiscrimination provisions, stating that these provisions would promote the health equity for communities of color and increase access to coverage and care for those who have been historically underserved because of race, ethnicity, language, age, disability, and sex. Many commenters stated that OCR should finalize the provisions without delay.

[98] *See, e.g.,* 45 CFR 80.6(b).

Another commenter supported the proposed discrimination prohibitions as consistent with the ACA, and another requested that more support be provided for educating the public about the nondiscrimination obligations of health programs and activities.

Response: OCR agrees that the nondiscrimination provisions are one important tool to address health disparities and advance health equity. OCR will continue to provide technical assistance and public education related to compliance with section 1557 and encourages covered entities to continue to visit our website for technical assistance materials.

Comment: Numerous commenters stated that section 1557's explicit prohibition on discrimination based on multiple grounds fills a critical gap by protecting patients who may experience multiple forms of discrimination. Commenters provided numerous examples of simultaneous discrimination on more than one protected basis, including, but not limited to, discrimination against LGBTQI+ individuals of color, with disabilities, with LEP, or who are immigrants; and Black and Hispanic/Latino older adults. Numerous commenters recommended that OCR revise § 92.101(a)(1) to include ''or any combination thereof'' to explicitly account for intersectional discrimination within the regulatory text.

Response: OCR agrees that simultaneous discrimination on multiple prohibited bases, is important to account for and is prohibited by section 1557. As we noted in the Proposed Rule, a recent study examined disability and pregnancy as intersecting traits and how this may impact risk for maternal morbidity and mortality, underscoring the importance of ensuring nondiscrimination against women with disabilities. 87 FR 47837. The Proposed Rule also provided information regarding Black maternal health and the alarming disparities in maternal mortality rates for Black women and American Indian/Alaska Native women. 87 FR 47832.

Therefore, to account for the fact that individuals can experience discrimination based on two or more protected bases (race, color, national origin, sex, age, and disability), we have amended the language of § 92.101(a)(1) to include ''or any combination thereof.'' This language has also been amended throughout the final rule for consistency. The addition intends to clarify that an individual is protected from discrimination on more than one protected basis that occurs at the same time.

Comment: A commenter provided a discussion of the harms and unaddressed discrimination faced by patients with rare diseases and requested that OCR explicitly prohibit discrimination against patients with rare diseases. Some commenters requested that specific recognition also be made for patients with liver diseases. A commenter requested that the proposed regulatory text or accompanying guidance provide examples of discrimination on the basis of disability.

Response: Discrimination against an individual with a rare or specific disease that meets the definition of ''disability'' will be addressed under section 1557's prohibition on discrimination on the basis of disability, which already appears in the rule. The commenter's request for further guidance will be taken into consideration. For additional information related to disability discrimination, please see the discussions under subpart C. OCR also provides guidance and examples, as well as answers to frequently asked questions related to disability discrimination on our website.

Comment: A number of commenters asked that vaccination status be added as a ground of prohibited discrimination, stating that their right to make their own health care decisions should be protected.

Response: Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, and disability. To the extent vaccination status is not related to these prohibited bases of discrimination specified by Congress in section 1557, we decline to include it as a ground of prohibited discrimination under this rule.

Comment: Some tribal organizations recommended that OCR acknowledge American Indian/Alaska Native (AI/AN) people as holding a political classification as compared to a race-based classification and to exempt Tribal health programs from the final rule. These commenters stated that recognizing the political classification of AI/AN people allows AI/AN providers to only serve AI/AN patients, which commenters said is necessary because of logistical capacity constraints.

Response: As discussed at § 92.2, OCR recognizes the unique relationship between the United States and federally recognized tribal entities. Federal Government preferences based on an individual's membership or eligibility in a federally recognized tribal entity are based on political classifications. Such classifications are not race-based. As such, preferences on this basis do not violate the Equal Protection Clause,[99] title VI,[100] or section 1557. As discussed at § 92.2, preferences based on the unique relationship between the United States and federally recognized Tribes are distinct from the protections afforded under Federal civil rights laws, which protect all individuals from discrimination on the basis of race, color, or national origin (including AI/AN individuals, regardless of tribal enrollment or affiliation). This final rule adopts by reference the Department's title VI regulatory provision at 45 CFR 80.3(d), which provides that an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law—such as the Indian Health Service—to individuals of a different race, color, or national origin. OCR will fully apply this provision as well as other applicable exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of section 1557 to Tribal entities in the context of individual complaints or compliance reviews.

Comment: A commenter suggested that nondiscrimination protections should be extended to health care workers, indicating that health care workers often experience discrimination, especially on the basis of race and that additional protections are needed.

Response: While OCR acknowledges that health care workers can face discrimination as they provide health care, OCR does not have jurisdiction over patients who may discriminate against health care workers, as patients are not covered entities under section 1557. Separately, and as previously noted, OCR does not intend for this rule to apply to employment discrimination. If OCR receives a complaint from a health care worker, we will determine if we have jurisdiction to investigate. Complaints received by OCR from health care workers alleging discrimination experienced in the context of employment will be referred to an appropriate agency, per §§ 92.303(b) and 92.304(a) (incorporating 45 CFR 85.61(e)), as this regulation does not apply to employment practices.

Comment: Many commenters expressed support for the explicit references to discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity as forms of

[99] *See Morton* v. *Mancari,* 417 U.S. 535 (1974).

[100] 45 CFR 80.3(d).

discrimination on the basis of sex in § 92.101(a)(2). Commenters pointed to evidence of health disparities and barriers to accessing health care faced by LGBTQI+ people, and how ongoing health care discrimination contributes to higher rates of substance use, mental health conditions, HIV, cancer, and cardiovascular disease for LGBTQI+ people relative to non-LGBTQI+ people.[101] Several commenters stated that § 92.101(a)(2)'s prohibitions should be mirrored in the CMS regulations addressed in section IV.

Response: It is well documented that LGBTQI+ people face significant health disparities and barriers to health care and insurance coverage,[102] and section 1557's protections are critical tools to combat those disparities. We appreciate commenters' view that CMS regulations within this rulemaking should mirror the language provided in § 92.101(a)(2), and we refer readers to section IV (CMS Amendments).

Comment: A number of comments addressed discrimination in the context of organ transplantation. Several commenters noted that people with disabilities are routinely denied access to organ transplants due to stereotypical assumptions about compliance with post-operative care and policies that deny transplants to otherwise eligible individuals with disabilities.[103]

Several commenters noted that existing practices in organ transplants appear to discriminate against Black, Hispanic/Latino, and Native American/Alaska Native individuals, as those individuals are more likely to develop end stage renal disease but are less likely to receive a kidney transplant than white individuals.[104] Another commenter stated that providers may discriminate against immigrant patients during the assessment process by assuming they lack social support or the ability to care for themselves after organ transplantation, resulting in a denial of care.[105]

Response: Discrimination on the basis of disability and race in the provision of health care, including organ transplantation, is a continuing issue that limits opportunities for life-saving treatment. This final rule provides OCR with a powerful tool to help address this ongoing issue. While section 1557 does not prohibit discrimination on the basis of immigration status, section 1557's protections apply regardless of someone's citizenship or immigration status, and individuals who believe they have been discriminated against based on certain characteristics such as race, color, and national origin can file a complaint. We will continue to address discrimination in organ transplantation through robust enforcement of not only section 1557, but all Federal civil rights laws.[106]

Comment: Numerous commenters generally supported the inclusion of the prohibition of discrimination on the basis of gender identity and sexual orientation as prohibited types of sex discrimination in proposed § 92.101(a)(2). They maintained that inclusion was consistent with *Bostock* v. *Clayton County,* 590 U.S. 644 (2020), in which the Supreme Court held that title VII's prohibition of discrimination because of sex includes discrimination on the basis of sexual orientation and gender identity. Commenters supported the application of the reasoning in *Bostock* to title IX by citing several cases, DOJ resource materials, and Executive Order (E.O.) 13988.[107] Another commenter cited several cases stating that courts have treated title VII and title IX protections as consistent with one another in support of the application of *Bostock* to title IX.[108] A few commenters cited *City of Los Angeles Department of Water and Power* v. *Manhart,* 435 U.S. 702 (1978), as indicating that, for decades, sex discrimination prohibitions have covered sex stereotypes. The commenters also cited several opinions from district courts and one appellate court as indicating that discrimination on the basis of gender identity, gender transition, sex stereotypes, or transgender status are, similarly, unlawful types of sex discrimination.[109] Other commenters provided cites to numerous other cases as including gender identity and sexual orientation as characteristics protected by sex discrimination law.[110]

Conversely, several commenters stated that *Bostock* does not support § 92.101(a)(2) as written. Some commenters stated that *Bostock* defined sex to include only ''biological distinctions between male and female'' and used the term ''transgender status''

[101] *See, e.g.,* Charlotte Patterson et al., Nat'l Acads. of Sci., Eng'g, & Med., *Understanding the Well-Being of LGBTQI+ Populations* (2020), *https://doi.org/10.17226/25877*; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* (2010), *www.lambdalegal.org/health-care-report*; Cornell Univ., *What Does the Scholarly Research Say about the Effects of Discrimination on the Health of LGBT People?* (2019), *https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/.*

[102] *See, e.g.,* Sharita Gruberg et al., Ctr. for Am. Progress, *The State of the LGBTQ Community in 2020* (2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/*; Sandy E. James et al., Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey,* p. 97 (2016), *https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf. See also* Caroline Medina et al., Ctr. For Am. Progress, *Discrimination and Barriers to Well-Being: The State of the LGBTQI+ Community in 2022* (2023), *https://www.americanprogress.org/article/discrimination-and-barriers-to-well-being-the-state-of-the-lgbtqi-community-in-2022/.*

[103] *See* Nat'l Council on Disability, *Organ Transplant Discrimination Against People with Disabilities* (2019), *https://www.ncd.gov/assets/uploads/reports/2019/ncd_organ_transplant_508.pdf.*

[104] *See* U.S. Renal Data System, *2021 Annual Report: End Stage Renal Disease* ch. 1 (2021) (Figure 1.8); Hannah Wesselman et al., *Social Determinants of Health and Race Disparities in Kidney Transplant,* 16 Clin. J. Am. Soc'y Nephrol. 262, 262 (2021).

[105] *See* Garyphallia Poulakou, Oscar Len & Murat Akova, *Immigrants as Donors and Transplant Recipients: Specific Considerations,* 45 Int. Care Med. 401 (2019), *https://pubmed.ncbi.nlm.nih.gov/30701293/.*

[106] *See, e.g.,* U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Disability Complaint of Individual Who Was Denied the Opportunity for Health Transplant List Placement* (Feb. 12, 2019), *https://www.hhs.gov/about/news/2019/02/12/ocr-resolves-disability-complaint-individual-who-was-denied-opportunity-heart-transplant-list.html.*

[107] E.O. 13988, 86 FR 7023 (Jan. 25, 2021). U.S. Dep't of Justice, Title IX Legal Manual, *https://www.justice.gov/crt/title-ix. See, e.g., Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616–17 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied,* 976 F. 3d 399 (4th Cir. 2020), cert. denied, No. 20–1163 (June 28, 2021); *B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 2:21–CV–00316, 2021 WL 3081883, at *7 (S.D.W. Va. July 21, 2021); *Koenke* v. *Saint Joseph's Univ.,* No. CV 19–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–CV–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020).

[108] *See, e.g., Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Emeldi* v. *Univ. of Or.,* 698 F.3d 715, 725 (9th Cir. 2012); *Franklin* v. *Gwinnett Cnty. Pub. Sch.,* 503 U.S. 60, 75 (1992); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020).

[109] *See Kadel* v. *Folwell,* 620 F. Supp. 3d 339, 379 (M.D.N.C. 2022); *Fain* v. *Crouch,* 618 F .Supp. 3d 313, 326–27 (S.D.W. Va. 2022); *Fletcher* v. *Alaska,* 443 F. Supp. 3d 1024, 1027, 1030 (D. Alaska 2020); *Flack* v. *Wisconsin Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1019–22 (W.D. Wis. 2019); *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 1002–03 (W.D. Wis. 2018); *Cf. Brandt by & through Brandt* v. *Rutledge,* 2022 WL 3652745, at *2 (8th Cir. Aug. 25, 2022).

[110] *See,* among others cited, *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 593, 616, 619 (4th Cir. 2020), *reh'g en banc denied,* 976 F.3d 399 (4th Cir. 2020); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034, 1049–50 (7th Cir. 2017); *Fain* v. *Crouch,* No. 3:20–0740, 2022 U.S. Dist. LEXIS 137084, at *35–36 (S.D. W. Va. Aug. 2, 2022); *Scott* v. *St. Louis Univ. Hosp.,* No. 4:21–cv–01270–AGF, 2022 U.S. Dist. LEXIS 74691, at *18 (E.D. Mo. Apr. 25, 2022); *C.P.* v. *Blue Cross Blue Shield of Ill.,* 536 F. Supp. 3d 791, 793 (W.D. Wash. 2021); *Flack* v. *Wis. Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1014–15 (W.D. Wis. 2019); *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 997, 1002–03 (W.D. Wis. 2018); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 953 (D. Minn. 2018); *Prescott* v. *Rady Children's Hosp.-San Diego,* 265 F. Supp. 3d 1090, 1098–1100 (S.D. Cal. 2017); *Adams* v. *Sch. Bd. of St. Johns Cnty.,* 968 F.3d 1286, 1305 (11th Cir. 2020); *Zarda* v. *Altitude Express, Inc.,* 883 F.3d 100, 112–13 (2nd Cir. 2018); *Franchina* v. *Providence,* 881 F.3d 32, 53–54 (1st Cir. 2018); *Hively* v. *Ivy Tech,* 853 F.3d 339, 340–41 (7th Cir. 2017).

rather than ''gender identity.'' A commenter argued that title VII should be treated as distinct from title IX because title IX uses the term ''on the basis of sex''—language the commenter described as requiring more than ''but for causation''—while title VII uses ''because of . . . sex.'' Other commenters discussed title IX to support arguments that discrimination on the basis of sex does not include discrimination on the basis of sexual orientation or gender identity, and that title IX only protects people on the basis of ''biological sex.''

Some commenters cited to various cases in opposition to the inclusion of gender identity and sexual orientation in proposed § 92.101(a)(2), including *State of Tennessee* v. *Department of Education,* 615 F. Supp. 3d 807 (E.D. Tenn. 2022), to support the belief that agencies cannot rely on the reasoning in *Bostock* to interpret what constitutes sex discrimination under title IX. Another commenter stated that E.O. 13988 improperly expands the application of *Bostock* and cited *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016) in support. Some commenters stated that RFRA's religious protections may supersede the sex discrimination protections described in *Bostock,* and one commenter cited *Hosanna-Tabor Evangelical Lutheran Church and School* v. *EEOC,* 565 U.S. 171 (2012), for the proposition that that First Amendment protections may supersede employment discrimination laws. Another commenter stated that OCR's interpretation of what is prohibited sex discrimination is contrary to law, citing to *Franciscan Alliance, Inc.* v. *Becerra* [111] and *Christian Employers Alliance* v. *EEOC.*[112]

Response: Case law offers strong support for the position that sex discrimination under section 1557 includes discrimination on the basis of gender identity and sexual orientation. As previously noted, a body of developing case law explains how to identify unlawful sex discrimination. As part of its prohibition on sex discrimination, this rule prohibits discrimination against individuals who do not conform with stereotypical notions of how an individual is expected to present as male or female, regardless of gender identity. This is consistent with longstanding case law; more than 30 years ago, a plurality of the Supreme Court held in *Price Waterhouse* that discrimination based on sex stereotypes was a prohibited form of sex discrimination. We have included a number of examples throughout the preamble discussion to help covered entities better understand their obligations. OCR is also committed to providing technical assistance to support compliance with this final rule and may consider additional guidance that may assist covered entities with their obligations.

As noted in the Proposed Rule, the inclusion of ''sexual orientation'' and ''gender identity'' in § 92.101(a)(2) is consistent with the Supreme Court's reasoning in *Bostock.* 87 FR 47858. Title IX and section 1557 prohibit discrimination ''on the basis of sex.'' [113] And the *Bostock* Court used the phrase ''because of sex'' and ''on the basis of sex'' interchangeably.[114] Because the statutory prohibitions against sex discrimination in title VII and title IX are similar, the Supreme Court and other Federal courts look to interpretations of title VII to inform title IX.[115] Thus, *Bostock's* discussion of the text of title VII informs the OCR's analysis of title IX and section 1557. Given the similarity in nondiscrimination language between title VII and title IX, many Federal courts that have addressed the issue have interpreted section 1557 and title IX consistent with *Bostock's* reasoning.[116] Since *Bostock,* three Federal courts of appeals have held that the plain language of title IX's prohibition on sex discrimination must be read similarly to title VII's prohibition.[117] OCR agrees with the reasoning in these cases.[118] Additionally, there is a significant amount of case law, pre-and post-*Bostock* that affirms that sex discrimination includes discrimination based on gender identity.[119]

We disagree with commenters' assertion that the Court's use of the term ''transgender status'' in *Bostock,* rather than ''gender identity,'' results in any meaningful distinction regarding protections afforded to transgender individuals or other individuals experiencing discrimination on the basis of their gender identity. The Court's choice of language reflects that it was addressing the gender identity of the plaintiff before it, who was transgender, and does not preclude the case's application to other gender identities. Indeed, even the dissent stated that ''there is no apparent difference between discrimination because of transgender status and discrimination because of gender identity.'' 590 U.S. at 686, n.6 (Alito, J. joined by Thomas, J., dissenting).

Additional citations by those opposing the language in § 92.101(a)(2) are either not applicable, already discussed in the Proposed Rule, or outdated. To begin, this rule does not

---

[111] 553 F. Supp. 3d 361 (N.D. Tex. 2021), *amended,* No. 7:16–cv–00108–O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), *appeal docketed,* No. 21–11174 (5th Cir. Nov. 26, 2021); *see also Franciscan All., Inc.* v. *Becerra,* 47 F.4th 368 (5th Cir. 2022).

[112] *Christian Emp'rs All.* v. *EEOC,* No. 21–cv–00195, 2022 WL 1573689 (D.N.D. May 16, 2022).

[113] 20 U.S.C. 1681(a); 42 U.S.C. 18116.

[114] *See, e.g.,* 590 U.S. 653, 662, 681.

[115] *See, e.g., Franklin* v. *Gwinnett Cnty. Pub. Sch.,* 503 U.S. 60, 75 (1992); *Jennings* v. *Univ. of N.C.,* 482 F.3d 686, 695 (4th Cir. 2007); *Gossett* v. *Okla. ex rel. Bd. Of Regents for Langston Univ.,* 245 F.3d 1172, 1176 (10th Cir. 2001).

[116] *See, e.g., Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020); *but cf. Adams* v. *Sch. Bd. of St. Johns Cnty,* 57 F.4th 791, 811–15 (11th Cir. 2022) (en banc)).

[117] *See A.C. by M.C.* v. *Metro. Sch. Dist. Of Martinsville,* 75 F.4th 760, 769 (7th Cir. 2023); *Grabowski* v. *Ariz. Bd. Of Regents,* 69 F.4th 1110, 1116–17 (9th Cir. 2023); *Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (Mem) (2020).

[118] OCR acknowledges that at least one court has held that it would be a misapplication of *Bostock* to interpret the definition of ''sex discrimination'' under section 1557 and title IX to include gender identity and sexual orientation. In *Neese* v. *Becerra,* 640 F. Supp. 3d 668, the U.S. District Court for the Northern District of Texas held that the Department misapplied *Bostock* when it issued a public notice, 86 FR 27984 (May 25, 2021), stating that it would interpret section 1557 and title IX's prohibition on sex discrimination to include discrimination on the basis of sexual orientation and gender identity. The Department appealed that decision to the U.S. Court of Appeals for the Fifth Circuit and oral argument was held on January 8, 2024. The Department is not applying the challenged interpretation to members of the *Neese* class pending the appeal.

[119] *See, e.g., Whitaker By Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. Of Educ.,* 858 F.3d 1034 (7th Cir. 2017) (title IX); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566 (6th Cir. 2004) (title VII); *Rosa* v. *Park W. Bank & Trust Co.,* 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schroer* v. *Billington,* 577 F. Supp. 2d 293 (D.D.C. 2008) (title VII); *Boyden v. Conlin,* 341 F. Supp. 3d 979 (W.D. Wis. 2018) (section 1557 and title VII); *Flack* v. *Wis. Dep't. of Health Servs.,* 395 F. Supp 3d 1001, 1014 (W.D. Wis. 2019) (section 1557 and Equal Protection Clause); *Prescott* v. *Rady Children's Hosp. San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (section 1557); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (section 1557). *See also Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), cert. denied, 141 S. Ct. 2878 (Mem) (2020); *Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *28-*29 (M.D.N.C. June 10, 2022); *Scott* v. *St. Louis Univ. Hosp.,* No. 4:21–cv-01270–AGF, 2022 WL 1211092, at *6 (E.D. Mo. Apr. 25, 2022); *C.P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–cv–06145–RJB, 2021 WL 1758896, at *4 (W.D. Wash. May 4, 2021); *Koenke* v. *Saint Joseph''s Univ.,* No. CV 19–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–cv–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020); *Maxon* v. *Seminary,* No. 2:19–cv–9969, 2020 WL 6305460 (C.D. Cal. Oct. 7, 2020); *B.P.J.* v. *W. Va. State Bd. Of Educ.,* No. 2:21–cv–00316, 2021 WL 3081883, at *7 (S.D.W. Va. July 21, 2021); *Clark Cnty. Sch. Dist. V. Bryan,* 478 P.3d 344, 354 (Nev. 2020).

rely on E.O. 13988 for its authority, so criticisms of that order do not undermine the final rule. *State of Tennessee* is inapposite. There, the court held that the plaintiffs had demonstrated a reasonable likelihood of success on the claim that two other Federal agencies violated the Administrative Procedure Act by foregoing notice-and-comment procedures.[120] That is not at issue here, as this is notice-and-comment rulemaking and not the issuance of informational documents. *Hosanna-Tabor* involved First Amendment limitations on the application of employment discrimination laws—specifically the ''ministerial exception'' that precludes application of employment discrimination laws to ''claims concerning the employment relationship between a religious institution and its ministers.'' 565 U.S. at 188. As discussed throughout the Proposed Rule, beginning at 87 FR 47826, OCR is aware of and discusses both *Franciscan Alliance* v. *Becerra* and *Christian Employers Alliance* v. *EEOC,* and the Department is not prohibited from finalizing this rule by either decision. 87 FR 47826. Additionally, the final rule adopts new procedures for recipients wishing to invoke Federal religious freedom and conscience protections. For more on those procedures, see § 92.302.

Finally, OCR disagrees with the commenters who cited *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016), in support of the view that section 1557 and title IX's prohibition on sex discrimination does not include discrimination on the basis of sexual orientation and gender identity. The legal landscape in this area has changed since that decision issued and the publication of the Proposed Rule. The *Franciscan Alliance* v. *Burwell* court concluded that the 2016 Rule's definition of ''sex'' as including ''gender identity'' was contrary to section 1557 because ''Title IX and Congress' incorporation of it in [section 1557 of] the ACA unambiguously adopted the binary definition of sex.'' *Id.* at 689. Four years later, the Supreme Court held that the prohibition on discrimination ''because of . . . sex'' under title VII covers discrimination on the basis of gender identity and sexual orientation, even assuming that ''sex'' refers ''only to biological distinctions between male and female.'' *Bostock,* 590 U.S. at 655. The *Bostock* Court held that the statute's prohibition on employment discrimination ''because of sex'' encompasses discrimination on the basis of sexual orientation and gender identity. *Id.* at 670–71.

Comment: Several commenters generally asserted that sex is an immutable, biological binary. Some commenters relayed that their religious beliefs include that sex is an immutable binary. A commenter stated that sex has a biological component that impacts medical care.

A commenter argued that if the rule does not recognize that sex is a biological binary, there will be increased confusion in the provision of medical services. Another commenter expressed concern that the rule would diminish the quality of health care received by some patients because some health conditions, such as symptoms of heart attacks, are based on ''biological sex characteristics.'' A commenter said that a prohibition of discrimination on the basis of gender identity would validate the recognition of gender identity and increase gender dysphoria.

Response: OCR recognizes that sex has biological components and knowledge of an individual's biological attributes is an essential component of providing high quality health care for all patients. For example, in the Proposed Rule, we discussed the various health disparities experienced by women, which require that providers have adequate knowledge of biology and anatomy to effectively address. 87 FR 47833–34.

OCR disagrees with commenters suggesting that nondiscrimination protections on the basis of gender identity will either cause confusion in the medical profession or lead to diminished quality of care. Health care providers are highly trained in issues of biology, anatomy, and physiology. This rule requires that individuals be treated without discrimination on the basis of sex. There is no evidence that demonstrates that compliance with civil rights protections, including on the basis of sex, has caused any confusion in the medical field. On the contrary, evidence suggests that when patients are protected on the basis of sex in health care programs, quality of care improves because patients at risk of discrimination are more likely to seek and receive high quality care. For example, research shows that individuals who are experiencing gender dysphoria—defined by the American Psychiatric Association to include ''clinically significant distress or impairment related to gender incongruence''—have a clinically significant decrease in distress if they have access to medically necessary care.[121]

Moreover, section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide.

With respect to commenters' concerns about potential conflicts between the final rule and individuals' or organizations' sincerely held religious beliefs, we refer commenters to the discussion of this topic at § 92.302.

Comment: Some commenters stated that because OCR relied on *Bostock,* it is bound by the definition of ''sex'' in *Bostock* and that definition should be included in the final rule. These commenters opined that the term ''sex characteristics'' as used by OCR is sometimes contrary to a binary understanding of the term ''sex,'' and accordingly ''sex characteristics'' either must be avoided in the regulations or used in a manner not to contradict the term ''sex'' being binary.

Response: OCR has determined it is not necessary to define ''sex'' in this rule, as we have addressed a non-exhaustive list of what constitutes discrimination on the basis of sex at § 92.101(a)(2). The Supreme Court did not define the term ''sex'' in *Bostock,* but rather noted that nothing in their approach to the cases considered turned on the debate over whether ''sex'' was limited to ''biological distinctions between male and female,'' and the Court therefore proceeded on the assumption that ''sex'' carried that meaning. 590 U.S. at. 655.

OCR declines to remove reference to ''sex characteristics'' (including intersex traits) from § 92.101(a)(2). Discrimination on the basis of sex characteristics, including intersex variations, is a prohibited form of sex discrimination because discrimination based on anatomical or physiological sex characteristics is inherently sex-based. *See* 87 FR 47858.

Comment: Numerous commenters supported the explicit inclusion of

[120] *Tennessee* v. *U.S. Dep't of Educ.,* 615 F. Supp. 3d 807 (E.D. Tenn. 2022); *appeal docketed,* No. 22–5807 (6th Cir. Sept. 13, 2022) (oral argument held April 26, 2023).

[121] Jack Turban, M.D., M.H.S., *What is Gender Dysphoria?,* Am. Psychiatric Assoc., *https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria* (Aug. 2022).

discrimination based on sex characteristics, including intersex traits, stating that discrimination based on intersex traits is inherently sex-based. Several commenters supported this proposal, citing barriers to appropriate care and coverage resulting from discrimination suffered by intersex patients.[122] These commenters cited a report in which more than half of intersex respondents reported that a provider refused to see them because of their sex characteristics or intersex variation and that almost two-thirds reported having concerns that if they disclosed their intersex status to a provider, they could be denied quality medical care.[123] A few commenters recommended that § 92.101(a)(2) include concrete examples of sex discrimination, specifically on the basis of intersex traits.

Response: Discrimination based on sex characteristics is a prohibited form of sex discrimination because discrimination based on anatomical or physiological sex characteristics is inherently sex-based. 87 FR 47858. It follows that discrimination on the basis of intersex traits is prohibited sex discrimination because the individual is being discriminated against based on their sex characteristics.

Comment: Numerous commenters generally supported the inclusion of pregnancy or related conditions as protected bases of sex discrimination at § 92.101(a)(2) and recommended that OCR include examples of pregnancy-related discrimination. Commenters recommended including protection for pregnancy-related conditions as a standalone provision to emphasize the importance of these protections. Commenters stated that protection against discrimination on the basis of pregnancy or related conditions would protect many patients. Commenters also pointed out that as drafted, the Proposed Rule does not consistently define sex discrimination to include pregnancy-related conditions because other sections just state ''pregnancy'' as opposed to ''pregnancy or related conditions.'' The commenters urged OCR to be consistent throughout the rule.

Response: The inclusion of ''pregnancy or related conditions'' is consistent with the longstanding interpretation of the ''ground'' of discrimination prohibited under title IX because pregnancy-based discrimination has long been understood as a form of sex-based discrimination under title IX. For many years preceding the enactment of the ACA, the Department (along with other agencies) determined that discrimination based on pregnancy or related conditions is discrimination based on sex.[124] Discrimination on the basis of pregnancy or related conditions may include, but is not limited to, instances of individuals who experience discrimination throughout pregnancy, labor and delivery, or the postpartum period. OCR agrees that the explicit inclusion of pregnancy or related conditions in the rule text is important for protecting many patients from discrimination.

As discussed in the Proposed Rule, OCR considered inclusion of a provision to specifically address discrimination on the basis of ''pregnancy or related conditions.'' 87 FR 47878. We received comments stating that a separate section was not appropriate. Those comments recommended that this issue be addressed under either § 92.101 (Discrimination prohibited) or § 92.206 (Equal program access on the basis of sex). Accordingly, we maintain the inclusion of ''pregnancy or related conditions'' here under § 92.101(a)(2). For a further discussion of ''pregnancy or related conditions,'' please refer to the preamble discussion at § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status).

Comment: A commenter stated that protections from pregnancy-based discrimination should include an informed consent requirement for abortion and childbirth, because the commenter asserted that consent for a Cesarean delivery is often obtained through coercion.

Response: As noted in the Proposed Rule, 87 FR 47868, informed consent to any medical treatment is both a legal and ethical standard, regardless of the type of care, and serves as a basis for shared decision making.[125] OCR declines to make any changes in response to this comment.

Comment: Numerous commenters recommended that, in light of the Supreme Court's decision in *Dobbs* v. *Jackson Women's Health Organization,* 142 S. Ct. 2228 (2022), and increased restrictions on reproductive health, OCR should provide that ''pregnancy or related conditions'' includes termination of pregnancy in the final rule. A group of commenters opined that the definition of ''pregnancy or related conditions'' should expressly exclude an abortion.

Several commenters stated that OCR should clarify that this provision protects patients from discrimination on the basis of actual or perceived prior abortions. Several commenters stated that, as a result of abortion bans that have gone into effect post-*Dobbs,* women have been denied critical care, such as cancer treatment, because of abortion-related concerns. A commenter wrote that abortion is often necessary to save patients' lives, especially from complications like ectopic pregnancy or premature rupture of membrane.

Response: OCR appreciates commenters' concerns and recognizes that the Supreme Court decision in *Dobbs* changed the legal landscape as to abortion access. While we agree that protections afforded for pregnancy or related conditions include termination of pregnancy, OCR declines to revise the language at § 92.101(a)(2) to include or exclude specific examples and will interpret section 1557's protections on the basis of sex consistent with applicable case law addressing discrimination on the basis of sex, including pregnancy or related conditions.

OCR has concluded as a matter of statutory interpretation that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision, *see* preamble discussion at § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status). At the same time, OCR emphasizes that a covered provider's decision not to provide abortions does not itself constitute discrimination in violation of section 1557. Also, a covered provider's willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion also is not discrimination under section 1557. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. A covered provider that generally offered abortion care could violate that prohibition if, for example, it refused to provide an abortion to a particular patient because of that patient's race or disability. But a covered provider does not engage in

[122] Lambda Legal & interACT Advocates, *Providing Ethical and Compassionate Health Care to Intersex Patients: Intersex-Affirming Hospital Policies* (2018), *https://legacy.lambdalegal.org/sites/default/files/publications/downloads/resource_20180731_hospital-policies-intersex.pdf.*

[123] *See* Caroline Medina & Lindsay Mahowald, Ctr. for Am. Progress, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (2022), *https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities.*

[124] *See* 45 CFR 86.21(c)(2), (3); 86.40(b)(1), (4), and (5); 86.51(b)(6); 86.57(b)(d) (title IX regulation).

[125] Am. Med. Ass'n, *Informed Consent, https://www.ama-assn.org/delivering-care/ethics/informed-consent.*

discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason.

It bears emphasis that nothing in the ACA, including section 1557, has ''any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). In addition, nothing in the ACA, including section 1557, preempts or has any effect on State laws regarding ''the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions'' as provided in section 1303 of the ACA, 42 U.S.C. 18023(c)(1).

Against this legal landscape, OCR will evaluate specific claims of discrimination on prohibited bases on a case-by-case basis, and we decline to revise the language at § 92.101(a)(2). We note also that, as commenters suggested, this provision protects patients from discrimination on the basis of actual or perceived prior abortions. For example, a recipient's denial of unrelated medical care that the provider generally provides to other patients to an individual based solely on the fact they had a prior abortion would constitute prohibited discrimination within the meaning of section 1557. Moreover, both the 2016 and 2020 Rules recognized that discrimination on the basis of pregnancy termination can be a form of sex discrimination.

Comment: Conversely, a commenter argued that OCR should not interpret ''pregnancy or related conditions'' to include ''termination of pregnancy'' because of a concern that it will force health care providers to participate in abortions and requested that OCR provide further clarification as to what types of conduct would be prohibited discrimination under the rule. Another commenter stated the Proposed Rule wrongly treats abortion as a right protected from sex discrimination and that title IX contains an abortion neutrality provision that the rule would contravene.

Response: As discussed above, a covered provider's decision not to provide abortions does not itself constitute discrimination in violation of section 1557. A covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason. A covered entity that chooses to provide abortion care but refuses to provide an abortion for a particular individual on the basis of a protected ground—such as race—would violate section 1557. For discussion regarding the title IX abortion neutrality provision, please see § 92.208.

Comment: Several commenters requested that OCR clarify that § 92.101(a)(2) prohibits discrimination against individuals when they are seeking or accessing fertility care, maternity care, and other reproductive health care specifically. A commenter recommended that OCR clarify that pregnancy-related care applies throughout pregnancy, childbirth, and the postpartum period.

Response: Section 1557 protects individuals against prohibited discrimination in all covered health programs and activities regardless of the type of care they are seeking or accessing, including fertility care, maternity care, and other reproductive health care. Similarly, section 1557 protects individuals seeking or accessing health programs and activities provided for or during preconception, pregnancy, childbirth, and postpartum recovery. Ensuring that section 1557's protections apply throughout the continuum of care is especially critical for Black women and other people of color, who face worse health outcomes and experience higher rates of discrimination throughout pregnancy and the postpartum period.[126]

Comment: Many commenters raised concerns about barriers to reproductive health care faced by LGBTQI+ patients. A commenter strongly urged more explicit inclusion of ''fertility'' as a form of impermissible sex-based discrimination—so that § 92.101(a)(2)(ii) prohibits discrimination on the basis of ''pregnancy, fertility, or related conditions''—as infertility is a serious issue that impacts many LGBTQI+ populations. Commenters stated that LGBTQI+ people continue to face barriers to fertility treatment, such as in vitro fertilization (IVF), and that coverage of fertility treatments often limit or exclude LGBTQI+ patients.

Response: OCR acknowledges the unique challenges faced by LGBTQI+ individuals seeking fertility treatment. Individuals are protected from discrimination regardless of the type of health care they seek, and we have concluded it is unnecessary to provide provisions for each specific form of health care available. Whether discrimination on the basis of sexual orientation or gender identity occurred in the provision or coverage of assistive reproductive technology—such as IVF—is necessarily fact specific. However, if a covered entity elects to provide or cover fertility services but categorically denies them to same-sex couples, it may violate section 1557's prohibition on sex discrimination.

Comment: Numerous commenters generally supported inclusion of sexual orientation as a protected basis for sex discrimination, and said that its inclusion would improve health care for LGBTQI+ individuals. Many commenters stated that LGBTQI+ individuals face discriminatory challenges to accessing health care and that the rule would alleviate these issues. Many commenters wrote that LGBTQI+ individuals often anticipate that they will experience discrimination in health care and thus often may not seek out care.

Response: It is well documented that LGBTQI+ individuals face discrimination when accessing or attempting to access health care and health insurance. Section 1557 is a critical tool in combating such discrimination and addressing the resulting health disparities and other negative impacts.

Comment: Numerous commenters generally supported the inclusion of discrimination on the basis of gender identity as a prohibited form of sex discrimination. Other commenters recommended including ''transgender or nonbinary status,'' ''nonbinary and gender-nonconforming,'' and ''including status as transgender, nonbinary, gender nonconforming, two-spirit, or other gender.''

Response: OCR recognizes that individuals use various terminology to describe their gender identity. For this reason, we decline to provide a definition of ''gender identity'' or ''transgender status'' in the regulation. We reiterate here that OCR will investigate discrimination against an individual based on having a gender identity that is different from their sex assigned at birth as discrimination on the basis of gender identity, regardless of whether the individual identifies with or uses the term ''transgender'' or another identity.

OCR is aware that the *Bostock* majority uses the term ''transgender

[126] Saraswathi Vedam et al., *The Giving Voice to Mothers Study: Inequity and Mistreatment During Pregnancy and Childbirth in the United States,* 16 Reprod. Health 1 (2019), *https://doi.org/10.1186/s12978-019-0729-2.*

status'' exclusively. But *Bostock* reasoned that when a person discriminates ''against transgender persons, the employer unavoidably discriminates against persons with one sex identified at birth and another today'' such that ''[a]ny way you slice it, the employer intentionally refuses to hire applicants in part because of the affected individuals' sex, even if it never learns any applicant's sex.'' *See Bostock,* 590 U.S. at 669. This therefore includes discrimination against a person because they are transgender, or because they identify in some other way that is inconsistent with their sex assigned at birth, *e.g.,* because they are gender nonconforming. Such discrimination is also based on requiring persons to conform to stereotypical norms about sex and gender, which can also serve as the basis for impermissible sex discrimination. *See, e.g., Whitaker,* 858 F.3d at 1048–49 (*citing Price Waterhouse,* 490 U.S. at 251). Therefore, the prohibition against discrimination based on gender identity, rather than just transgender status, more fully protects individuals from prohibited sex discrimination. Indeed, the *Bostock* dissent stated that, as defined by the American Psychological Association, ''there is no apparent difference between discrimination because of transgender status and discrimination because of gender identity.'' 590 U.S. at 686, n.6 (Alito, J. joined by Thomas, J., dissenting).

Comment: Several commenters supported OCR's general goal at § 92.101(b) of explicitly incorporating the prohibitions on discrimination found in title VI, section 504, title IX, and the Age Act and thought this approach is prudent, given that some health care entities may not be readily familiar with the specific regulatory standards and obligations that apply to them under civil rights laws. A few commenters noted that incorporating section 504 regulations pertaining to accessibility could create conflicting obligations and specifically objected to incorporating 45 CFR 84.23(c), which applies an outdated standard (the Uniform Federal Accessibility Standards) to new facility constructions. These commenters recommended including additional language in § 92.101(b)(1)(i) that expressly states ''(except for § 84.23(c)).''

Response: We appreciate commenters' concerns regarding inclusion of § 84.23(c). Because the rule has a separate subsection with respect to ''Accessibility for buildings and facilities,'' commenters should refer to this preamble's discussion of § 92.203.

Comment: Some commenters requested that OCR restore the 2016 Rule clarification that any age distinctions exempt from the Age Act are also exempt from section 1557 enforcement.

Response: OCR appreciates commenters' request for clarity regarding the Age Act's permitted age distinctions. This rule adopts by reference the Age Act implementing regulation provisions at 45 CFR part 91 (subpart B), which explicitly recognize that some age distinctions may be necessary to the normal operation of a program or activity or to the achievement of any statutory objective. *See* 45 CFR 91.13 (adopting statutorily permissive age distinctions found at 42 U.S.C. 6103(b)(1)).

Comment: A commenter stated that OCR should exercise its authority to enforce disparate impact claims in order to address systemic discrimination in health care.[127] Another commenter supported the approach taken by OCR in the Proposed Rule to not include the site location provision from the 2016 Rule, stating they believed section 1557's context, structure, and text make evident that Congress did not intend to import multiple, piecemeal legal standards and burdens of proof derived from different statutory contexts into the doctrinal patchwork; and that section 1557 provides the full range of enforcement mechanisms and remedies available to any person pursuing a discrimination claim under section 1557, regardless of their protected characteristic.

Response: After reviewing comments, OCR declines to include provisions similar to former 45 CFR 92.101(b)(3)(ii) and (iii), which are not included in the 2020 Rule. OCR will preserve the longstanding treatment of discrimination in the referenced statutes' implementing regulations consistent with relevant case law.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provision as proposed in § 92.101, with modifications. We added ''or any combination thereof'' after disability and deleted the ''or'' before disability in § 92.101(a)(1).

Subpart C—Specific Applications to Health Programs and Activities

Because of section 1557's specific application to health programs and activities, subpart C provides additional detail regarding nondiscrimination requirements in these settings. The provisions in this subpart are responsive to the nature and importance of health care, health insurance coverage, and other health-related coverage, and related health programs and activities as those health-related issues impact individuals and communities protected by section 1557's prohibition of discrimination. These provisions are intended to provide clear instruction to covered entities and are informed by OCR's experience in both enforcement and in providing technical assistance as well as outreach to interested parties.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

In proposed § 92.201, we proposed provisions to effectuate section 1557's prohibition on national origin discrimination as it is applied to individuals with LEP in covered health programs and activities. In § 92.201(a), we proposed that covered entities ''must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.''

In § 92.201(b), we proposed that language assistance services required under § 92.201(a) must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an individual with LEP.

In § 92.201(c), we proposed specific requirements for interpreter and translation services. Section 92.201(c)(1) proposed that when interpreter services are required under this part, a covered entity must offer a qualified interpreter. Section 92.201(c)(2) proposed that when translation services are required under this part, a covered entity must use a qualified translator.

In § 92.201(c)(3), we proposed regulatory language requiring a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an individual with LEP; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language. We sought

[127] Ruqaiijah Yearby et al., *Structural Racism in Historical and Modern US Health Care Policy,* 41 Health Affairs 187 (2022), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01466*; Joe Feagin & Zinobia Bennefield. *Systemic Racism and U.S. Health Care,* 103 Soc. Sci. & Med. 7 (2014), *https://doi.org/10.1016/j.socscimed.2013.09.006*; Cara A. Fauci, *Racism and Health Care in America: Legal Responses to Racial Disparities in the Allocation of Kidneys,* 21 Boston Coll. Third World J. 35 (2001); Amitabh Chandra et al., *Challenges to Reducing Discrimination and Health Inequity through Existing Civil Rights Laws,* 36 Health Affairs 1041 (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5654529/.*

comment on the use of machine translation in health programs and activities generally, other possible approaches to address this issue, and whether there should be an exception to this provision to allow for the limited use of machine translation in exigent circumstances.

In § 92.201(d), we addressed how the Director will evaluate compliance with this section. In § 92.201(d)(1), we proposed that the Director shall evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with LEP. Proposed § 92.201(d)(2) provides that the Director shall take into account other relevant factors, including the effectiveness of the covered entity's written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to proposed § 92.8(d).

In § 92.201(e), we proposed restrictions on the use of certain persons to provide language assistance services for individuals with LEP. In § 92.201(e)(1), we proposed prohibitions on covered entities from requiring individuals with LEP to provide, or pay for, their own interpreters. Proposed § 92.201(e)(2) provided for very limited situations in which an adult, not qualified as an interpreter, accompanying an individual with LEP can serve as an interpreter. Section 92.201(e)(3) proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with LEP immediately available. In § 92.201(e)(4), we proposed prohibiting reliance on staff other than qualified interpreters, qualified translators, or qualified bilingual or multilingual staff to communicate directly with individuals with LEP.

In § 92.201(f), we proposed standards for video remote interpreting (VRI).

In § 92.201(g), we proposed standards for audio remote interpreting services.

In § 92.201(h), we proposed that nothing in this section shall be construed to require an individual with LEP to accept language assistance services.

The comments and our responses regarding § 92.201 are set forth below.

Comment: Many commenters were very supportive of § 92.201(a)'s requirement that covered entities must take reasonable steps to provide meaningful access to ''each'' individual with LEP eligible to be served or likely to be directly affected by its health programs and activities. Commenters also supported OCR's revision concerning individuals with LEP ''likely to be directly affected'' by a health program or service, as opposed to the previous ''likely to be encountered,'' as it provides greater clarity about the applicability of this rule and reduces some burden on health care practices. Commenters maintained that this standard provides a better description for providers to understand. Other commenters supported inclusion of ''eligible to be served or likely to be directly affected'' because they believe it expands the definition of who can receive language access and better reflects how language service needs are experienced by people seeking health care. Many commenters recommended that OCR clarify that companions are expressly included, noting that this is especially important for caretakers of minor children or those accompanying older adults.

Response: OCR appreciates commenters' thoughts on the language at § 92.201(a) and confirms that covered entities' language access obligations also apply to companions (defined in § 92.4), as companions are ''directly affected by [a covered entity's] health programs and activities'' by virtue of their relationship with the person whom they are accompanying. For example, a covered entity will need to take reasonable steps to provide meaningful access to a parent with LEP whose minor child is being treated or an individual with LEP who may be assisting their spouse with post-operative care. To reinforce this requirement, OCR is adding a parenthetical to the text of § 92.201(a) to clarify that individuals with LEP who are covered under this part include companions with LEP. This language is consistent with the requirement to provide effective communication for companions with disabilities under § 92.202.

Comment: Various commenters appreciated OCR providing clarity on the terms ''reasonable steps'' and ''meaningful access,'' noting that the 2020 Rule's deletion of meaningful access requirements was detrimental to the health of communities with LEP. A few commenters recommended that clearer directives should be included as to what types of services constitute ''reasonable steps,'' suggesting this could be clarified by providing examples of ''reasonable steps,'' or by adding definitions of ''reasonable steps'' and ''meaningful access'' to § 92.4 (Definitions). Another commenter cautioned that the lack of clarity could result in covered entities coming to the determination that no services are required of them. Others stated that additional guidance is needed specifically for providers and payers.

Response: OCR appreciates the request for additional definitions; however, we decline to provide a definition for ''reasonable steps'' or ''meaningful access,'' as these terms are not unique to section 1557 and reflect longstanding requirements under title VI. OCR will consider developing additional guidance on this topic but also refers commenters to the Department's longstanding HHS LEP Guidance, 67 FR 47311, as well as the Department's 2023 Language Access Annual Progress Report. The 2023 Progress Report describes the Department's reconstituted Language Access Steering Committee based on the HHS Equity Action Plan issued under E.O. 13985, clarifies benchmarks for meaningful language access in key areas such as developing best practices for oral interpretation and internet-based access to written translation, and sets forth current plans to update the Department's Language Access Plans and issue related guidance.[128]

Comment: A number of commenters stated that failure to provide meaningful access may violate both section 1557's national origin prohibition and the prohibition on race discrimination. Several commenters stated that there are instances in which an individual experiences discrimination based on their limited English proficiency, in addition to another protected characteristic. For example, a person who is Black and has limited English proficiency is more likely to experience discrimination in health care settings than an individual who is Black but does not have limited English proficiency or an individual with limited English proficiency but who is not Black.[129] Commenters stated that this type of discrimination may deter patients from seeking critical health care services, leading to adverse health outcomes and decreased trust in the health care system.[130] Commenters also

[128] U.S. Health & Hum. Servs., Off. for Civil Rts., *2023 Language Access Annual Progress Report* (2023), *https://www.hhs.gov/sites/default/files/language-access-report-2023.pdf.*

[129] Neelam H. Ahmed et al., *Moderation of the Association Between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022), *https://www.mdpi.com/1660-4601/19/13/7750.*

[130] Neelam H. Ahmed et al., *Moderation of the Association between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022),

Continued

provided data showing that almost one in four health center patients communicate in a language other than English;[131] 63 percent of individuals with LEP identify as Hispanic/Latino;[132] language barriers have been proven to contribute to health inequities for Asian American, Native Hawaiian, and Pacific Islander individuals in particular;[133] and people with LEP are less likely to receive primary care and preventive care, such as breast and cervical cancer screenings.[134]

Some commenters also specifically addressed the importance of language assistance services for older individuals with LEP. These commenters submitted research demonstrating that it is especially difficult for older adults with LEP to communicate with providers because of limited English proficiency, low health literacy, and lack of translators and interpreters.[135] Many commenters argued that to ensure access to quality care, covered entities must have translators and interpreters available at all points of contact at no cost to an individual. This is because older adults may be less inclined to ask for language assistance or may rely on family members who are not qualified to interpret health information. Additionally, the commenters noted that language assistance services are critical for people at the end of life who, absent these services, cannot give true informed consent or thoroughly understand their end-of-life care options.

Response: OCR appreciates these comments and the data submitted. As discussed elsewhere in this preamble, section 1557's language access requirements derive from the statute's prohibition on discrimination against national origin. OCR also appreciates, and agrees with, comments highlighting the ways in which individuals may experience discrimination on multiple grounds as well as comments about the importance of language assistance services for older individuals with LEP. The provisions for § 92.201(a) enhance health access and reduce discrimination by requiring covered entities to take reasonable steps to provide meaningful access to each individual with LEP.

Comment: Many commenters stated that language assistance has often been costly to the individuals with LEP, and translations have often been inaccurate, incomplete, or both. Commenters additionally noted that language assistance has often been provided later in time than other services and that interpretation has not been done in a way that protects patient privacy. Other commenters submitted examples of individuals with LEP being provided with incomplete information, such as being told of only one treatment option, rather than be told of other available treatment options.

Response: We appreciate concerns raised regarding cost, timeliness, and privacy concerns, which we address in § 92.201(b). Consistent with language access requirements in the 2016 and 2020 Rules, required language assistance services must be provided free of charge, be accurate and timely, and protect the privacy of the individual with LEP. Inaccurate or incomplete translations or interpretation may violate the accuracy standard found in this provision and the overarching requirement to take reasonable steps to provide meaningful access. Accuracy issues are further addressed by requiring covered entities to use the services of qualified interpreters and translators, at § 92.201(c).

Comment: Commenters noted a lack of definition for timeliness in § 92.201(b), and one recommended OCR establish time, distance, and wait time standards. Another commenter suggested that the timeliness standard take into account the geographic location of the covered entity and the hour of the day when the need for language assistance services arises.

Response: As OCR discusses in the HHS LEP Guidance, timeliness may depend on multiple variables and so no one definition would be reasonable or applicable to ''all types of interactions at all times by all types of recipients.'' 68 FR 47316. However, language assistance should be provided at a time and place that avoids the effective denial of the service, benefit, or right at issue or the imposition of an undue burden on or delay in important rights, benefits, or services to the person with LEP. 68 FR 47316. When evaluating a complaint, OCR will consider the context, including the urgency and importance of many health care services. We encourage covered entities to review the HHS LEP Guidance for additional guidance.

Comment: Several commenters stated that language assistance services should be required to include cultural competency and that providers should reflect the community around them in order to build trust. One commenter noted that during listening sessions they conducted, participating health centers emphasized the important role that bilingual and bicultural staff who represent the community served to provide accurate and culturally comprehensible interpretation. A few commenters recommended requiring covered entities to ensure sufficient staff with appropriate training and to administer language proficiency assessments to confirm competency of bilingual and multilingual staff.

Some commenters urged that translators and interpreters be from or a part of the impacted community in which they serve, with some suggesting that community-based interpreters and translators may be more qualified for a number of reasons, including familiarity with local dialect and cultural competency. Others, however, stated that family members and community service providers or other external groups should not have to bear the burden of interpreting.

Response: OCR generally agrees that cultural competency is essential for

https://www.mdpi.com/1660-4601/19/13/7750: Francisco Ramos-Gomez et al., *Addressing Social Determinants of Oral Health, Structural Racism and Discrimination and Intersectionality among Immigrant and Non-English Speaking Hispanics in the United States,* 82 J. Pub. Health Dentistry 133 (2022), *https://doi.org/10.1111/jphd.12524*.

[131] Kathryn Pitkin Derose et al., *Limited English Proficiency and Latinos' Use of Physician Servs.,* 57 Med. Care Rsch. Rev. 76 (2000), *https://doi.org/10.1177/107755870005700105*.

[132] Jie Zong & Jeanne Batalova, Migration Pol'y Inst., *The Limited English Proficient Population in the United States in 2013* (2015), *https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013*.

[133] Gilbert C. Gee et al., *Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California,* 100 Am. J. of Pub. Health 891 (2010), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2853608/*.

[134] Elizabeth A. Jacobs et al., *Limited English Proficiency and Breast and Cervical Cancer Screening in a Multiethnic Population,* 95 Am. J. Pub. Health, 1410 (2005), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449374/*; Israel De Alba et al., *English Proficiency and Physicians' Recommendation of Pap Smears Among Hispanics,* 30 Cancer Detection & Prevention 292 (2006), *https://pubmed.ncbi.nlm.nih.gov/16844320/*; Lisa Diamond et al., *A Systematic Review of the Impact of Patient–Physician Non-English Language Concordance on Quality of Care and Outcomes,* 34(8) J. Gen. Internal Med. 1591 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6667611/*; Kelly H. Bruce et al., *Barriers and Facilitators to Prevent Cancer Screening in Limited English Proficient (LEP) Patients: Physicians' Perspectives,* 11 Commc'ns. Med. 235 (2014), *https://journal.equinoxpub.com/CAM/article/view/8592*.

[135] U.S. Dep't of Health & Hum. Servs., Ctr. for Disease Control, *Adults with Disabilities: Ethnicity and Race, https://www.cdc.gov/ncbddd/disabilityandhealth/materials/infographic-disabilities-ethnicity-race.html* (citing Elizabeth A. Courtney-Long et al., *Socioeconomic Factors at the Intersection of Race and Ethnicity Influencing Health Risks for People with Disabilities,* 4 J. Racial and Ethnic Health Disparities 213 (2017), *https://pubmed.ncbi.nlm.nih.gov/27059052/*); Francisco J. Medrano et al., *Limited English Proficiency in Older Adults Referred to the Cardiovascular Team,* 136 Am. J. of Med. 466 (2023); Terceira A. Berdahl et al., *Patient-Provider Communication Disparities by Limited English Proficiency (LEP): Trends from the US Medical Expenditure Panel Survey, 2006–2015,* 34 J. Gen. Internal Med. 1434 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6667581/*.

equitable language access and communications.[136] This is especially important considering variations in dialects, expressions, or ''regionalisms.'' For example, a Spanish word that may be understood to mean something for someone from Puerto Rico may mean something else for someone from Mexico. Thus, cultural competency is a key factor in providing accurate interpretation and translation, and accuracy is a necessary component of meaningful access.

OCR recognizes that community members may be more likely to be culturally competent but declines to include in the regulatory text a requirement that translators and interpreters be from the community they serve. Covered entities are free to determine their own hiring and contracting processes for utilizing the services of qualified interpreters and translators, and hiring bilingual/multilingual staff, as long as these individuals meet the requirements for their respective positions as provided in § 92.4 (Definitions).

Comment: Many commenters supported the novel proposal to address machine translation in this regulation, with some requesting that machine translation *always* be checked by a qualified human translator and that patients be advised when a translation has been completed by machine translation due to high error rates. One commenter specified that covered entities should not use Google Translate as the only resource for translations as it generates errors, pointing to a State Department of Health website translating ''the vaccine is not required'' for COVID–19 to ''the vaccine is not necessary'' in Spanish (since corrected). Other commenters stated that the rule does not adequately account for future innovations and that the final rule should include an exception for exigent circumstances. Insurance entities and other providers commented that machine translation is a viable option to reduce costs in some instances.

Response: OCR recognizes that machine translation is an evolving technology. However, given that it still carries significant potential for error, we believe this provision strikes an appropriate balance between the convenience some may find in this technology and the critical nature of communications in the health care context. We appreciate commenters' concerns regarding exigent circumstances, where use of machine translation technology may provide immediate language assistance capabilities in very urgent circumstances. As provided under § 92.201(a), ''[a] covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency (including companions with limited English proficiency) eligible to be served or likely to be directly affected by its health programs and activities.'' For example, if an emergency medical technician must provide urgent medical care to an individual with LEP, and no other language assistance services are available, it may be reasonable to use machine translation technology to communicate with that person while a qualified interpreter is identified. We note that the definition for machine translation found at § 92.4 under this final rule ''means automated translation . . . that is text based and provides instant translations between various languages,'' which includes automated translation covers speech as well as written communications. However, given the importance of communication and understanding in the health care and services setting, OCR requires that in such circumstances, the machine translation must be subsequently checked by a qualified human translator as soon as practicable. OCR also recommends that, if machine translation is used in circumstances that do not require human review (*i.e.,* those circumstances that do not meet the criteria set forth in § 92.201(c)(3)), the patients should be warned that it may contain errors. OCR directs commenters to § 92.4 (Definitions) for further discussion on machine translation and future technology.

Comment: OCR received limited comments on our proposed revisions to the factors the Director will take into account when evaluating compliance with language access obligations (proposed § 92.201(d)). Several commenters supported discontinuing the 2020 Rule's use of the ''four-factor analysis,'' 45 CFR 92.101(b)(1), found in the HHS LEP Guidance, 68 FR 47314–16, to determine compliance with a covered entity's language access requirements under section 1557. These commenters stated that the four-factor analysis is too vague to be useful for oversight of compliance and does not provide direction on how each of the factors would be weighed against each other. Conversely, a few commenters recommended that OCR retain the four-factor analysis since it provides covered entities more flexibility. These commenters noted that recipients must have flexibility in achieving compliance with requirements for language access because of their limited resources and patient populations.

A few commenters noted that the phrase ''other relevant factors'' in § 92.201(d) is vague and should either be removed or clarified. Specifically, they said that compliance has been an ongoing problem and more information is needed to help covered entities understand the factors that will be used for evaluation of compliance. Additionally, one commenter recommended that the final rule include the geographic location of the covered entity and the hour of the day when the need for language assistance services arises as one of the factors for OCR to consider in evaluating compliance. For example, the ability of a small, rural provider to find an interpreter for an individual with LEP at midnight on a Saturday is going to be substantially more challenging than it would be for a provider in an urban setting.

Response: As discussed in the 2022 NPRM, 87 FR 47862, after additional consideration OCR determined that the four-factor test was not a sufficiently precise or flexible compliance tool. Section 92.201(d)(1) provides flexibility that allows the Director to take into account a range of relevant factors, including the ''nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency.'' Additionally, § 92.201(d)(2) allows for the consideration of ''other relevant factors,'' including those that relate to whether ''reasonable steps'' were taken in a given situation. Thus, the Director may take into account the geographic location and timing considerations posed by the commenter's example in evaluating whether ''reasonable steps'' were taken.

Comment: Many commenters supported the inclusion of an explicit prohibition on the use of certain persons to interpret or facilitate communication, including the expectation that in an emergency situation, reliance on an accompanying adult or minor should be ''a temporary measure'' at § 92.201(e).

[136] *See* U.S. Dep't of Health & Hum. Servs., Off. of Minority Health, *Think Cultural Health, National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf* (recommending that health organizations: ''[p]rovide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs,'' through providing language assistance and ''[e]stablish[ing] culturally and linguistically appropriate goals, policies, and management accountability, and infuse them throughout the organization's planning and operations'').

Commenters stated that children oftentimes are asked to interpret medical information for which they do not have the vocabulary or content knowledge. Some also stated that older adults with LEP may feel pressure to rely on family members as interpreters, even if those family members are not qualified to interpret health information, which can inhibit the older adult's understanding of their health status and instructions from their provider.

Response: We appreciate the commenters' support and underscore that untrained ''interpreters'' are more likely to make errors, violate confidentiality, and increase the risk of poor outcomes. Research has shown that the ability of a provider to accurately diagnose a patient's condition can be jeopardized by untrained interpreters, such as family and friends, and especially minor children who are prone to omissions, additions, substitutions, volunteered opinions, semantic errors, and other problematic practices.[137] Additionally, the use of children as interpreters raises not only the same concerns as those of an accompanying adult who is not qualified as an interpreter, but also poses other problems including exposing children to complex health care interactions for which they are not developmentally prepared, upsetting a family power dynamic, causing embarrassment, and conveying incorrect or incomplete information. 87 FR 47863.

Comment: Some commenters requested that OCR provide emergency exceptions for using bilingual/multilingual staff as interpreters. These commenters noted that covered entities should be able to use their staff's skills in different languages when needed in emergency situations.

Response: We appreciate commenters' concerns regarding obtaining the services of a qualified interpreter in emergency situations. Under § 92.201(e)(2) introductory text, a covered entity may ''[r]ely on an adult, not qualified as an interpreter, accompanying a limited English proficient individual to interpret or facilitate communication'' as a temporary measure in an emergency pending the retention of a qualified interpreter. OCR has revised § 92.201(e)(2) introductory text to remove references limiting reliance on a non-qualified interpreter to only an adult ''accompanying an individual with LEP.'' This provision now allows for a covered entity to rely on a bilingual/multilingual staff member—or other adult not accompanying an individual with LEP—to serve as an interpreter as a temporary measure in such emergency situations. Furthermore, the interpreter services of bilingual/multilingual staff who are also qualified interpreters may be utilized in any situation, including emergency situations. However, covered entities should consider how to obtain the services of a qualified interpreter as quickly as possible in emergency and exigent circumstances, and only rely upon other persons in highly exceptional circumstances.

Comment: A couple of commenters recommended that OCR revise § 92.201(e)(2)(ii) to allow a covered entity to use a qualified interpreter even in situations where the patient has requested that a family member or friend interpret or facilitate communication. These commenters explained that if a provider believes that the family member or friend may not be accurately communicating with the patient or appears to be struggling when interpreting or if a health provider suspects in good faith that an individual may be a victim of trafficking or abuse, then the health provider should be able to utilize a qualified interpreter.

Another commenter recommended that OCR clarify that an accompanying adult may only facilitate communication at the request of an individual with LEP when the request is made in private, without the adult present. The commenter expressed concern that the exception as written could interfere with the autonomy of the individual with LEP seeking sexual or reproductive health services, especially if the individual is accompanied by an abusive partner that objects to certain sexual and reproductive health services.

Additionally, one commenter noted that the prohibition of an accompanying adult acting as an interpreter—absent the individual with LEP's consent or in the case of an emergency—is particularly important for survivors of domestic and sexual violence. The commenter stated that without such a restriction, victims and survivors are faced with situations where their abuser, child, or family member may be used to interpret traumatic and sensitive information, compounding the risk to victims and trauma to themselves as well as their children. Another commenter recommended OCR specify that if an individual with LEP requests an accompanying adult to facilitate one time, this does not mean the covered entity can assume the individual with LEP will continue to bring that same adult or choose to use that adult as an interpreter for future interactions. The covered entity must offer language services each and every time it encounters an individual with LEP.

One commenter requested OCR also address nonemergency situations where the patient does not ''specifically request'' that an accompanying adult interpret or facilitate communication, but where, despite best efforts to find a qualified interpreter, it is not possible to find a qualified interpreter for the individual with LEP, such as when a patient speaks a rare dialect of a language.

Response: We appreciate the commenters' concerns regarding when it may or may not be appropriate to grant an adult with LEP's request for an individual not qualified as an interpreter to interpret or facilitate communication. When considering reliance on an accompanying adult to interpret, the covered entity must consider whether that reliance is appropriate—this includes whether the covered entity believes the accompanying adult can adequately convey the information being discussed and whether they may have a conflict or bias, as in the case of intimate partner violence. Any agreement by a covered entity to allow an accompanying adult to interpret or facilitate communication may only be at the affirmative and independent request of the individual with LEP so as to protect individuals in situations such as intimate partner violence, abuse, or trafficking. We clarify that OCR appreciates the critical role parents and guardians play in medical decision-making for their children and that the rule does not prevent parents from being involved in their children's health care decisions. To address the concern of coercion and the like, we are finalizing § 92.201(e)(2)(ii) to include a requirement that the individual with LEP make their request without the accompanying adult present and with the services of a qualified interpreter, which does not include the exigent circumstances exception found at § 92.201(e)(2)(i).

Comment: One commenter encouraged OCR to include a specific provision at § 92.201(e) ensuring privacy and confidentiality for individuals with LEP, such as not having sensitive discussions in waiting rooms and other public spaces.

Response: We appreciate the commenter's concern regarding privacy and confidentiality for individuals with

[137] Joseph R. Betancourt et al., The Disparities Solutions Ctr., *Mongan Inst. for Health Pol'y, Mass. Gen. Hosp., Improving Patient Safety Systems for Patients with Limited English Proficiency: A Guide for Hospitals,* pp. 3–5, 10–11, 14–16 (2012), *https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

LEP and restate that one of the key components of the definition of ''qualified interpreter for an individual with limited English proficiency'' is that they must adhere to generally accepted interpreter ethics principles, including client confidentiality. Additionally, covered entities that are subject to both HIPAA and section 1557 must comply with the requirements of both laws.[138]

Comment: Several commenters supported the restoration of requirements related to video remote interpreting (VRI) for individuals with LEP. Commenters noted that the 2020 Rule removed requirements related to VRI for individuals with LEP, yet many covered entities use video interpreting not only for deaf or hard of hearing patients but also patients with LEP. Further, these commenters noted that the quality of video interpreting should be the same for all individuals who use it. A couple of commenters specifically noted the importance of high-quality picture, video, and transmissible audio for all parties in order for interpreters to perform their job effectively. For example, one commenter noted the importance of restoring VRI standards for individuals with LEP given frequent concerns about the poor quality of interpreter services using VRI. A couple of other commenters mentioned that the use of such technology will facilitate discussion between qualified interpreters and individuals with LEP and will also assist individuals who may have disabilities who are aided by using such technology. One commenter, who supported inclusion of VRI standards, recommended in-person interpretation should be sought as a first step because it is more responsive than VRI.

Response: We agree with commenters that it is important to have parity in VRI quality standards for all individuals who use it. The final rule reinstates the VRI standards from the 2016 Rule, former 45 CFR 92.201(f), which were based on standards found in the implementing regulations for title II of the ADA.[139] This provision is designed to achieve parity with the VRI requirements found in § 92.202 regarding effective communication for people with disabilities.

We recognize that VRI is not always the most appropriate method for providing language assistance services. This provision does not require a covered entity to provide VRI but rather ensures that when such services are used, they meet a minimum quality standard. To also clarify that the language assistance services delivered via VRI must provide meaningful access, we are revising § 92.201(f) to require that when a covered entity uses VRI services, it ''must ensure the modality allows for meaningful access.''

Comment: A few commenters raised concerns with the proposed technical requirements for VRI services. A couple of commenters requested OCR provide emergency exceptions for performance standards for video remote interpreting. These commenters also expressed concern with the requirement that VRI must be over a dedicated high-speed, wide-bandwidth video connection or wireless connection since it may be difficult to meet that standard in an emergency, such as a natural disaster that disrupts access to the high-speed connection.

Another commenter suggested revising the rule to require covered entities to use audio and video communications for interpretation services that are consistent with those available in the community served by the health program or activity. The commenter explained the communications framework in a community, such as a rural community, may not fully meet the standards proposed.

Response: We appreciate commenters' concerns regarding the ability to meet the VRI standards proposed. In the event of a natural disaster or locations where high-speed wide-bandwidth video capabilities may not be available, covered entities may not be able to meet the required standards. In these circumstances, a reasonable step to achieving meaningful access may be through using the services of a qualified interpreter via telephone (or in-person, if available). As in all circumstances, OCR will consider the specific facts of whether a covered entity has taken reasonable steps to provide meaningful access under the circumstances.

Comment: A couple of commenters recommended that VRI requirements be reflective of and adaptable to the specific community or individual. One organizational commenter recommended that the rule clarify that covered entities should follow an individual's preference with respect to interpreter services where appropriate. The commenter noted that the majority of their members and patients with LEP communicate through telephonic interpretation services and that there are also situations where a member or patient may express a preference to use an audio interpreter service rather than be required to participate in a video session.

Response: We appreciate commenters' suggestions regarding prioritizing an individual with LEP's preference when determining the manner in which interpreting services will be provided. However, we decline to revise the requirements for VRI standards. These standards set minimum requirements for when language assistance services are provided via VRI; they do not, however, *require* a covered entity to use such technology. Covered entities are free to use audio-only interpretation if that is a reasonable step to provide meaningful access to an individual with LEP, including if it is the expressed preference of an individual with LEP.

Comment: A few commenters recommended OCR establish further requirements with respect to VRI. These commenters suggested OCR specify that the covered entity should be held responsible for ensuring that the VRI device connects to a qualified interpreter within five minutes of the arrival of the VRI device in the room and ensure that there are no interruptions in communication, such as disconnections or screensavers. Further, commenters recommended that health care entities should have personnel available on a 24-hour basis who are trained and able to operate the VRI system efficiently. These commenters stressed that hospitals are already responsible for the maintenance and upkeep of multiple types of equipment necessary for health care and, as such, the same strict standards for optimal operation and upkeep should apply to VRI technology as well. A few commenters stated that covered entities should have policies and procedures in place to procure video remote interpretation.

Response: OCR appreciates the commenters' recommendations for providing further requirements related to VRI. The rule requires that language assistance services be provided in a timely manner. We decline to mandate a specific time period in which an interpreter must be made available once

[138] Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by section 1557 or the part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates. *See* U.S. Health & Hum. Servs., Off. for Civil Rts., *Health Information Privacy FAQs, https://www.hhs.gov/hipaa/for-professionals/faq/760/must-a-covered-provider-obtain-individual-authorization-to-disclose-to-an-interpreter/index.html.*

[139] *See* 28 CFR 35.160(d)(1)–(4). In contrast to 28 CFR 35.160(d)(2), which regulates the size of the video image to ensure that the screen shows one's face, arms, hands, and fingers, § 92.201(f)(2) in this final rule does not regulate the size of the video image because this component is less relevant for oral interpretation between English and non-English languages or two non-English spoken languages.

a VRI device is present, as it does not allow for the necessary flexibility that may be required to account for the specific circumstances giving rise to the interaction, such as whether it is scheduled or unscheduled. We agree it is important to ensure a covered entity has personnel who can maintain and efficiently set up and operate VRI technology. To this end, the rule requires covered entities to maintain language access procedures per § 92.8(d), and to provide adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the VRI device per § 92.201(f)(4). Although we support covered entities having policies and procedures in place related to the procurement of video remote interpretation, we decline to require them to do so because we do not believe imposing such a requirement is warranted at this time.

Comment: OCR received a few comments on the standards for audio remote interpreting services at § 92.201(g), which were generally supportive. One commenter expressed that audio-only interpretation is often a poor substitute for video remote or in-person interpretation and recommended OCR consider audio-only interpretation to be a last resort.

Response: We appreciate the commenter's concern and recognize that audio remote interpreting may not be adequate to provide meaningful access to an individual with LEP. However, there are situations in which audio remote interpreting may be the only option available to a covered entity and so we decline to place further restrictions on its use. To address concerns that audio remote interpreting may fail to provide meaningful access, we are revising § 92.201(g) to require that when a covered entity uses audio remote interpreting services, it ''must ensure the modality allows for meaningful access.''

Comment: One commenter recommended OCR explicitly prohibit covered entities from coercing individuals with LEP to decline language assistance services, which was stated in the preamble to the 2015 NPRM. 80 FR 54185. The commenter noted that the 2022 NPRM did not capture this important concept and covered entities should be prohibited from discouraging individuals with LEP from exercising their rights, which may be a form of discrimination.

Response: We appreciate the commenter's concern and reiterate that a covered entity may not coerce an individual with LEP to decline language assistance services. In the same way that a covered entity is prohibited from requiring an individual with LEP to accept language assistance services, § 92.201(h), a covered entity similarly cannot require or coerce an individual to decline such services.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the provisions as proposed in § 92.201, with modifications. In § 92.201(a), we are adding ''(including companions with limited English proficiency)'' after the term ''individual with limited English proficiency.'' In § 92.201(e)(2), we are deleting the clause ''accompanying a limited English proficient individual.'' In § 92.201(e)(2)(i), we are replacing ''the accompanying adult'' with ''an initial adult interpreter.'' In § 92.201(e)(2)(ii) we are adding the phrase ''in private with a qualified interpreter present and without an accompanying adult present,'' after ''where the individual with limited English proficiency specifically requests.'' In § 92.201(f), we are adding the phrase ''ensure the modality allows for meaningful access and must . . .'' after ''through video remote interpreting services in the covered entity's health programs and activities must . . .'' In § 92.201(g), we are adding the phrase ''ensure the modality allows for meaningful access and must . . .'' after ''through audio remote interpreting services in the covered entity's health programs and activities must . . .''

We are also making technical revisions. Throughout § 92.201, we are replacing the term ''limited English proficient individual'' with ''individual with limited English proficiency.'' In § 92.201(c)(2), we are replacing the phrase ''a covered entity must use a qualified translator'' with ''a covered entity must utilize the services of a qualified translator.'' In § 92.201(e)(2)(ii), we are replacing the word ''the'' in the phrase ''by the accompanying adult is documented'' with ''by an accompanying adult is documented.'' In § 92.201(e)(4) we are striking the word ''directly'' as technically incorrect to describe the manner in which a covered entity communicates to an individual with LEP via the services of a qualified interpreter or qualified translator.

Effective Communication for Individuals With Disabilities (§ 92.202)

Proposed § 92.202 addressed requirements related to providing effective communication for individuals with disabilities.

In § 92.202(a), we proposed requiring a covered entity to take appropriate steps to ensure that communications with individuals with disabilities, and companions with disabilities, are as effective as communications with individuals without disabilities in its health programs and activities, incorporating the standards found at 28 CFR 35.130 and 35.160 through 35.164 of the regulation implementing title II of the ADA.

In § 92.202(b), we proposed to require covered entities to provide appropriate auxiliary aids and services to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such individuals an equal opportunity to benefit from the service in question.

The comments and our responses regarding § 92.202 are set forth below.

Comment: While commenters generally expressed support for § 92.202, many discussed the extensive lack of compliance with current effective communication requirements under section 1557, section 504, and title II of the ADA by covered entities. Some referenced costs as the key issue, and one commenter stated that some providers have a policy of only providing an interpreter if the cost is covered by the patient's health insurance. Another commenter stated that even when the State has a Medicaid billing code, the patients still are faced with the burden of having to educate prospective providers about the availability of the code and the provider's obligation to provide auxiliary aids and services.

Other commenters mentioned that compliance will require implementing programs to develop, maintain, and communicate clear policies, and train on the provision of language assistance services and auxiliary aids and services for effective communication.

Response: OCR is aware that some covered entities fail to comply with their responsibility to ensure effective communication with individuals with disabilities, including through requiring an individual to bring their own interpreter, only providing interpreter services when covered by the individual's health insurance coverage or other health-related coverage, or incorrectly citing health privacy laws as a reason to not provide interpreter services.

In an effort to proactively address compliance concerns and resulting lack of access to covered health programs and activities, we are requiring all covered entities to develop and

maintain effective communication procedures, per § 92.8(e). OCR encourages covered entities to include any necessary billing codes in such procedures. We are further requiring covered entities to train relevant employees on these procedures, per § 92.9.

Comment: A patient advocacy group recommended requiring that states establish a medical communication access fund that pools fees from State-mandated medical licenses to pay for effective communication. The commenter expressed that this method spreads out the costs of auxiliary aids and services so that no single covered entity bears the costs.

Response: All covered entities must provide auxiliary aids and services when needed to communicate effectively with people with disabilities. OCR encourages covered entities to develop creative approaches to support the provision of these required aids and services. OCR declines to include a specific requirement for states to establish mandatory medical communication access funds in this rulemaking as such a requirement would exceed the authority granted to OCR for this rulemaking.

Comment: Some commenters expressed appreciation and support for the inclusion of ''companions'' in the text of § 92.202. One commenter added that doctors and hospitals have told patients that their legal counsel informed them that they are not obligated to provide communication access to anyone who is not a patient. One commenter recommended that OCR include that the selection of ''appropriate'' companion(s) be made by the individual not the provider.

Response: Section 1557 requires that covered entities ensure effective communication for individuals with disabilities, including companions. The definition in § 92.4 is consistent with the definition of ''companion'' from the implementing regulations for title II of the ADA, which similarly requires that a public entity ''take appropriate steps to ensure that communications with . . . companions with disabilities are as effective as communications with others.'' 28 CFR 35.160(a).

Comment: A couple of commenters mentioned that patients are sometimes told that due to confidentiality they cannot have a friend, family member, advocate, or attorney be present for an appointment for effective communication purposes. One commenter provided the following example: An individual with Autism Spectrum Disorder (ASD) was required to enter the hospital without his mom, who could assist him in communicating, and likely because of that he was misdiagnosed and required to return to the emergency room within a week.

Response: Unless a covered entity has a specific confidentiality concern regarding the presence of a specific companion, the individual with a disability should be permitted to select a companion and have them present when accessing a covered health program or activity. Further, and consistent with instruction under the ADA, a companion may need to help the patient with information or instructions given by hospital personnel.[140] Companions may be an essential part of ensuring an individual with a disability is afforded effective communication and should not be separated from an individual with a disability outside of extenuating circumstances. However, we note that a covered entity may not rely on a person accompanying an individual with a disability to interpret or otherwise facilitate communication; this is only permitted when the individual with a disability specifically requests that an accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances. *See* 28 CFR 35.160(c)(2)(ii), incorporated by § 92.202.

Comment: Several commenters thanked OCR for proposing to restore the requirements for quality measures in VRI, while some raised concerns regarding the appropriateness of VRI in various circumstances. They shared that, for example, VRI may not be effective for a person lying on their back for a medical procedure due to challenges with viewing the screen and that VRI has been inappropriately used during high-risk childbirth. Yet another commenter mentioned that VRI is not appropriate for individuals who are deafblind (*i.e.,* individuals who have combined hearing and vision loss that limit access to both auditory and visual information). One commenter expressed concern that a provider made it a policy that their facility only uses VRI and never uses the services of in-person interpreters.

Response: We acknowledge the concerns with VRI and note that it may not provide effective communication for all individuals in all situations. Covered entities are required to take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with individuals without disabilities in their health programs and activities. If the use of VRI does not provide an individual equal opportunity to participate in or benefit from the service in question, then the communication is ineffective and does not meet section 1557 requirements.

Several cases have found that VRI was ineffective due to hospital staff's lack of knowledge about how to operate the VRI equipment or technology issues with the equipment itself, including the attempted use of VRI during labor.[141] Settlement agreements with the United States have similarly found concerns with VRI, including one settlement decree that specified that VRI would not be considered effective in specific situations, including situations due to: ''(1) a patient's limited ability to move his or her head, hands or arms; vision or cognitive issues; or significant pain; (2) space limitations in the room; (3) the complexity of the medical issue; or (4) any other time when there are indicators that VRI is not providing effective communication.'' [142]

This enforcement activity suggests that VRI may not always afford a person with a disability an equal opportunity to participate in and enjoy the benefits of the program or activity of a covered entity. Thus, policies that require the exclusive use of VRI, or the exclusive use of any particular auxiliary aid or service, are likely to result in the eventual failure to provide effective communication and therefore should not be adopted.

Comment: One patient advocacy group recommended that OCR emphasize that family members should not act as interpreters for a deaf or hard of hearing patient, except in certain exigent circumstances.

[140] 75 FR 56183, 56223–24 (Sept. 15, 2010).

[141] *Sunderland* v. *Bethesda Hosp., Inc.,* 686 F. App'x 807 (11th Cir. 2017); *Silva* v. *Baptist Health S. Fla., Inc.,* 303 F. Supp. 3d 1334 (S.D. Fla. 2018), *aff'd in part, vacated in part, remanded,* 838 F. App'x 376 (11th Cir. 2020); *Juech* v. *Children's Hosp. & Health Sys., Inc.,* 353 F. Supp. 3d 772 (E.D. Wis. 2018); Settlement Agreement Between the United States of America and Floyd Medical Center (2016), *https://archive.ada.gov/floyd_sa.html*; *see also* Manako Yabe, *Healthcare Providers' and Deaf Patients' Interpreting Preferences for Critical Care and Non-Critical Care: Video Remote Interpreting,* 13.2 Disability and Health J. 100870 (2020), *https://pubmed.ncbi.nlm.nih.gov/31791822/*; Nat'l Ass'n for the Deaf, *Minimum Standards for Video Remote Interpreting Services in Medical Settings, https://www.nad.org/about-us/position-statements/minimum-standards-for-video-remote-interpreting-services-in-medical-settings/.*

[142] Settlement Agreement Between the U.S. and Swedish Edmonds Hospital (2014), *https://archive.ada.gov/swedish_edmonds_sa.htm*; Settlement Agreement Between the U.S. and Grady Memorial Hospital (2016), *https://archive.ada.gov/grady_sa.html.*

Response: Covered entities are responsible for providing effective communication, including through utilizing the services of a qualified interpreter, and cannot require an individual to bring someone to interpret for them. Persons with disabilities can, however, bring an interpreter of their choosing, including a family member, and OCR declines to add the suggested language prohibiting this choice. This approach is consistent with existing ADA title II regulations, 28 CFR 35.160(c), and with the approach OCR has followed in the section 504 proposed rule. 88 FR 63392, 63508 (Sept. 14, 2023) (proposed 45 CFR 84.77(c)(2)(ii)).

Comment: One group recommended that the final rule include language that requires health care entities to consider a patient's preference for gender of the interpreter as a means of ensuring more effective communication. This group noted that given the intimate nature of medical assessments and treatments, patients may not be comfortable with an interpreter of a different gender than themselves, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: While OCR appreciates that a patient may prefer an interpreter of a particular gender and recommends consideration of a patient's preference for a particular gender whenever possible, including when the request is made based on an individual's religious practices and beliefs, we decline to include such language in the rule regarding the gender of a qualified interpreter for an individual with a disability. OCR notes that some organizations, such as the National Association of the Deaf and Deaf Seniors of America, have issued position statements to guide providers in adopting internal VRI policies, and have stated that medical providers ''shall honor the preference of the deaf or hard of hearing patient and/or companion with respect to the gender of video interpreter.'' [143] However, OCR notes that whether a covered entity has ensured their communication is effective for an individual with disability does not inherently depend on whether the covered entity is able to satisfy a patient's preference regarding the interpreter's gender.

Comment: An organizational commenter said that providers should be required to ''affirmatively ask'' patients what they need to make documents accessible and should document that requirement so that it does not need to be repeatedly asked and answered.

Response: OCR understands the frustration experienced by individuals who have to inform their providers of their need to receive communication in accessible formats multiple times. We note that the Department has implemented a process by which Medicare beneficiaries who are blind or have low vision can request Medicare Summary Notices in an accessible format, and following the initial request, the required accessible format will be the default format of the document mailed to the beneficiary.[144] We recognize this as a best practice, and while we decline to require that such need be documented, we encourage covered entities to implement such a practice in the written effective communication procedures required under § 92.8(e).

Comment: Some organizational commenters urged OCR to incorporate the following OCR guidance documents directly into the final regulations, as well as all subsequent similar guidance, technical assistance, and enforcement activities: enforcement efforts related to support persons in hospital settings[145] and Bulletin on Civil Rights, HIPAA, and the Coronavirus Disease 2019.[146]

Response: OCR thanks commenters for their suggestion to incorporate guidance and enforcement materials into the final rule. Guidance documents advise members of the public how an agency understands its legal authorities.[147] Similarly, covered entities and others may be able to look to OCR's enforcement to gain clarity regarding regulatory requirements. As guidance, technical assistance, and enforcement activities are constantly evolving, we decline to codify the referenced materials in this rule.

Comment: Multiple commenters, including organizations, recommended that § 92.202(b) explicitly parallel the language in § 92.201(b) by stating that auxiliary aids and services must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making of the individual with a disability. The commenters noted that while this section adopts by reference 28 CFR 35.160 through 35.164 (ADA title II communication requirements), some covered entities may simply read the regulatory language and note the difference in language between §§ 92.201 and 92.202. Noting this difference, several commenters also requested that OCR develop technical assistance materials on 28 CFR 35.160 through 35.164 in plain language.

Response: Like multiple places in this regulation, the text of § 92.202 adopts ADA title II standards by reference, including the requirements related to auxiliary aids and services. OCR appreciates the concerns raised by commenters regarding the apparent lack of parity between §§ 92.201(b) and 92.202(b), and how this may lead to confusion on behalf of covered entities and the public and may increase the likelihood that individuals with disabilities may either not receive or may be required to pay for auxiliary aids and services. Therefore, in light of comments received and continued compliance concerns, we are revising § 92.202(b) as follows.

First, OCR is revising the text, consistent with 28 CFR 35.160(b)(1), to clarify that all individuals with disabilities must be afforded appropriate auxiliary aids and services and an equal opportunity to ''participate in and enjoy the benefits of'' the health program or activity in question.

Further, OCR agrees with commenters that it is important that those reading this regulation can immediately identify that appropriate auxiliary aids and services must be provided free of charge. Some commenters and our enforcement experience demonstrate that this requirement, similar to that in the ADA and section 504, is not always clear or adhered to by covered entities. Thus, OCR is adding a sentence to § 92.202(b) stating that auxiliary aids and services must be provided free of charge. OCR notes that this is similar to the approach taken in DOJ's implementing regulations for title II and title III of the ADA, which forbid surcharges on persons with disabilities or groups of persons with disabilities to

[143] Nat'l Ass'n of the Deaf, *Minimum Standards for Video Remote Interpreting Services in Medical Settings, https://www.nad.org/about-us/position-statements/minimum-standards-for-video-remote-interpreting-services-in-medical-settings/.*

[144] Beneficiaries can find information on how to request Medicare Summary Notices in accessible formats at Medicare.gov, *Accessibility & Nondiscrimination Notice, https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice*; *see also* 88 FR 22120, 22122 (April 12, 2023).

[145] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Complaints after State of Connecticut and Private Hospital Safeguard the Rights of Persons with Disabilities to Have Reasonable Access to Support Persons in Hospital Settings During COVID–19* (June 9, 2020), *https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/06/09/ocr-resolves-complaints-after-state-connecticut-private-hospital-safeguard-rights-persons.html.*

[146] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *March 28, 2020 BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID–19)* (Mar. 28, 2020), *https://www.hhs.gov/guidance/document/march-28-2020-bulletin-civil-rights-hipaa-and-coronavirus-disease-2019-covid-19.*

[147] *Kisor* v. *Wilkie,* 139 S. Ct. 2400, 2420 (2019) (plurality opinion) (quoting *Perez* v. *Mortgage Bankers Ass'n,* 575 U.S. 92, 97 (2015)).

cover the provision of auxiliary aides and services. 28 CFR 35.130(f) (title II), 36.301(c) (title III). For parity with 28 CFR 36.160(b)(2) and 45 CFR 92.201(b), we are also revising the text to clarify that auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way to protect the privacy and the independence of the individual with a disability.

OCR appreciates commenters' suggestion to develop technical assistance materials regarding effective communication under 28 CFR 35.130 and 35.160 through 35.164. These are regulations promulgated and enforced by DOJ, and we will continue to coordinate and collaborate with DOJ to develop technical assistance materials related to effective communication requirements under our respective authorities.[148]

Comment: A few organizational commenters argued that the provision of auxiliary aids and services is necessary but not a sufficient tool for avoiding and remedying effective communication discrimination. The commenters said that individuals who cannot rely on natural speech for effective communication require ''effective access to the robust language-based alternative and augmentative communication they need to express themselves and be understood.'' Another group said that OCR should expand on the definition of ''auxiliary aids and services'' to include plain language and screen reader capabilities.

Response: Covered entities are required take appropriate steps to ensure effective communication. Though the provision of appropriate auxiliary aids and services is addressed in § 92.202(b), the examples of auxiliary aids and services provided at § 92.4 (Definitions) is non-exhaustive and covered entities may use additional auxiliary aids and services to achieve effective communication.

Effective communication for patients with cognitive, neurological, and psychiatric disabilities may require auxiliary aids and services or strategies different from those employed with patients with other disabilities. For example, while an individual who is deaf or hard of hearing may require an ASL interpreter to effectively communicate with a provider, an individual with a cognitive disability may require additional time with the provider to ask questions and receive plain language answers about a specific health care decision.

In addition, one type of auxiliary aid or service that may be required is the acquisition or modification of equipment or devices, including for augmentative and alternative communication, and the provision of training and assistance to the individual with a disability on how to use them. Augmentative and alternative communications devices include, but are not limited to, speech generating devices, single-message devices, computers, tablets, smartphones, amplification devices, telecommunications devices, voice amplifiers, artificial phonation devices, picture and symbol boards, paper-based aids, and other equipment or devices used to compensate for impairments to speech-language production or comprehension, including spoken and written modes of communication. In some instances, the use of augmentative and alternative communication is necessary for individuals with certain disabilities that impair speech production and comprehension to access vital health and human services programs and activities. Often, the most effective way for recipients to ensure effective communication is to provide training on the use of this equipment.

Comment: A health care organization requested that this provision should be modified to state that covered entities ''must make a reasonable attempt'' to provide auxiliary aids and services, ''unless the covered entity can demonstrate that providing such auxiliary aids or services would fundamentally alter the nature of the service in question or result in an undue burden, *i.e.,* significant difficulty or expense.''

Response: OCR declines to modify the standard for effective communication, which requires that covered entities ensure that communications with people with disabilities are as effective as communications with others. The language on fundamental alteration or undue burden related to the provision of communications, found in 28 CFR 35.164, is already adopted into this section by reference.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.202, with modification. We are revising § 92.202(b) to read: ''A covered entity must provide appropriate auxiliary aids and services where necessary to afford individuals with disabilities an equal opportunity to participate in, and enjoy the benefits of, the health program or activity in question. Such auxiliary aids and services must be provided free of charge, in accessible formats, in a timely manner, and in such a way to protect the privacy and the independence of the individual with a disability.''

Accessibility for Buildings and Facilities (§ 92.203)

In § 92.203, we proposed adding a general provision establishing that no qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies, consistent with OCR's section 504 regulation. OCR also proposed incorporating the identical language found in the 2020 Rule at § 92.103, except that the definitions for 1991 Americans with Disabilities Act Standards for Accessible Design (1991 ADA Standards), 2010 ADA Standards for Accessible Design (2010 ADA Standards), and Uniform Federal Accessibility Standards (UFAS), Public Law 90–480; 42 U.S.C. 4151 *et seq.,* are now located in § 92.4.

OCR also notes that the section 504 regulatory provisions incorporated into subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. Title II of the ADA and section 504 require that covered entities operate their programs and activities so that, when viewed in their entirety, they are readily accessible to individuals with disabilities; neither statute has been interpreted to require that each existing facility be made accessible.[149] Nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under section 504 and the ADA. Section 92.203 establishes specific accessibility standards for new construction and alterations under section 1557.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Some commenters emphasized the importance of a

[148] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Disability Resources for Effective Communication, https://www.hhs.gov/civil-rights/for-individuals/special-topics/hospitals-effective-communication/disability-resources-effective-communication/index.html*; *see also Medicaid.gov, Unwinding Documents, https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/state-letters/index.html.*

[149] *See* 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird* v. *Lewis & Clark Coll.,* 303 F.3d 1015, 1021 (9th Cir. 2002) (''the central inquiry [under the ADA and section 504] is whether the program, when viewed in its entirety is readily accessible to and usable by individuals with disabilities'').

continued push towards universal compliance with the 2010 ADA Standards. Many commenters also noted how critical it would be for OCR to provide oversight to ensure that covered entities' buildings and facilities come into compliance with the 2010 ADA Standards. These commenters also noted that the uniform application of the 2010 ADA Standards will also enable greater consistency among implementing agencies.

Response: OCR appreciates the comments regarding the existing standards and the push towards universal compliance with the 2010 ADA Standards and will continue to retain the requirement that new construction or alteration of buildings or facilities must comply with the 2010 ADA Standards.

Comment: Some commenters did not support the incorporation of 45 CFR 84.23(c) at § 92.101(b) because they stated it would allow facilities to only conform with UFAS instead of the more recent 1991 ADA Standards or 2010 ADA Standards. They also expressed concern that the application of the UFAS to new facilities would be outdated. These commenters believe that the UFAS permits facilities to maintain barriers that exclude people with disabilities that impact their mobility or strength.

Response: OCR appreciates the commenters concerns regarding the incorporation of the UFAS. However, this rule does not allow UFAS to be used as the accessibility standard for new facilities. UFAS is only used to determine if a building built before July 18, 2016, was designed and constructed in accordance with the standards at the time. Any alteration or addition of any building or facilities built after July 18, 2016, must follow the 2010 ADA Standards.

Comment: Some commenters also recommend incorporating existing standards relating to accessible Medical and Diagnostic Equipment (MDE) that were developed by the U.S. Access Board. 82 FR 2810 (Jan. 9, 2017), codified at 36 CFR part 1195 (U.S. Access Board 2017 Standards for MDE). Commenters also noted that the lack of access to MDE should constitute both a discriminatory benefit design and network inadequacy.

Response: On September 14, 2023, OCR published a NPRM proposing modifications to the implementing regulations for section 504. The NPRM proposes adopting the U.S. Access Board 2017 Standards for MDE used by recipients of Federal financial assistance to ensure accessibility for patients with disabilities. 88 FR 63450–55, 63511 (proposed 45 CFR 84.92). OCR will continue to address accessible MDE in that rulemaking.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provisions as proposed in § 92.203 with modification. We are making two technical corrections to add ''or alteration'' after ''construction'' in § 92.203(b) and (c) for consistency with the description of the 2010 Standards elsewhere in the provision. We have replaced the phrase ''and such facility was not covered by the 1991 Standards or 2010 Standards'' in § 92.203(c) with ''and such facility would not have been required to conform with a different accessibility standard under 28 CFR 35.151'' for clarity and consistency. We have also added language clarifying the timeframes for compliance with either the 2010 Standards or the UFAS standards for existing facilities where construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS but the facility or part of the facility was not covered by the 2010 Standards. That addition reads, ''If construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS, and the facility or part of the facility was not covered by the 2010 Standards prior to July 18, 2016, then it shall be deemed to comply with this section requirements of this section and with 45 CFR 84.23(a) and (b).''

Accessibility of Information and Communication Technology for Individuals With Disabilities (§ 92.204)

Proposed § 92.204 addressed the accessibility of information and communication technology (ICT) for individuals with disabilities.

In § 92.204(a), OCR proposed requiring covered entities to ensure that their health programs and activities provided through ICT are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. If an action required to comply with this subpart would result in such an alteration or burdens, a covered entity is required to take any other action that would not result in such an alteration or burdens but would nevertheless enable, to the maximum extent possible, individuals with disabilities to receive the benefits or services of the health program or activity provided by the covered entity.

In § 92.204(b), OCR proposed requiring recipients and State Exchanges to ensure that their health programs and activities provided through websites and mobile applications comply with the requirements of section 504 as interpreted in a manner consistent with title II of the ADA.

Given the crucial role that ICT can play for individuals with disabilities accessing health programs and activities, OCR sought comment on whether the section 1557 rule should include a provision requiring covered entities to comply with specific accessibility standards, such as the Web Content Accessibility Guidelines (WCAG) developed by the Web Accessibility Initiative. Additionally, OCR invited comments on whether to adopt a safe harbor provision under which covered entities that are in compliance with established specific accessibility standards are deemed in compliance with proposed § 92.204(a) and (b); whether OCR should require covered entities to comply with the most recent edition of a published standard; and the timeline necessary for covered entities to come into compliance with a new standard.

The comments and our responses regarding § 92.204 are set forth below.

Comment: Many commenters, including civil rights groups, health care organizations, and a group of Federal elected officials, expressed general support for the ICT requirements for people with disabilities in the Proposed Rule. Several commenters said they are concerned that this section only focuses on accessibility for individuals with disabilities, saying that this section should be applicable to all individuals covered by section 1557. These commenters noted that section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that § 92.204 provide that covered entities must ensure that their health programs or activities provided through ICT are accessible to individuals on all protected bases, not just disability.

Response: Section 92.204 prohibits discrimination based on disability in health programs and activities provided through ICT because individuals with certain disabilities are often unable to access certain aspects of ICT when that ICT is not developed to be accessible. For example, OCR has received complaints from people with disabilities, including those who are blind or have low vision, alleging that the ICT of covered entities is

inaccessible to them and not compatible with screen reader software, resulting in a denial of access to health programs and activities. While § 92.204 addresses ICT accessibility issues for individuals with disabilities, it does not limit the application of general nondiscrimination principles found throughout section 1557 regulations to the accessibility of health programs and activities offered through ICT to other groups. Thus, the general prohibition against discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through ICT, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: Several groups recommended adding that ''covered entities must procure, design, maintain and use accessible ICT in all aspects of providing health programs and activities'' to remind covered entities that their civil rights obligations apply in procurements. One group said that OCR should clarify that covered entities should be aware that third-party providers of ICT are not directly covered by this regulation, and that covered entities are obligated to ensure that they procure ICT that is accessible. Several commenters suggested the use of a Voluntary Product Accessibility Template,[150] a document that indicates compliance with section 508 standards,[151] should be completed by the third-party vendors.

Response: Regardless of the method that a covered entity uses to acquire ICT, the health programs and activities it provides through that ICT must be accessible to individuals with disabilities. Due to the increasing importance of ICT in the provision of health care, health insurance coverage, and other health-related coverage, OCR will continue to closely monitor this area. Both OCR and DOJ recently issued NPRMs addressing the accessibility of web content and mobile apps used by recipients of Federal financial assistance and public entities, respectively.[152] Those rulemakings provide greater clarity on obligations to ensure that web content and mobile applications are accessible.

Comment: An organizational commenter asked OCR to provide more guidance on what constitutes undue burden or fundamental alteration.

Response: This rulemaking does not create a different standard for fundamental alteration or undue burden beyond the standards in section 504 and the ADA. As DOJ noted in its August 4, 2023 NPRM, Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities, there are current undue burden and fundamental alteration limitations in the ADA title II regulation that are familiar to public entities. 88 FR 51948, 51978. The current limitations are in the ADA title II implementing regulation at 28 CFR 35.150(a)(3) (program accessibility) and 35.164 (effective communication) for fundamental alteration and undue burden limitations and 28 CFR 35.130(b)(7) (reasonable modifications in policies, practices, or procedures) for fundamental alteration limitations. DOJ also provides additional context for fundamental alteration and undue burden on its ADA.gov website.[153] Additionally, DOJ's technical assistance manual on title III of the ADA provides guidance on what constitutes fundamental alteration and undue burden for public accommodations under title III.[154]

Comment: A professional association asked OCR to work with small, independent, and under-resourced physician practices to ensure they have the resources, tools, and financial assistance necessary to ensure ICT accessibility for patients with disabilities.

Response: OCR will continue to develop technical assistance and educational materials to assist covered entities' compliance with section 1557 and this regulation. However, we are unable to provide other resources or financial assistance to ensure ICT accessibility.

Comment: One organizational commenter said that OCR should provide technical assistance to covered entities servicing populations with digital inequities, such as populations of older adults that may not be as digitally savvy or individuals who do not have stable internet connections.

Response: OCR recognizes that many people lack internet connectivity and may therefore be unable to access web-based tools and resources provided by covered entities, and OCR encourages entities to develop creative means to meet the needs of these individuals. However, though this issue may raise civil rights concerns in some contexts, it is outside the scope of this regulation.

Covered entities have general nondiscrimination obligations under § 92.101(a), including that a covered entity may not discriminate based on age. Accordingly, covered entities that use web-based health programs and activities must ensure that older adults are not denied participation, denied benefits, or otherwise discriminated against in the provision of those web-based health programs and activities. For example, a covered entity may not decline to provide an electronic appointment reminder to an older individual because of a stereotype that older individuals may experience difficulties using such technology.

Comment: One organizational commenter recommended extending the full ICT requirements to recipients and State exchanges.

Response: Recipients and State Exchanges are required to comply with both § 92.204(a) and (b), per the text of the section.

Comment: Multiple commenters requested the explicit inclusion of mobile applications within this section. They stated that it would spur greater awareness among software developers of the need for fully accessible mobile applications that are also compatible with mobile devices and internet platforms. One organizational commenter warned that there could be privacy concerns with certain mobile apps used for substance use disorder treatment and recommended that OCR collaborate with the Substance Abuse and Mental Health Services Administration (SAMHSA) to determine if Federal privacy laws apply to mobile application health information, and communicate that information to consumers.

Response: OCR appreciates these comments. Mobile applications are a form of information and communication technology and are explicitly included in the regulatory text under § 92.204(b); thus, to the extent covered entities use mobile applications as part of their health programs and activities they must be accessible for individuals with disabilities. Though privacy protections are outside of the scope of this rulemaking, OCR reminds commenters

[150] Section508.gov, *Voluntary Product Accessibility Template (VPAT), https://www.section508.gov/sell/vpat/.*

[151] 36 CFR part 1194, appendix A. Section 508 of the Rehabilitation Act imposes accessibility requirements for information and communication technology that Federal departments and agencies develop, procure, maintain, or use.

[152] 88 FR 63392 (Sept. 14, 2023) (HHS) and 88 FR 51948 (Aug. 4, 2023) (DOJ).

[153] *See* U.S. Dep't of Justice, *State and Local Governments, https://www.ada.gov/topics/title-ii/.*

[154] *See* U.S. Dep't of Justice, ADA Title III Technical Assistance Manual, *https://www.ada.gov/resources/title-iii-manual/.* This guidance document on title III of the ADA defines fundamental alteration as ''a modification that is so significant that it alters the essential nature of the goods, services, facilities, privileges, advantages, or accommodations offered.'' It defined undue burden as a ''significant difficulty or expense'' that can be determined based on the nature and cost of the action, the overall financial resources of the site involved, geographical separateness, overall financial resources of the parent entity, and the type of operation of the parent entity.

that it has issued guidance on the application of the HIPAA Privacy, Security, and Breach Notification Rules to mobile health apps.[155]

Comment: Many commenters recommended OCR require covered entities to comply with specific accessibility standards, such as section 508 standards, the WCAG 2.0 standards, the WCAG 2.1 standards, or other standards that provide equal or greater accessibility. Several commenters, including organizations, recommended requiring covered entities to comply over time with the latest WCAG as they are updated by the Web Accessibility Initiative of the World Wide Web Consortium (W3C). The commenters also said that a requirement to adhere to the latest standards could offer a range of time for compliance, with larger entities that have more resources being required to comply with a new WCAG standard within a shorter timeline than smaller entities. A technology company said that OCR should not establish a requirement to conform to the latest standard, but rather a requirement to conform to technical specifications that are proven and generally accepted for achieving and maintaining reasonable levels of accessibility; currently that is WCAG 2.1 levels A and AA.

Some organizational commenters suggested that OCR should incorporate a functional, evergreen standard for accessibility that will adapt to changes in technology and accessibility practices. Such a standard would require the ICT to be perceivable, operable, understandable, and robust, and ''enable individuals with disabilities to access the same information as, to engage in the same interactions as, to communicate and to be understood as effectively as, and to enjoy the same services offered to other individuals with the same privacy, same independence, and same ease of use as, individuals without disabilities.''

Several commenters, including health care organizations, advocacy groups, and a trade association, offered suggestions for the timeline for compliance with new standards. These included 60 days, 12 months, 18 months, and 2 years. A health care organization recommended that OCR only require initial compliance in fields that are ''critical to utilizing telehealth services'' and that covered entities be required to meet the minimum conformance levels of the two most recent versions of the W3C guidelines.

Some commenters supported compliance with accessibility standards, provided that OCR conducts real-world testing with successful results across a variety of physician offices before requiring compliance. The commenter also suggested that OCR work with the Office of the National Coordinator for Health Information Technology and vendors to ensure that compliance does not place an undue financial or administrative burden on physician practices. Expressing concern about the cost of compliance, a professional association requested an exemption for businesses classified as small businesses by the Small Business Administration.

A few commenters, including a trade association, health care organizations, and health insurance entities, suggested that OCR establish a safe harbor by which covered entities compliant with WCAG 2.1 Level AA are deemed in compliance with the section 1557 requirements. Other commenters argued that OCR should not establish a safe harbor because compliance with a set of accessibility standards is not necessarily evidence of compliance with accessibility requirements; there may be ICT that meets published standards but remains inaccessible. Another commenter said OCR should not establish a safe harbor because the ADA, the Rehabilitation Act, and other Federal laws must continue to provide standalone protections.

Response: OCR appreciates commenters' input on this important topic but has decided not to adopt specific accessibility standards or a safe harbor at this time. This is in part due to OCR and DOJ recently publishing NPRMs proposing specific accessibility requirements for section 504 and title II of the ADA, respectively.[156] Those NPRMs propose to require that recipients of Federal financial assistance and public entities must ensure that their web content and mobile applications comply with set accessibility standards. In this rulemaking, OCR continues to require covered entities to ensure that health programs and activities provided through ICT are accessible to individuals with disabilities sufficient to provide equal access to the health program or activity, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the entity's health program or activity. OCR strongly encourages covered entities that offer health programs and activities through ICT to incorporate current WCAG standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.204, without modifications.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed requiring covered entities to make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. Section 92.205 is the same as § 92.205 in the 2016 Rule and § 92.105 in the 2020 Rule. The term ''reasonable modifications'' will be interpreted as set forth in the regulation implementing title II of the ADA at 28 CFR 35.130(b)(7), such that ''[a covered entity] shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the [covered entity] can demonstrate that making the modifications would fundamentally alter the nature of the [health] service, program, or activity'' and ''[a covered entity] is not required to provide a reasonable modification to an individual who meets the definition of 'disability' solely under the 'regarded as' prong of the definition of 'disability' at § 35.108(a)(1)(iii).''

The comment and our response regarding § 92.205 are set forth below.

Comment: One commenter urged OCR to strengthen the section by adding language to clarify that a modification to add something that is medically necessary for individuals with disabilities, or to eliminate exclusions related to medically necessary services, are not considered fundamental alterations to the nature of the health program.

Response: OCR appreciates the commenter's request for clarifying language related to fundamental alterations. In promulgating this rule, OCR cannot address how the requirements of section 1557 apply to every scenario that may arise. OCR also

[155] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Resources for Mobile Health Apps Developers, https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[156] *See* 88 FR 63392 (Sept. 14, 2023) (section 504) and 88 FR 51948 (Aug. 4, 2023) (ADA title II).

cannot state every modification that could result in a fundamental alteration because determining whether a modification is a fundamental alteration is a fact-specific process.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provisions as proposed in § 92.205, without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

OCR proposed a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex.

In proposed § 92.206(a), we described a covered entity's general obligation to provide individuals equal access to the covered entity's health programs or activities without discrimination on the basis of sex.

In proposed § 92.206(b)(1) through (4), we clarified certain types of discriminatory actions that would be prohibited for a covered entity in its provision of access to health programs or activities.

In § 92.206(b)(1), we proposed prohibiting a covered entity from denying or limiting health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(b)(2), we proposed prohibiting covered entities from denying or limiting a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(b)(3), we proposed prohibiting a covered entity from applying any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than *de minimis* harm.

In § 92.206(b)(4), we proposed prohibiting a covered entity from denying or limiting health services sought for the purpose of gender-affirming care that the covered entity would provide to a person for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(c), we proposed that nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity reasonably determines that such health service is not clinically appropriate for that particular individual.

In § 92.206(d), we proposed that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a).

The comments and our responses regarding § 92.206 are set forth below.

Comment: Numerous commenters supported OCR's proposal to specifically address equal access on the basis of sex in the final rule. A supporter of the provision argued that patients who trust their provider not to discriminate against them will share better information, enabling better treatment. Some commenters specifically requested this section be strengthened by including specific examples of what constitutes discrimination based on sex characteristics.

Response: OCR agrees that open communication between a provider and their patient is a bedrock of the provision of quality care, and that cannot happen where the patient experiences or expects that they will face discrimination by the provider. In addition, we note that the question of whether prohibited discrimination has occurred is often context specific and fact intensive, so it is difficult to provide succinct examples of scenarios that would constitute prohibited discrimination in each and every instance.

Comment: Commenters urged OCR to include specific language related to reproductive health care and fertility treatments in §§ 92.206 and 92.207. A few commenters urged OCR to specify the full range of reproductive health care protected from discrimination under section 1557, including protections against discrimination based on reproductive health decisions. A few commenters said the final rule should make clear that section 1557 prohibits discrimination related to maternity care, such as failing to provide accessible medical equipment or transfer assistance, leaving wheelchair users unable to access care. Another commenter opined that the final rule should make clear that section 1557 prohibits discrimination relating to treating pregnancy emergencies and complications, including termination of pregnancy, miscarriage management, and other pregnancy outcomes.

Response: Matters related to reproductive health care, fertility, pregnancy, family status, and maternity care are addressed in § 92.208, and OCR refers commenters to that section. Covered entities must ensure accessibility of their health programs and activities for individuals with disabilities, which includes accessible equipment and transfer assistance.

Comment: Some commenters argued that it would be more appropriate to address the impacts of the *Dobbs* decision and protections against discrimination on the basis of obtaining an abortion in § 92.206 rather than in § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status), because addressing abortion in the section on marital, parental, or family discrimination could convey that denying abortion care is only discriminatory in those contexts.

Conversely, many commenters expressed opposition to the inclusion of termination of pregnancy within the scope of equal program access on the basis of sex, primarily stating that the rule would force health care professionals to perform abortions or deem their refusal to do so discrimination.

Response: OCR appreciates commenters' feedback regarding the addition of pregnancy or related conditions in § 92.206 rather than in § 92.208. Based on a review of the totality of the comments, additional language has not been added to § 92.206, and we discuss this issue further in § 92.208. Further, the ACA itself provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). OCR will comply with this provision. For further discussion regarding a health care professional's decision not to provide an abortion, including due to a sincerely held religious belief or conscience objection to performing the procedure, *see* §§ 92.208 and 92.302.

Comment: Many commenters recommended that in addition to the specific forms of discrimination based on gender identity, it is important to include specific forms of reproductive health and pregnancy-related care discrimination in § 92.206(b). Many commenters recommended incorporating a provision or provisions under § 92.206(b) to clarify that covered entities are prohibited from denying or limiting services—or denying or limiting a health professional's ability to provide services—based on a patient's

pregnancy or related conditions, including termination of pregnancy, contraceptive use, miscarriage management, assisted reproduction, fertility care, and pregnancy-related services. One of these commenters recommended that the language of this provision not be limited to reproductive or sexual ''health *care* decisions,'' as covered entities also discriminate based on reproductive and sexual health histories such as past experiences with sexual violence, which exist beyond the realm of services and that including ''care'' here could limit how covered entities understand this form of discrimination. Some commenters also stated that failure to codify some of the most prevalent forms of sex discrimination will directly undermine efforts to implement proposed §§ 92.101 and 92.206.

Response: OCR appreciates the recommendations regarding discrimination based on pregnancy or related conditions, including the request to provide additional examples, and directs commenters to the discussion at § 92.208. The rule does not include language related to discrimination based on health *care* decisions. The rule is not so limited—it prohibits discrimination in health programs and activities generally. This includes discrimination on the basis of sex in the context of health decisions or histories related to reproductive and sexual health.

Comment: Many commenters supported § 92.206 as important to ensure access to necessary health services that might otherwise be denied to people due to discrimination on the basis of sexual orientation or gender identity, with many providing specific examples of discrimination faced by LGBTQI$_+$ individuals. Some commenters recommended specifically addressing protections for LGBTQI$_+$ people seeking fertility treatments. A commenter recommended that OCR consider adding a subsection to § 92.206 or § 92.208 to discuss the prohibition of discrimination on the basis of sexual orientation and gender identity in access to fertility services, and provided examples of the numerous barriers that LGBTQI$_+$ individuals and same-sex couples face in accessing this type of reproductive health care.

Response: Section 1557 and this rule prohibit discrimination on the basis of sex, including sex characteristics, sexual orientation, and gender identity, in health care access. Depending on the specific facts at issue, barriers described may rise to the level of discrimination and would be evaluated under this rule's general prohibition of discrimination under § 92.101(a)(1), to make a case-by-case determination as to whether prohibited discrimination has occurred. In general, OCR anticipates that if a covered entity elects to provide or cover fertility services, but categorically denies them to same-sex couples or to individuals on the basis of sexual orientation or gender identity, such a denial of care or coverage may violate section 1557's prohibition on sex discrimination. We decline to add such specific language to the regulatory text as proposed.

Comment: Commenters recommended that OCR should add language to § 92.206(b) affirming that section 1557 prohibits covered entities from denying, limiting access to, or otherwise placing special caps, costs, or additional procedural requirements on medications or treatments needed specifically by people with disabilities, irrespective of whether those medications or treatments can also be used to end or complicate pregnancies or fertility.

Response: We address special caps, costs, or additional procedural requirements related to health insurance coverage and other health-related coverage in § 92.207, and direct commenters to that section. A discussion of medications and treatments related to pregnancy and fertility care is in § 92.208.

Comment: Many commenters recommended including ''transgender status'' in § 92.206(b)(1), (2), and (4) because there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between transgender status and gender identity.

Response: As noted in the discussion for § 92.101(a)(2), the term ''gender identity'' necessarily encompasses transgender status and the two terms are often used interchangeably.[157] We decline to enumerate the full range of identities protected under the term ''gender identity.''

Comment: Multiple commenters expressed support for the rule's prohibition on denying or limiting care on the basis of a patient's assigned sex at birth, gender identity, or gender otherwise recorded at § 92.206(b)(2). A commenter expressed support for the rule's prohibition on covered entities denying or limiting a clinician's ability to provide clinically appropriate care when the failure to do so would constitute discrimination.

Another commenter supported this provision, arguing that it is necessary to ensure that specialists and providers who see LGBTQI+ patients every day do not experience retaliation for providing care. Pointing to State legislative efforts seeking to restrict or ban providers from offering safe and effective treatment to LGBTQI$_+$ patients, the commenter argued that such protections are particularly important to alleviate providers' fears that they may be subject to retaliation or loss of licensure for providing gender-affirming care. Another commenter similarly argued that covered entities sometimes discriminate against transgender patients by prohibiting their providers from providing certain services.

Response: As noted in the Proposed Rule, 87 FR 47866, this provision recognizes that prohibited discrimination may take the form of restrictions on individual providers, such as attending physicians, that have the effect of discriminating against patients. Where a covered entity imposes such a restriction based on a patient's gender identity or sex assigned at birth, the restriction may constitute prohibited discrimination in violation of this rule, even if the form that the restriction takes is a limitation on the ability of providers to prescribe or provide care.

Regarding providers' fears that they may be subject to retaliation by their employer or loss of licensure, this rule does not apply to employment practices, as discussed in § 92.2(b), but employees of covered entities remain protected against retaliation as provided in §§ 92.303 and 92.304. Not all State licensure boards receive Federal financial assistance from the Department; upon receipt of a complaint against a licensure board, OCR would need to first determine whether we have jurisdiction before commencing an investigation.

Also, we note that a health care provider's decision not to provide any service due to a sincerely held religious belief or conscience objection is discussed further in §§ 92.208 and 92.302.

Comment: Many commenters suggested that § 92.206(b)(2) would be clearer if the following phrase was deleted because it is redundant: ''if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity.''

Response: OCR appreciates the suggestion and has considered it, but we

[157] *See, e.g., Bostock* v. *Clayton Cnty., Georgia,* 590 U.S. 644, 658–59 (2020); *Doe* v. *Mass. Dep't of Correction,* No. CV 17–12255–RGS, 2018 WL 2994403 (D. Mass. June 14, 2018); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017).

will maintain the proposed language, as the phrase provides additional explanation of what would constitute discrimination. As we noted in the Proposed Rule, 87 FR 47866, this is modeled on the provision in the title VI regulations that notes that certain discriminatory employment practices may be prohibited to the extent that they result in discrimination against program participants, even though the primary objective of title VI is not to regulate employment practices. *See* 45 CFR 80.3(c)(3). Likewise, the phrase commenters propose deleting here clarifies that these restrictions on providers are prohibited only insofar as they result in discrimination against individuals on the basis of sex in a covered health program or activity. This phrase is necessary to establish a violation because a discriminatory act under this rule is one in which the individual is excluded from, denied the benefits of, or otherwise subjected to discrimination under a health program or activity on the basis of sex.

Comment: A few commenters stated that it appears that § 92.206(b)(2) is directly aimed at the United States Conference of Catholic Bishops' Ethical and Religious Directives for Catholic Health Care Services.[158] These commenters recommended that OCR disavow this provision and affirm support for the value of religiously affiliated health care and the right of faith-based hospitals to operate in accordance with their convictions.

Response: As stated throughout this preamble, OCR values the vital role that faith-based hospitals and other health care providers and systems play in our nation's health care system. With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer commenters to the discussion at § 92.302. The aim of § 92.206(b)(2) is to address discrimination that has a secondary effect on the ability of individuals to participate meaningfully in and/or to receive health care from a covered health program in a nondiscriminatory manner. OCR did not, nor did it intend to, single out any religious teachings and will respect all guarantees of Federal religious freedom and conscience laws.

Comment: Commenters highlighted that transgender and nonbinary people face unique discrimination in inpatient settings that are separated by sex, particularly those that have only male and female facilities available. These commenters noted that this results in nonbinary people not having access to facilities consistent with their gender identity.

A few commenters raised concerns about the application of § 92.206(b)(3) to arrangements and practices involving patients who share intimate space with, or require intimate personal assistance from, other individuals. The commenters argued that the requirement to treat individuals consistent with their gender identity may raise concerns for privacy.

Response: OCR appreciates the commenters' feedback. As specified in the preamble discussion for § 92.101, this final rule protects all people regardless of gender identity, including transgender and nonbinary people. Nothing in this rule prohibits a covered entity from operating sex separated programs and facilities, so long as it does not subject anyone, including transgender and nonbinary individuals, to more than *de minimis* harm on the basis of sex. When a nonbinary individual seeks participation in a single-sex health program or activity or a health program or activity that maintains sex separate facilities, the covered entity should work with that individual to determine where they will best be served and where they can benefit the most from the health program or activity without experiencing trauma, distress, or threats to their safety due to an incorrect placement. A covered entity must not deny a nonbinary individual access to a health program or facility on the basis that the program or facility separates patients based on sex or offers separate male and female programs or facilities.

Courts have held that all individuals' safety and privacy can be protected without also excluding transgender individuals from accessing sex-separate facilities and activities consistent with their gender identity.[159] Nothing in the rule prevents covered entities from implementing policies or procedures to preserve any patient's privacy—consistent with the requirements of this rule and any other applicable laws. Providers have a range of tools at their disposal to accommodate individuals' privacy concerns and patient interests in a nondiscriminatory manner. For example, a provider generally may accommodate a patient's preferences about roommate assignments. A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm. We also note that no application of this rule shall be required insofar as it would violate Federal religious freedom and conscience laws. Recipients may rely on those protections directly, *see* § 92.3(c), or they may seek an assurance of a religious freedom or conscience exemption, *see* § 92.302(b).

Comment: A commenter opposed the rule on the grounds that it would violate the U.S. Constitution's Equal Protection Clause standard for sex discrimination claims, which the commenter asserted allows men and women to be treated differently based on inherent differences in biology when such differences are real and not based on stereotypes. The commenter argued that proposed § 92.206(b)(3) would inappropriately prohibit providers from using any sex-based distinction unless they can prove it does not cause more than *de minimis* harm. This commenter alleged that the true purpose of such a provision is not equal treatment for all patients but special treatment for transgender individuals, particularly with respect to the use of sex-separate facilities. This commenter also argued that the provision would contradict the Voluntary Resolution Agreement the Department entered into with Michigan State University (MSU) under section 1557, which requires the presence of a chaperone—the sex of whom should be determined by the wishes and comfort of the patient—for all sensitive examinations.[160]

Response: Not all differential treatment on the basis of sex constitutes unlawful discrimination under section 1557, and the final rule does not prohibit all differential treatment.[161] If a

[158] U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (6th ed. 2018), *https://www.usccb.org/resources/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06_0.pdf.*

[159] *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 613–15 (4th Cir. 2020); *see also Cruzan* v. *Special Sch. Dist. # 1,* 294 F.3d 981, 984 (8th Cir. 2002) (per curiam) (holding that transgender woman's mere presence in a sex-separate space did not constitute actionable sexual harassment of her female co-workers); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034, 1052–53 (7th Cir. 2017).

[160] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Hum. Servs., Off. for Civil Rights & The Bd. of Trs. of Mich. State Univ., dba Mich. State Univ. & MSU HealthTeam & MSU Health Care, Inc. (2019), *https://www.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf.*

[161] Several courts have held that discrimination against transgender people constitutes sex discrimination under the Equal Protection Clause. *See, e.g., Hecox* v. *Little,* Nos. 20–35813, 20–35815, 2023 WL 5283127, at *12 (9th Cir. Aug. 17, 2023); *Brandt* v. *Rutledge,* 551 F. Supp. 3d 882, 889 (E.D. Ark. 2021), *aff'd sub nom. Brandt ex rel. Brandt* v. *Rutledge,* 47 F.4th 661, 670 (8th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 608 (4th Cir. 2020); *Whitaker by Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034,

Continued

sex-based distinction has only a *de minimis* impact, it is not prohibited discrimination.[162] But treating individuals differently on the basis of sex constitutes sex discrimination where it imposes a more-than-*de minimis* level of harm. Under the rule, providers may use sex-based distinctions to administer individualized care, provided those distinctions do not cause more than *de minimis* harm.

We disagree with the proposition that purpose of § 92.206(b)(3) is special treatment for transgender individuals, particularly with respect to the use of sex-specific facilities. The purpose of this section is to prevent unlawful discrimination on the basis of sex. The prevention of discrimination on the basis of gender identity is an important government objective that is substantially achieved by this rule.

Further, the Voluntary Resolution Agreement entered into with MSU, provides that a patient may request a chaperone to be present at any time and that the patient's ''wishes and comfort should determine the sex of the chaperone.'' [163] It further specifies that MSU ''shall accommodate, to the extent practicable, the Patient's request for a same-sex chaperone.'' [164] The final rule does not prohibit patients from requesting or receiving a chaperone of the sex of their choosing.

Finally, OCR disagrees with the commenter that the rule violates the Equal Protection Clause. OCR's authority to promulgate this rule stems from a Federal non-discrimination statute, section 1557. This rule does not purport to interpret the Equal Protection Clause. Thus, even assuming the commenter is correct that the rule bans certain sex-based distinctions that would be permitted under the Equal Protection Clause, such a discrepancy would not mean the rule is unlawful. OCR may promulgate a rule that imposes different non-discrimination requirements on recipients of Federal funds than the non-discrimination requirements the Equal Protection Clause imposes on the government.[165]

Comment: A health research organization expressed support regarding § 92.206(b)(3)'s discussion of the impact on health research and clinical trials. The commenter commended OCR on its guidance on sex-specific health research. This commenter stated that the standard for limiting research outlined by OCR in the 2022 NPRM was reasonable and health researchers will typically be able to demonstrate the requisite justification for a sex-specific research project or clinical trial based on research protocols. However, the commenter requested OCR provide similar guidance for the final rule on whether health research protocols that target or exclude individuals with disabilities would be considered discriminatory.

Conversely, another organizational commenter disagreed with the statement on sex-specific clinical trials because the commenter believed it would pressure clinical researchers and organizations to disregard sex-based distinctions for fear of inviting a gender identity discrimination claim. The commenter claimed that the rule would contradict National Institutes of Health (NIH)'s expectation for clinical trials, which the commenter claimed required specifying the ''biological sex'' of subjects, by laying down an ''unscientific marker'' that sex-specific clinical trials can only be justified in limited circumstances.[166] The commenter further argued that this would represent a backward step for women's health, because the evaluation of diseases and treatments improved when researchers recognized that sex must be taken into account as a biological variable in medicine.

Response: OCR appreciates these comments regarding the application of this provision to sex-specific health research and clinical trials and the standard proposed for evaluating claims of discrimination in such health programs and activities. We agree that researchers should not have challenges showing necessary justifications for nondiscriminatory research distinctions grounded in a participant's reproductive, anatomical, and genetic characteristics.

We disagree with the proposition that OCR is disregarding sex-based distinctions in medicine. Health research and clinical trial protocols are not prohibited from specifying an individual's sex consistent with their reproductive, anatomical, and genetic characteristics, where those characteristics are relevant to the clinical trial. However, there are ways in which health research and protocols may result in discrimination, such as disallowing participation based on gender identity rather than on the basis of scientific requirement of the research.

Should the need arise, OCR will consider issuing guidance on the impacts of disability protections on research participation.

Comment: Several commenters supported the rule's prohibition on sex-specific health programs or activities that subject any individual to more than *de minimis* harm. One supportive commenter argued that this approach recognizes harm as the primary measure of discrimination and creates flexibility to identify new forms of harm, and another argued the standard of no more than *de minimis* harm is consistent with applicable case law, including *Bostock.* A commenter expressed appreciation for the Proposed Rule's detailed explanation of *de minimis* harm and the difference between clinical care for a patient.

Conversely, another commenter stated the Proposed Rule ''cherry picks'' a title IX court decision to justify a standard of ''more than *de minimis* harm'' as the basis for ''adjudicating gender identity,'' arguing that title IX has never required sex to be recognized as anything but ''objectively, biologically based.'' Similarly, another commenter argued the rule applies beyond denial or limitations on health services. The commenter argued that the rule would prohibit health care professionals, medical facilities, and insurance companies from using any sex-based distinction unless they can prove it does not cause more than *de minimis* harm, and that if a provider asks the wrong question or asks an appropriate question in the wrong manner then the provider will likely face a claim of discrimination on the basis of gender identity.

Response: OCR appreciates the range of comments provided on the proposed language regarding *de minimis* harm, and after careful review, OCR is finalizing the language as proposed. The rule does not prohibit all sex-based distinctions in health programs or activities, nor does it broadly prohibit any policy or practice of treating

1048 (7th Cir. 2017), *abrogated on other grounds as recognized by Ill. Republican Party* v. *Pritzker,* 973 F.3d 760, 762 (7th Cir. 2020); *Glenn* v. *Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011); *Smith* v. *City of Salem,* 378 F.3d 566, 572, 577 (6th Cir. 2004); *but see L. W. by & through Williams* v. *Skrmetti,* 83 F.4th 460 (6th Cir. 2023).

[162] *See, e.g., Oncale* v. *Sundowner Offshore Servs., Inc.,* 523 U.S. 75, 81 (1998) (title VII does not reach non-harmful ''differences in the ways men and women routinely interact with'' each other); *see also Burlington N. & Santa Fe Ry. Co.* v. *White,* 548 U.S. 53, 59–60 (2006) (''No one doubts that the term 'discriminate against' refers to distinctions or differences in treatment that injure protected individuals.'').

[163] MSU Agreement at IV.D.1.v.

[164] MSU Agreement at IV.D.1.vi.

[165] *Cf. Fitzgerald* v. *Barnstable Sch. Comm.,* 555 U.S. 246, 257 (2009) (recognizing that the liability standards under title IX and the Equal Protection Clause ''may not be wholly congruent'').

[166] The commenter does not provide a citation when making this statement; however earlier in their comment, the commenter cites a Notice from the National Institutes of Health (NIH): U.S. Dep't of Health & Hum. Servs., Nat'l Inst. of Health, *Consideration of Sex as a Biological Variable in NIH-funded Research,* NOT–OD–15–102 (June 9, 2015), *https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html.*

individuals differently based on sex. As noted in the Proposed Rule, although intentional differential treatment on the basis of sex would generally be considered prohibited discrimination, separation by sex or differential treatment on the basis of sex is permissible under section 1557 where it does not cause more than *de minimis* harm. 87 FR 47866. This distinction generally allows for sex-specific clinical trials when sex is relevant to the trial, for example, while still prohibiting differential treatment that causes harm.

Providers often need to make inquiries about a patient's sex-related medical history, health status, or physical traits related to sex in the course of providing care and this rule does not prohibit or inhibit that. 87 FR 47867–68. Such inquiries are not per se discriminatory, even where they touch on intimate or sensitive matters. For example, it is not discriminatory for a provider treating a patient presenting with symptoms consistent with an ectopic pregnancy to inquire about the possibility that the patient could be pregnant, regardless of that patient's gender identity. Similarly, when providing appropriate care to a patient, asking medically relevant questions about a patient's anatomy or medical history in a way that causes inadvertent distress—on its own—would not violate section 1557. However, it is important to note that if such questions are not relevant to assessing the patient's condition, or the patient has answered the questions and makes clear that further questions are unwelcome, the inquiries may rise to the level of harassment on the basis of sex. For example, if the conduct is so severe or pervasive that it denies a patient access to medical care, it would no longer be permissible. OCR will evaluate these types of harassment claims on a case-by-case basis to determine whether the alleged harassment was ''sufficiently severe, pervasive, and objectively offensive,'' to meet the standards for discriminatory harassment.[167]

In response to commenters that questioned the legal basis for our *de minimis* standard, we discussed in the 2022 NPRM, 87 FR 47866, n. 412, that sex-based distinctions that have only *de minimis* impact are not the type of discrimination that Congress envisioned.[168]

Comment: A commenter recommended that, based on existing racial disparities in maternal health and overall poor maternal health outcomes in the United States, § 92.206(b)(3) be amended to specify that harm exceeding the threshold of *de minimis* harm with respect to pregnancy and maternal health can include policies or practices that subject people to rough handling, harsh language, undertreatment of pain or pregnancy-related conditions, or other discriminatory mistreatment during childbirth or the prenatal or postpartum periods.

Response: OCR recognizes that there is ample research demonstrating the significant racial disparities in maternal health outcomes.[169] Section 92.206(b)(3) specifically addresses different treatment on the basis of sex, such as through sex-separate health programs and activities. Depending on the specific facts at issue, the treatment described by the commenter may rise to the level of discrimination and would be evaluated under this rule's general prohibition of discrimination under § 92.101.

Comment: An organizational commenter strongly supported the additional guidance provided by proposed §§ 92.206 and 92.207 and noted that the forms of discrimination highlighted in proposed §§ 92.206(b)(3) and (4) and 92.207(b)(3) through (5), in particular, affect many intersex people.

Response: OCR appreciates the commenter's feedback regarding the discrimination addressed in §§ 92.206(b)(3) and (4) and 92.207(b)(3) through (5) affecting intersex people as well. This final rule makes explicit in regulatory text that sex discrimination includes discrimination based on sex characteristics, including intersex traits, as reflected in § 92.101(a)(2).

Comment: Many commenters expressed support for the proposed provisions related to gender-affirming care at § 92.206(b)(4). These commenters stated that such care can be critical to the well-being of transgender and nonbinary people, and that accessing such care can reduce the risk of negative physical and mental health outcomes associated with gender dysphoria. Commenters discussed the negative impact of widespread health care discrimination against transgender people, stating that transgender people of color and transgender people with disabilities are at particularly high risk of discrimination and associated harms.

Response: OCR appreciates these comments and agrees that the nondiscrimination protections are important to transgender and nonbinary people's ability to access clinically appropriate care, especially those who may face elevated risk of harm due to discrimination on multiple protected bases.

In determining whether a covered entity violated section 1557 by denying or limiting a health service sought for the purpose of gender-affirming care, OCR will continue to consider evidence that the covered entity would provide that same service for other purposes. Evidence that OCR may consider to establish that the type of care is ordinarily provided could include, among other things, statements by the provider, information showing that the provider has provided similar care in the past, or documentation regarding the provider's scope of practice.

Where there is other evidence that the covered entity has subjected the individual to differential treatment on the basis of sex apart from the denial of care itself, OCR may investigate and make a case-by-case determination as to whether prohibited discrimination has occurred.

Comment: A few commenters stated that OCR is explicitly asserting that it has authority under section 1557 to regulate the practice of medicine according to its own determination of what is appropriate and non-discriminatory care, along with authority to definitively determine what is the current standard of medical care. Some commenters requested OCR amend the provision to specify that care standards cannot facially discriminate or otherwise result in discrimination based on a protected characteristic, such that covered entities cannot mask discrimination behind clinical policies or criteria.

Response: Section 1557 prohibits discrimination on certain prohibited bases, and does not (and cannot) require a specific standard of care or course of treatment for any individual or otherwise interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or

[167] *Cf. Davis by Next Friend LaShonda D.* v. *Monroe Cnty. Bd. of Educ.,* 526 U.S. 629, 650 (1999) (Under title IX, discriminatory harassment must be ''severe, pervasive, and objectively offensive'').

[168] *See also Elborough* v. *Evansville Cmty. Sch. Dist.,* 636 F. Supp. 2d 812, 820–21 (W.D. Wis. 2009) (noting that Title IX does not ''authorize[ ]lawsuits for damages in all cases of differential treatment, no matter how isolated or minimal. The maxim that 'the law doesn't concern itself with trifles' applies to civil rights cases as it does to any other case.'').

[169] Donna L. Hoyert, U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, *Maternal Mortality Rates in the United States* (Feb. 2022), *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf*; Marian F. MacDorman et al., *Racial and Ethnic Disparities in Maternal Mortality in the United States Using Enhanced Vital Records, 2016–2017,* 111 a.m. J. Pub. Health 1673, 1671 (2021), *https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306375*.

whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide.

Section 92.206(c) is consistent with the general principle in nondiscrimination law that entities facing allegations of discrimination have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice but that such a basis may not be a pretext for discrimination.

Comment: Some commenters expressed concern that OCR is setting standards of care for gender-affirming care in this rule, and that is outside the scope of OCR's authority. Many commenters weighed in with their views on the state of medical evidence relating to gender-affirming care and submitted citations to research studies and other data. Some comments characterized the evidence as lacking or mixed, and highlighted their concerns relating to gender-affirming care for minors. Others stated that there is robust evidence, including from major medical associations, supporting the provision of gender-affirming care, including that such medically necessary care benefits the health and well-being of transgender patients.

Response: This final rule prohibits discrimination on the basis of sex, consistent with Federal law. As such, nothing in this rule impedes covered entities from taking nondiscriminatory actions based on current medical standards and evidence, such as making decisions about the timing or type of protocols appropriate for care. The rule does not (and cannot) require a specific standard of care or course of treatment for any individual, minor or adult. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: A number of commenters had concerns or questions about the scope of how OCR would define gender-affirming care. Some commenters requested a definition or an enumeration of what types of procedures would fall within this term. Others raised concerns about the impact of such care and the benefits of such care.

Response: As with the 2016 Rule, 81 FR 31435, OCR declines to provide a regulatory definition for gender-affirming care. However, when we used the term ''gender-affirming care'' in both §§ 92.206 and 92.207, we are generally referring to care designed to treat gender dysphoria that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other related services. 87 FR 47834 n.139. As noted elsewhere, the rule does not impose a categorical requirement that covered entities must provide gender-affirming care. Further, while we acknowledge comments in support of and opposed to gender affirming care and its subsequent impacts on individuals, we are not making any additional edits to the rule in response.

Comment: Some commenters opposing the rule raised First Amendment concerns and questioned the scope of what would be required of providers in terms of expressing support of transgender people who wish to access gender-affirming care, using the name and pronouns requested by patients, and speaking about gender-affirming care.

Response: OCR takes seriously concerns about, and is fully committed to upholding, the First Amendment, and nothing in these regulations restricts conduct protected by the First Amendment.[170] Whether discrimination is unlawful or considered harassment is necessarily fact-specific. This final rule does not purport to identify all of the circumstances that could constitute unlawful harassment. It is unlikely that an isolated incident with no other indications of animus or ill treatment would meet the standards for discriminatory harassment. Conversely, OCR notes that conduct, including verbal harassment, that is so severe or pervasive that it creates a hostile environment on the basis of sex is a form of sex discrimination.

Comment: A few commenters argued that providing gender-affirming care poses high malpractice lawsuit risks to providers, and therefore OCR should not categorically require providers to provide such services.

Response: As discussed elsewhere in this preamble, this final rule prohibits discrimination in the provision of health programs and activities and does not require provision of any specific services, including gender-affirming care. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: One commenter expressed concern that the rule would result in decreased access to health care, as providers may choose to leave Federal health care programs based on a belief that they will be required to provide gender-affirming care, especially if there is no avenue for providers with religious or conscience objections to certain types of care to request exemptions.

Response: Section 1557 requires that health care providers who receive Federal financial assistance must provide nondiscriminatory care. However, providers do not have an affirmative obligation to offer any health care, including gender-affirming care, that they do not think is clinically appropriate or if religious freedom and conscience protections apply. OCR believes that the majority of providers already provide nondiscriminatory care to their patients and will continue to do so. This commenter presented no evidence that a significant exodus of providers is likely, and we are not aware of any data to support a significant concern on this front. Providers with religious freedom or conscience concerns, however, may rely upon §§ 92.3 and 92.302.

Comment: A few commenters expressed support for nondiscrimination protections that prohibited discriminating against an individual because of their gender identity but opposed interpreting such protections to protect access to gender-affirming care.

Response: OCR appreciates these commenters' support for the rule's nondiscrimination protections on the basis of gender identity. We respectfully disagree, however, that such protections have no implications for the provision of gender-affirming care. A fact-specific analysis is necessary to determine whether prohibited discrimination has occurred, but the rejection of a practice closely linked with a protected status may, in conjunction with other evidence, lead to a finding of discrimination. This rule does not require or mandate the provision of any particular medical service. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere

[170] *See, e.g., W. Va. State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943) (''We think the action of the local authorities in compelling the flag salute and pledge transcends constitutional limitations on their power and invades the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control.'').

with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: An organizational commenter supported reference to the multi-factor test found in *Arlington Heights* v. *Metro. Housing Dev. Corp.,* 429 U.S. 252 (1977), and the burden-shifting framework of *McDonnell Douglas Corp.* v. *Green,* 411 U.S. 792 (1973), among a non-exhaustive list of tools that OCR may utilize for investigating discrimination claims. The commenter asserted that sex discrimination claims are hard to prove, and that together these approaches are appropriate for their adjudication by allowing people to rely on different types of circumstantial evidence to collectively demonstrate a discriminatory act by a covered entity and by placing the onus on the covered entity to provide a legitimate, nondiscriminatory reason for its actions. Similarly, another commenter encouraged OCR to clearly state in the final rule that the familiar but-for causation test applies to establishing a violation of section 1557; that the use of the phrase ''legitimate, nondiscriminatory reason'' in these sections should not be construed in any way to limit the method of proof for any section 1557 claim to the *McDonnell Douglas* burden-shifting framework; and that this method cannot be used to defend an express sex-based classification that causes injury. Another commenter recommended that OCR clarify in the preamble to the final rule that the *McDonnell Douglas* burden-shifting framework and legitimate non-discriminatory reason framework apply to circumstantial evidence cases but not where there is direct evidence of discrimination.

Response: OCR agrees that different methods of proof drawn from civil rights case law should be used in analyzing claims of discrimination under this section including, but not limited to, the *Arlington Heights* multi-factor test and the *McDonnell Douglas* burden-shifting framework. For cases where the alleged discrimination is not based on a facially discriminatory policy, we are clarifying that the phrase ''legitimate, nondiscriminatory reason'' in these sections is taken from, but should not be construed to limit, the method of proof to the *McDonnell Douglas* burden-shifting framework. As we noted in the Proposed Rule, *Arlington Heights* provides a method of proof that uses a number of different types of evidence—*e.g.,* direct, circumstantial, statistical, and anecdotal—that, taken collectively, can demonstrate that the covered entity acted because of a protected basis; the *McDonnell Douglas* burden-shifting framework is an inferential method of proof most commonly applied in cases alleging discrimination in individual instances where a plaintiff alleges that a defendant treated similarly situated individuals differently because of a protected basis. 87 FR 47865. Under the *Arlington Heights* framework, *McDonnell Douglas* evidence identifying similarly situated comparators can also be considered but is not required.[171]

Comment: Many commenters supported the rule's clarification that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care based on a belief that such care is never clinically appropriate. A great number of individuals and organizations provided comment on the types of rationales that might constitute a legitimate, nondiscriminatory basis for a provider declining to provide gender-affirming care. Some commenters opined that it should not be considered discriminatory to deny care when a provider categorically objects to gender-affirming care. Other commenters appreciated the clarification that a provider's personal belief that gender-affirming care is never appropriate is not a legitimate, nondiscriminatory basis for denying such care. The majority of commenters opined that the rule provides adequate protection for providers exercising nondiscriminatory clinical judgment about the appropriateness of particular care for a specific patient, though some commenters disagreed.

Response: OCR appreciates commenters' views on proposed § 92.206(c). In light of comments received, we are modifying the language in this provision to provide additional specificity regarding how OCR will evaluate a covered entity's proffered legitimate, nondiscriminatory reason for denying care. We also add a reference to § 92.302 to make clear that this provision does not limit a recipient's ability to seek assurance of an exemption based on religious freedom or conscience laws. Also, we note that while many commenters specifically discuss providers' personal beliefs, these changes clarify that the rule applies to covered entities rather than specific individuals.

To provide additional specificity, we are striking the second sentence of § 92.206(c), which previously read, ''[h]owever, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a State or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate,'' in its entirety and replacing it with: ''A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.'' Our reasons for this change are as follows:

First, many commenters strongly urged OCR to consider that providers may have a nondiscriminatory reason to not provide some aspects of or all gender-affirming care. OCR understands that a provider may have a legitimate nondiscriminatory reason not to provide a health service, which the newly revised § 92.206(c) makes clear. While this section has application in the gender-affirming care context, the revised language is also intended to make clear that it is not limited to that context. When OCR investigates claims of discrimination based on the denial of care, OCR will consider the covered entity's rationale for such denial, any supporting information the covered entity offers for its position, and any evidence of unlawful animus, bias, or other discriminatory factors in the case.

Second, and as discussed, section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a particular patient or that they are not qualified to provide.

Since the rule does not (and cannot) set a standard of care for gender-affirming care, the focus of any investigation will not be to generally

[171] *Pac. Shores Props., LLC* v. *Newport Beach,* 730 F.3d 1142, 1158–59 (9th Cir. 2013) (noting that a plaintiff need not rely on the *McDonnell-Douglas* approach to intentional discrimination but may instead produce other circumstantial evidence of intentional discrimination using *Arlington Heights,* as *McDonnell Douglas* ''is not a straightjacket requiring the plaintiff to demonstrate that such similarly situated entities exist'').

review a covered entity's clinical judgment but rather to determine whether the assertion of that judgment reflects unlawful animus or bias, or is a pretext for discrimination. Similarly, outside of the gender-affirming care context, OCR may find an invocation of clinical appropriateness to be pretextual if, for example, the evidence demonstrates that the covered entity asserted that pain medication was not clinically appropriate for a patient because of the belief that women exaggerate pain symptoms and inaccurately relay information about their symptoms.

Third, because many commenters expressed concern about the relationship between § 92.206(c) and religious or moral beliefs concerning gender-affirming care, we added an explicit reference in § 92.206(c) to § 92.302. The new language clarifies that § 92.206(c) does not preclude the process set forth in § 92.302 where a recipient's objection to gender-affirming care may be protected under religious freedom and conscience laws.

Comment: Many commenters also cited religious or moral objections to gender-affirming care, urging that these should be considered a legitimate, nondiscriminatory reason to decline to provide such care.

Response: OCR understands that recipients may have religious or conscience objections to the provision of certain types of care. Such an objection can serve as a legitimate, nondiscriminatory reason where it is neither pretextual nor discriminatory. If a provider typically declines to provide a particular health service to any individual based on a religious belief, regardless of individual's sex assigned at birth or gender identity, the provider likely meets § 92.206(c)'s standard for a ''legitimate, nondiscriminatory reason.'' And where a provider's religious belief causes the provider to treat individuals differently based on sex assigned at birth or gender identity, the provider may rely on the protections afforded by religious freedom and conscience laws or choose to seek assurance of those protections by making use of § 92.302(b)'s assurance of religious freedom and conscience exemption process, a feature that both the 2016 and 2020 Rules lacked. As discussed in more detail below, OCR is making several modifications to § 92.302 to strengthen and clarify this process.

Comment: Many commenters supported the inclusion of § 92.206(c) but recommended that OCR strengthen the language pertaining to providers complying with a State or local law as a justification for denying gender-affirming care, abortions, or other reproductive health care to clarify that as a Federal civil rights law, the rule preempts any such State or local law restricting access to such care. Some commenters suggested including language in the preamble to make clear that the majority of States' policies that restrict transgender and nonbinary people's access to health care would be barred. Another commenter expressed support for explicit preemption language, because otherwise providers would be forced to attempt to comply with State and local laws, while also trying not to run afoul of OCR's case-by-case judgment concerning what conduct may be considered discriminatory. Some commenters expressed concern that the rule could deem physicians' conduct discriminatory when declining to provide services because of State or local laws restricting those services, leaving them in an untenable position. Other commenters criticized the rule because they believe it preempts State laws restricting abortion and gender-affirming care and seeks to preempt State laws on religious freedom and conscience. A commenter expressed confusion as to how the rule would preempt State law as opposed to simply disallowing Federal funds from entities that do not comply.

Response: OCR understands providers' concerns that the provision's reference regarding compliance with State or local law would place them in a difficult position with regard to the conflicting demands of this rule's nondiscrimination requirements and various State and local laws restricting access to abortion or gender-affirming care. While we have removed the language from § 92.206(c) that many commenters supported, section 1557's nondiscrimination requirements nevertheless generally preempt conflicting State law for the reasons stated earlier in this preamble. That said, in exercising and determining its enforcement priorities, OCR will consider the specific factual record of each complaint on a case-by-case basis. This may include, among other things, consideration of whether any covered entity that is taking discriminatory actions under the rule is doing so because it believes in good faith it is obligated to do so by State or local law, whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care, or is otherwise engaging in good faith efforts to ensure patients are receiving medically necessary care.

Comment: Several commenters expressed support for § 92.206(d)'s clarification that the enumeration of specific forms of prohibited discrimination in § 92.206(b) does not limit the general prohibition against discrimination in § 92.206(a), while recommending that additional preamble language be added to the final rule citing additional examples of discrimination and to provide confirmation that OCR's investigations will not be limited by the enumerated examples in § 92.206(b).

Response: We emphasize that § 92.206(b) is not an exhaustive list of all scenarios that would constitute of sex discrimination under the rule. We have provided additional examples of sex discrimination in this preamble, and OCR's investigations will not be limited by the enumerated forms of discrimination addressed in § 92.206(b) or elsewhere.

Comment: One commenter stated that OCR ignored *Burwell* v. *Hobby Lobby,* 573 U.S. 682 (2014), in the Proposed Rule and that the Proposed Rule is comparable to the Department's actions in that case, in which the Court found that the government's compelling interest in protecting women's health could be accomplished in a less restrictive manner.

Response: OCR has considered *Hobby Lobby* and will be mindful of it when carrying out enforcement of the final rule. For a further discussion of views regarding application of Federal conscience or religious freedom laws, refer to § 92.302.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provision as proposed in § 92.206, with modifications. We have revised § 92.206(b)(1) to state: ''Deny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex . . . .'' We are revising § 92.206(c) to remove the sentence that reads: ''However, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.'' To the end of § 92.206(c) we are adding sentences that read: ''A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.''

Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

In § 92.207, OCR proposed to prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. This proposed section would apply to all covered entities that provide or administer health insurance coverage or other health-related coverage that receive Federal financial assistance, and the Department in the administration of its health-related coverage programs.

In § 92.207(a), OCR proposed a general nondiscrimination requirement, and § 92.207(b) proposed specific examples of prohibited actions.

In § 92.207(b)(1), OCR specified that covered entities are prohibited from denying, cancelling, limiting, or refusing to issue or renew health insurance coverage or other health-related coverage, or denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability.

In § 92.207(b)(2), OCR proposed prohibiting marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability.

In § 92.207(b)(3), OCR proposed that it is prohibited discrimination to deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth, gender identity, or gender otherwise recorded. We invited comment on this provision, including whether it sufficiently addresses the challenges transgender and gender nonconforming individuals are experiencing when seeking access to medically necessary care due to a discordance between their sex assigned at birth and their sex as recorded by their issuer.

In § 92.207(b)(4), OCR proposed to prohibit a covered entity from having or implementing a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.[172]

In § 92.207(b)(5), OCR proposed to ensure that a covered entity does not impose discriminatory limits on coverage for specific health services related to gender transition or other gender-affirming care, which would generally be the case if such limits are not applied when those same health services are not related to gender transition or other gender-affirming care.

In § 92.207(b)(6), OCR proposed an integration provision that prohibits covered entities from having or implementing a benefit design that does not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

OCR sought comment on the scope and nature of the benefit design features that result in unjustified segregation or institutionalization of qualified individuals with disabilities or place such individuals at serious risk of institutionalization or segregation. We were interested in feedback on the application of the integration requirement to a wide variety of health services and were particularly interested in comments on the application of the integration requirement to coverage of post-acute services, mental health services, and other services commonly provided by non-State payers (*i.e.,* health insurance issuers, self-insured group health plans, and other payers). OCR was also interested in feedback on the application of the integration requirement to the Medicaid program and its statutory framework at title XIX of the Social Security Act. Specifically, we requested input on how State Medicaid agencies are able to achieve compliance with the integration requirement through benefit design, such as through reimbursement, service scope, and service authorization that do not incentivize institutional services over community services. In addition, OCR requested input on the amount of time needed to reach compliance with needed benefit design modifications.

In § 92.207(c), OCR stated that nothing in this section requires the coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements, such as medical necessity requirements, in an individual case.

Finally, in § 92.207(d), OCR made clear that the enumeration of specific forms of discrimination in § 92.207(b) does not limit the general applicability of the prohibition in § 92.207(a).

OCR generally invited comment on how section 1557 might apply to: provider networks; how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the network; the ways in which provider networks limit or deny access to care for individuals on the basis of race, color, national origin, sex, age, or disability; and the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network limits or denies access to care for individuals with disabilities. We also sought comment on the extent, scope and nature of value assessment methods that discriminate on the basis of race, color, national origin, sex, age, or disability. We were interested in feedback on the civil rights implications of value assessment across a wide variety of contexts, including utilization management, formulary design, price negotiations, alternative payment models and other relevant applications. Finally, OCR invited comment on all aspects of this section. In particular, we sought comment on the anticipated impact of the proposed application to excepted benefits and short-term, limited duration insurance (STLDI) when such products are offered by a covered entity; how the Proposed Rule's nondiscrimination requirements would impact the industry that offers excepted benefits and STLDI and the consumers who rely upon those products; the prevalence of excepted benefits and STLDI offered by covered entities and the standard industry practices under which such plans are designed and administered; and excepted benefits and STLDI plans' scope of coverage, types of exclusions and limitations, underwriting practices, premium setting, and actuarial or business justifications for industry practices (as applicable), that may raise concerns about discrimination under section 1557.

The comments and our responses regarding § 92.207 are set forth below.

For ease of reference, OCR may simply refer to ''health insurance issuers'' or ''issuers'' throughout the preamble, but other covered entities may also be subject to the section under

[172] As noted in the discussion of § 92.206 above, this preamble uses the terms ''gender transition'' and ''gender affirmation'' interchangeably in discussing the range of care that transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) may seek to treat gender dysphoria and support gender transition or affirmation. Because insurance coverage provisions and medical-necessity determinations more often use the term gender transition, within these provisions, the term gender affirmation encompasses gender transition, that is the terminology used in the text of the regulation. The use of the term ''gender transition'' in the regulation, however, is not intended to convey a narrower meaning than the term ''gender affirmation.''

discussion. In addition, for purposes of this preamble only, OCR uses the term ''health plan'' or ''plan'' interchangeably to refer generally to health insurance coverage and other health-related coverage that is subject to this rule. As used in this preamble, ''health plan'' or ''plan'' may include health insurance coverage or other health-related coverage offered in the group and individual markets, group health plan coverage, Medicare Advantage plans, Medicare Part D plans, and Medicaid programs that are subject to this rule. OCR does not intend ''health plan'' or ''plan'' to be regulatory terms in this regulation or to replace any existing or proposed term in Federal law.

OCR notes that a variety of entities may be considered covered entities subject to § 92.207, including but not limited to health insurance issuers, group health plans, Medicare Advantage Organizations, Medicare Part D plan sponsors, Medicaid managed care plans, pharmacy benefit managers, third party administrators (as part of a covered entity's operations when it meets the criteria in paragraph (2) of the definition of ''health program or activity'' under § 92.4), and the Department.

Comment: Commenters strongly supported the inclusion of an explicit provision related to prohibited discrimination in health insurance coverage and other health-related coverage, noting that it will help provide clarity for covered entities. Many commenters stated that it is clear from the statutory text of the ACA that Congress intended for section 1557 to apply to health insurance. Commenters stated that the 2020 Rule's rescission of similar protections created confusion, was contrary to the intent and purpose of the ACA, and increased the burden on States to monitor and enforce nondiscrimination laws. Commenters noted that ensuring covered entities provide health insurance coverage and other health-related coverage in a nondiscriminatory manner will reduce adverse health outcomes and address some of the barriers vulnerable communities face in accessing health insurance coverage and other health-related coverage. Commenters from the health insurance industry were generally supportive of reinstating the section with some suggested modifications. This includes one commenter noting that, as an employer, they appreciated the Proposed Rule's clarification prohibiting categorical exclusions, noting that the 2016 Rule's similar prohibition had allowed them to negotiate a nondiscriminatory plan to cover their employees.

One organizational commenter opposed to the inclusion of § 92.207 argued that health insurance issuers could face substantial costs, including compliance costs and claims costs, as a result of having to alter their coverages and business practices, which would result in higher premiums. This commenter also argued OCR is engaging in expansive and detailed regulation of numerous issuer business decisions in an arbitrary and capricious manner that could result in issuers facing heightened business risks and increased liability exposure.

Response: OCR agrees that section 1557 applies broadly, including to prohibit discrimination by covered entities that provide or administer health insurance coverage and other health-related coverage. As discussed throughout this preamble, particularly under the discussion of the definition of ''health program or activity'' under § 92.4, the ACA is clearly intended to apply to health insurance coverage and other health-related coverage and prohibit the discriminatory practices therein.

OCR disagrees that § 92.207 imposes expansive regulation of health insurance issuers and their business decisions in an arbitrary and capricious manner. The plain text of section 1557 applies to health insurance coverage and other health-related coverage; OCR is implementing Congressional intent to prohibit discrimination in health insurance coverage and other health-related coverage in § 92.207. In addition to section 1557, health insurance issuers are required to comply with myriad State and Federal laws regulating the practice of health insurance coverage and other health-related coverage. These laws include other Federal laws that regulate health insurance coverage and other health-related coverage practices, including nondiscrimination requirements.[173] Compliance with legal requirements, such as section 1557, is a standard business practice as a health insurance issuer. Further, health insurance issuers were subject to former § 92.207's requirements[174] from either July 18, 2016, or January 1, 2017 (if plan design changes were required as a result of the 2016 Rule), through August 18, 2020, the effective date of the 2020 Rule.

Comment: Some commenters supported § 92.207(b)(1), related to coverage denials and limitations. Some commenters asked OCR to state that cost sharing must not be used by covered entities in a discriminatory manner. Commenters acknowledged that cost sharing can be an effective tool, but they also expressed concern that insurance companies and pharmacy benefit managers are increasingly employing high cost sharing that disproportionately affects people with disabilities, chronic conditions, and other significant health needs. Commenters cited several studies that show patients who are uncertain about their ability to afford their out-of-pocket care expenses delay or forgo care or fall out of compliance with recommended follow-up steps.[175] Commenters noted that such gaps in care can have deadly consequences for individuals with certain conditions, such as people living with HIV/AIDS.

Commenters also provided examples of concerns related to cost sharing and patient financial assistance. A few commenters raised concerns about treatment of patient financial assistance, accumulator adjustment programs, copay maximizers, and alternative funding programs. Other commenters raised concerns about issuers designating drugs as ''non-essential-health-benefits'' to avoid certain

[173] *See, e.g.,* 42 CFR 422.100(f)(2) and (3), 422.110 (Medicare Advantage), 423.104(d)(2)(iii), 423.2262(a)(1)(iv) (Part D), 438.3(d) and (f) (Medicaid managed care), and 600.405(d) (Basic Health Program); 45 CFR 147.104(e) (group and individual health insurance markets), 156.125(a) and (b) (EHB), 156.200(e), and 156.225(b) (qualified health plans).

[174] Issuers were subject to those requirements except for provisions either enjoined or vacated through lawsuits. *See, e.g., Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016).

[175] *See, e.g.,* Joel F. Farley, *Medicaid Prescription Cost Containment and Schizophrenia,* 48 Med. Care 5, 440–47 (2010), *https://pubmed.ncbi.nlm.nih.gov/20351586/*; Teresa B. Gibson & Ronald J. Ozminkowski, *The Effects of Prescription Drug Cost Sharing: A Review of the Evidence,* 11 a.m.. J. Managed Care 11, 730–40 (2005), *https://pubmed.ncbi.nlm.nih.gov/16268755/*; Daniel M. Hartung et al., *Impact of a Medicaid Copayment Policy on Prescription Drug and Health Services Utilization in a Fee-for-Service Medicaid Population,* 46 Med. Care 6, 565–72 (2008), *https://pubmed.ncbi.nlm.nih.gov/18520310/*; Nantana Kaisaeng et al., *Out-of-Pocket Costs and Oral Cancer Medication Discontinuation in the Elderly,* 20 J. Managed Care Pharmacy 7, 669–75 (2014), *https://pubmed.ncbi.nlm.nih.gov/24967520/*; Deliana Kostova & Jared Fox, *Chronic Health Outcomes and Prescription Drug Copayments in Medicaid,* 55 Med. Care 5, 520–27 (2017), *https://pubmed.ncbi.nlm.nih.gov/28234755/*; Sujha Subramanian, *Impact of Medicaid Copayments on Patients With Cancer,* 49 Med. Care 9, 842–47 (2011), *https://pubmed.ncbi.nlm.nih.gov/21577164/* ; Samantha Artiga et al., *The Effects of Premium and Cost-Sharing on Low-Income Populations: Updated Review of Research Findings,* Kaiser Family Found., pp.1–5 (2017), *https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/*; David B. Ridley & Kirsten J. Axelsen, *Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence,* 24 Pharmacoeconomics Suppl. 3, 65–78 (2006), *http://www.ncbi.nlm.nih.gov/pubmed/17266389.*

essential health benefits (EHB) requirements.[176]

One organizational commenter expressed concerns about § 92.207(b)(1) and argued that this provision would impose new nondiscrimination tests on issuer business decisions that result in the denial or limitation of payment for a claim, on variations in cost sharing under the terms of a health plan, or on the imposition of other limitations or restrictions on coverage. The commenter argued this would result in expansive and detailed regulation of numerous issuer business decisions in an arbitrary and capricious manner.

Response: OCR appreciates commenters' concerns regarding cost sharing, which is explicitly addressed in § 92.207(b)(1). Covered entities are prohibited from ''impos[ing] additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability.'' We disagree with the commenter's concerns that this provision arbitrarily or capriciously imposes new nondiscrimination tests on issuer business decisions. Covered entities subject to this rule are prohibited from engaging in unlawful discrimination in their health programs or activities, including in health insurance coverage or other health-related coverage. Cost sharing is standard industry practice that is a feature of an issuer's health insurance coverage or other health-related coverage. Nothing in this rule dictates the business decisions an issuer should make in establishing its coverage limitations, including with regard to cost sharing. To the extent an issuer imposes cost sharing in its coverage, it cannot do so in a discriminatory manner. Comments related to violations of EHB requirements are outside the scope of this regulation.[177]

Comment: Commenters generally supported the prohibition on discriminatory marketing practices in § 92.207(b)(2). Commenters discussed that covered entities might use marketing practices to dissuade enrollment by individuals with high-cost conditions. For example, commenters noted that plans present inaccurate or confusing information about formularies and hide or fail to provide information about certain drugs. Several commenters referenced a 2022 study by the AIDS Institute that found 57.9 percent of the 299 Exchange plan documents reviewed did not list PrEP (pre-exposure prophylaxis to prevent HIV infection) as a free preventive service, though health insurance issuers were required to include such coverage for all plans offered through the Exchanges in 2022.[178] Commenters asked OCR to provide an example of discriminatory marketing practices in regulatory text. They further requested that OCR coordinate the study of marketing practices with other regulatory agencies.

Response: OCR concurs with the importance of ensuring that an issuer's marketing practices are not designed or implemented in a way that discriminates against individuals with a specific disability or on any other basis prohibited under section 1557. Inaccuracies or omissions in plan marketing materials may impede an individual's ability to determine what treatments and services are covered. While certain inaccuracies or omissions in marketing materials may not be prohibited discrimination under this section, inaccuracies or omissions that were intended to or resulted in discouraging individuals from enrolling in health insurance coverage and other health-related coverage or steering individuals away from enrolling in health insurance coverage and other health-related coverage on the basis of disability or other prohibited basis would raise concerns of prohibited discrimination. The determination of whether a particular marketing practice is prohibited under this section requires a case-by-case analysis dependent on the facts of the challenged marketing practice. Accordingly, OCR declines to specify particular examples in the regulation, though we included an example in the Proposed Rule, stating that covered entities that avoid advertising in areas populated by a majority of people of color to reduce the enrollment of people of color in their health insurance coverage could violate § 92.207. 87 FR 47869–70. We note that covered entities may be subject to other Departmental and Federal regulations governing marketing practices.[179] While OCR declines to coordinate a study of marketing practices, we continue to coordinate with other regulatory agencies on health insurance-related matters.

We note that individuals with LEP or disabilities may face challenges in accessing a covered entity's marketing materials. This final rule addresses such concerns in multiple ways, including by requiring covered entities to provide a Notice of Nondiscrimination under § 92.10; a Notice of Availability under § 92.11 (including in member handbooks at § 92.11(c)(5)(x)); taking reasonable steps to provide meaningful access to individuals with LEP under § 92.201; and taking appropriate steps to ensure effective communication for individuals with disabilities under § 92.202.

Comment: Numerous commenters supported the prohibition on discriminatory health plan benefit designs in § 92.207(b)(2). Commenters stated that covered entities employ many features of benefit design and delivery to deny coverage or discourage people with significant or high-cost health needs from enrolling in their plans. These include exclusions, cost sharing, formularies, visit limits, provider networks, service areas, benefit substitutions, prior authorization, and other utilization management that the commenters allege are arbitrary and not clinically based or appropriate.

Some commenters requested that OCR define the term ''benefit design'' or include specific examples of benefit design features in the regulatory text of § 92.207(b)(2). While some commenters expressed concern that failing to define benefit design in the regulation would result in a lack of clarity as to what the rule prohibits, other commenters supported OCR's proposed approach to avoid defining the term in a prescriptive manner.

One organizational commenter opposed § 92.207(b)(2) as imposing nondiscrimination tests on insurance benefit design, which the commenter argued would result in expansive and detailed regulation of a number of issuer business decisions in an arbitrary and capricious manner.

Response: Benefit design features may result in a discriminatory denial of access to medically necessary care, particularly for individuals with disabilities who have significant health needs. To address this concern, covered entities are explicitly prohibited from having or implementing benefit designs

[176] *See* section 1302 of the ACA, codified at 42 U.S.C. 18022.

[177] *See* 42 U.S.C. 18022, 300gg–6(a); 45 CFR 156.100 through 165.155.

[178] Letter from The AIDS Institute to Dr. Ellen Montz, Deputy Admin'r & Dir. (June 9, 2022), *https://www.theaidsinstitute.org/letters/marketplace-insurance-plan-prep-compliance*. In general, under section 2713 of the PHS Act and its implementing regulations, plans and issuers must provide coverage, without cost sharing, for recommended preventive services for plan years (in the individual market, policy years) that begin on or after the date that is 1 year after the date the recommendation or guideline is issued. 26 CFR 54.9815–2713(b); 29 CFR 2590.715–2713(b); 45 CFR 147.130(b).

[179] *See, e.g.,* 45 CFR 147.104(e) (health insurance issuers offering coverage in the individual and group markets) and 156.225(b) (qualified health plans); 42 CFR 423.2263 (Medicare Part D marketing requirements).

that discriminate on any protected basis as set forth under § 92.207(b)(2).

We decline to define ''benefit design'' or specify types of benefit design features in the regulatory text. Section 92.207(b)(2) sufficiently notifies covered entities that discriminatory benefit designs are prohibited under this rule. In addition, we seek to avoid being overly prescriptive or unintentionally inconsistent with other Departmental regulations that may define benefit design.[180] While OCR declines to provide examples of specific benefit design features in the regulatory text, for purposes of applying section 1557 and this final rule, examples of benefit design features include, but are not limited to, coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network.

OCR disagrees with the organizational commenter's concern that this provision arbitrarily or capriciously imposes new nondiscrimination tests on issuer business decisions. This section does not dictate what business decisions an issuer must make in establishing its benefit design and does not specify any particular design feature must be included. OCR acknowledges that issuers have discretion in designing their plans; however, they must do so in a nondiscriminatory manner as discussed throughout this section.

Comment: Commenters requested that OCR provide a non-exhaustive list of presumptively discriminatory benefit design examples. Some commenters also suggested that OCR incorporate the presumptively discriminatory benefit design examples provided in CMS' EHB regulations [181] or otherwise rely on other nondiscrimination provisions in CMS regulations implementing the ACA. Commenters stated that allowing plan discretion on every benefit other than gender dysphoria undercuts the regulation. Many commenters stated that OCR should recognize that most benefit design elements are inherently discriminatory as they apply disproportionately to individuals with disabilities and chronic conditions. Commenters expressed concerns that without presumptively discriminatory benefit design examples, issuers will adopt designs that exclude or make lifesaving treatments unaffordable for individuals in protected categories. Commenters noted that such designs include cost-sharing requirements, restrictive medical necessity standards, narrow networks, drug formularies, adverse tiering, benefit substitution, utilization managements, exclusions, visit limits, quantity limits, waiting periods, service areas, and coercive wellness programs.

Response: OCR declines to provide specific examples of presumptively discriminatory benefit designs in the rule due to the fact-intensive analysis needed to determine whether a particular benefit design feature is discriminatory under this section. We also decline to give examples of presumptively discriminatory benefit designs similar to those in EHB regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets that CMS finalized in the preamble of its Notice of Benefit and Payment Parameters for 2023 final rule.[182] Essential health benefits are governed by CMS regulations and not by this final rule. While many of the practices cited by CMS would raise concerns of prohibited discrimination under this rule, OCR's determinations that a particular benefit design is discriminatory will be a fact-specific inquiry that OCR will conduct on a case-by-case basis. OCR's process for analyzing claims of discrimination in benefit design is discussed in more detail under the *Benefit Design Analysis* discussion later in this section. OCR will consider issuing guidance on discriminatory practices prohibited under this section in future guidance.

OCR disagrees that the prohibition against categorical exclusions or limitations of coverage for all health services related to gender transition or other gender-affirming care under § 92.207(b)(4) undercuts the regulation. Such explicit, categorical exclusions or limitations impermissibly single out an entire category of services based on an individual's transgender status and are presumptively discriminatory on the basis of sex as prohibited under this section. As discussed in detail under § 92.206, this rule includes specific provisions related to gender-affirming care given the widespread discriminatory denial of care for such services and its direct connection to an individual's transgender status.[183] As discussed in more detail below, covered entities may raise a defense under § 92.207(c) where they contend that they have a legitimate, nondiscriminatory basis for a coverage limitation that may otherwise appear to constitute discrimination. Recipients may also rely upon §§ 92.3 and 92.302(a) or request an assurance of exemption under § 92.302(b) based on their view that religious freedom or conscience protections apply.

We also decline to incorporate examples of presumptively discriminatory benefit designs similar to those in EHB regulations applicable to non-grandfathered health insurance coverage [184] in the individual and small group markets that CMS finalized in the preamble of its Notice of Benefit and Payment Parameters for 2023 final rule. Essential health benefits are governed by CMS regulations and are not addressed by this final rule. While many of the practices cited by CMS would raise concerns of prohibited

[180] Other Departmental and Federal regulations governing private health insurance and public health coverage refer to ''benefit design'' and ''marketing practices.'' *See, e.g.,* 45 CFR 147.104(e), 156.20, 156.125(a) (health insurance issuers offering coverage in the individual and group markets), 156.200(b)(3), 156.225(b) (qualified health plans), 156.110(d), and 156.111(b)(2)(v) (EHB benchmark plans); 42 CFR 422.100(f)(3) (Medicare Advantage), 423.2263 (Medicare Part D marketing requirements), 423.882, 423.894(d) (Medicare retiree prescription drug plans), 440.347(e) (Medicaid benchmark plans), and 600.405(d) (Basic Health Program); 29 CFR 2510.3–40(c)(1)(iv)(A) (multiple employer welfare arrangements under ERISA).

[181] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022).

[182] Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–05 (May 6, 2022) (providing the following examples of presumptively discriminatory benefit designs under CMS' EHB nondiscrimination regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets: (1) limitation on hearing aid coverage based on age; (2) autism spectrum disorder coverage limitations based on age; (3) age limits for infertility treatment coverage when treatment is clinically effective for the age group; (4) limitation on foot care coverage based on diagnosis (whether diabetes or another underlying medical condition); and (5) access to prescription drugs for chronic health conditions (adverse tiering)). We note these regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[183] *See, e.g., Bos. All. of Gay, Lesbian, Bisexual & Transgender Youth* v. *U.S. Dep't of Health & Hum. Servs.,* 557 F. Supp. 224, 239 (D. Mass. 2021) (''[p]laintiffs have shown a substantial risk that insurers will deny reimbursement for treatment they previously covered based on the elimination of the prohibition on categorical coverage exclusions. Out2Enroll's analysis indicates that ''the number of insurers using transgender-specific exclusions . . . more than doubled'' after HHS promulgated the 2020 Rule.'').

[184] In general, health coverage is considered grandfathered if it was in existence and has continuously provided coverage for someone (not necessarily the same person, but at all times at least one person) since March 23, 2010, provided the plan (or its sponsor) or the issuer has not taken certain actions resulting in the plan relinquishing grandfathered status, as more fully described at 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

discrimination under this rule, OCR's determinations that a particular benefit design is discriminatory will be a fact-specific inquiry that OCR will conduct on a case-by-case basis. OCR's process for analyzing claims of discrimination in benefit design is discussed in more detail under the *Benefit Design Analysis* discussion later in this section. OCR will consider issuing guidance on discriminatory practices prohibited under this section in future guidance.

Comment: Commenters asked OCR to include examples of discriminatory benefit design specifically related to prescription drug formularies. These commenters provided examples of practices they considered to be discriminatory, such as issuers placing most or all drugs used in the treatment of certain conditions into the highest cost sharing tier; excluding single tablet regimens even when they are the standard of care for a condition; requiring the use of specialty pharmacy programs that require mail delivery even when that adds unnecessary and burdensome administrative barriers and delays to obtaining drugs; and using quantity limits for an entire class of medications without scientific or clinical explanation. Commenters expressed concerns that discriminatory prescription drug formularies discourage enrollment among certain populations, including individuals with HIV, mental health needs, or other chronic conditions. Commenters noted that enrollees who need high-cost medications often must choose between plans that will provide adequate coverage of their medication or plans that cover their preferred providers. A commenter cited a study that showed that Black and Hispanic/Latino people are more likely to abandon medications at the pharmacy because of high cost.[185] Finally, some commenters recommended that OCR develop specific mechanisms to monitor prescription drug formulary practices and coverage of physician-administered ''medical benefit'' drugs to ensure that formularies are not used to discriminate against patients with specific disabilities.

Response: Benefit design practices related to prescription drugs have an enormous impact on individuals' access to medically necessary medication. Coverage of prescription drugs could pose concerns of prohibited discrimination and OCR would investigate such practices under the rule on a case-by-case basis. OCR declines to state that specific practices are per se discriminatory under the rule because each investigation is a fact-specific inquiry, based on nondiscrimination principles and relevant case law,[186] including consideration of the covered entity's reason for the design feature in question.

As discussed in the Proposed Rule, several benefit design practices related to drug formularies could be discriminatory under this section, including prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of their costs without placing similar utilization management controls on most or all drugs used to treat other conditions, and benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others. 87 FR 47874. OCR notes that coverage of physician-administered ''medical benefit'' drugs would be considered part of a plan's benefit design and therefore subject to this rule.

While we identify some prescription drug practices above that may raise concerns under section 1557, this rule does not prohibit covered entities from engaging in nondiscriminatory practices related to prescription drug benefit design. For example, covered entities may utilize preferred drug lists, such as preferred drug lists under the Medicaid program under title XIX of the Social Security Act, as long as the coverage criteria does not constitute prohibited discrimination. In addition, as discussed in more detail below, covered entities are not prohibited from applying nondiscriminatory utilization management techniques in their drug formularies.

Comment: Many commenters expressed concerns about benefit designs that impose coverage limitations or exclusions related to health services that could result in discrimination on the basis of disability. For example, some commenters argued that plans should not be permitted to have blanket exclusions for services related to ASD or applied behavioral analysis (ABA) therapy, a therapeutic intervention sometimes recommended for autistic children.

Several commenters raised concerns about how frequently insurance benefit design practices inappropriately limit coverage of durable medical equipment. Commenters noted that issuers place unique annual coverage caps on items such as wheelchairs, ventilators, and hearing aids. A commenter noted an example of an individual with hearing loss that requires treatment other than cochlear implants being denied coverage of hearing aids and outpatient visits to an audiologist due to their issuer's blanket exclusion of programs or treatments for hearing loss other than cochlear implants. Another commenter noted that issuers limit coverage of multiple-use speech-generating devices, which are most useful and effective for autistic individuals, even when those devices are less expensive than single-use speech generating devices.

Other commenters expressed concerns that covered entities include clinically inappropriate limits on the coverage of habilitative and rehabilitative services and devices. Commenters noted that such limitations, including on the number of covered visits, discriminate against people with more significant disabilities who need extensive habilitation or rehabilitation in order to gain, regain, or maintain functioning. Commenters requested that OCR clarify that blanket limitations or exclusions of habilitative services for individuals with specific disabilities are prohibited discrimination under section 1557 when those same services are allowed for rehabilitation of nondisabled persons. Commenters noted that people with developmental disabilities are routinely denied coverage for habilitative services needed to gain skills or improve functioning while an identical service is covered for individuals who require it for rehabilitative care to restore functioning. For example, a commenter noted that coverage of ''speech therapy to restore speech'' results in excluding all children with developmental delays who need the therapy to *attain* speech. Commenters noted that habilitative services are important for children who are delayed in walking or talking or need to learn other muscular skills for the first time and for individuals with disabilities to be able to live as independently as possible.

Response: OCR appreciates the variety of concerns raised by commenters. A coverage limitation or exclusion that is based on a specific disability or condition (or other basis prohibited by section 1557, such as age, discussed below), would be investigated as

[185] PhRMA, *Patient Experience Survey: Barriers to Health Care Access in the Patient Experience,* pp. 10–11 (2021), *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PES-Report_100621_Final.pdf* (stating that utilization management disproportionately impacts people of color (Black Americans (56 percent) and Hispanic Americans (60 percent) versus white Americans (36 percent)) and that barriers imposed by utilization management can contribute to poor medication adherence or prescription abandonment).

[186] *See, e.g., Doe* v. *CVS Pharmacy, Inc.,* 982 F.3d 1204, 1212 (9th Cir. 2020); *Doe* v. *BlueCross BlueShield of Tenn.,* 926 F.3d 235, 241 (6th Cir. 2019).

potentially discriminatory under this rule. Blanket exclusions of all treatments related to a particular condition, such as ASD or hearing loss, would raise significant concerns of prohibited discrimination on the basis of disability such that OCR would expect the covered entity to provide a legitimate, nondiscriminatory reason for the exclusion. Non-categorical exclusions or limitations for certain treatments related to a specific disability or condition may also raise concerns under the rule. This rule, however, does not require covered entities to cover all services related to a specific disability or condition. Application of standard disability discrimination principles requires a specific analysis of each claimed exclusion. We therefore decline to expressly state that a particular coverage exclusion or limitation is per se discriminatory on the basis of disability under this rule. Determinations of whether a particular coverage exclusion or limitation is discriminatory will be evaluated on a case-by-case basis, in accordance with longstanding civil rights principles and relevant case law, as discussed throughout this section. When investigating a potentially discriminatory exclusion or limitation, OCR will consider whether the covered entity has a legitimate, nondiscriminatory reason for the challenged design feature. If OCR determines that the covered entity's reason is a legitimate, nondiscriminatory reason that is not a pretext for discrimination, OCR will conclude that the challenged exclusion or limitation is not prohibited under the rule.

Regarding durable medical treatment, the commenters' example of exclusions of coverage for programs or treatments for hearing loss other than cochlear implants has been the subject of at least two court cases where the courts have held that such exclusions do not state a claim for proxy disability discrimination under section 1557.[187]

We also note that health insurance issuers may be subject to other Departmental authorities that are relevant to issues raised by commenters.[188] For example, to the extent durable medical equipment is an EHB, like hearing aids are in some states, covered entities may also be subject to CMS' EHB nondiscrimination regulations at 45 CFR 156.125 applicable to non-grandfathered health insurance coverage in the individual and small group markets.[189] Further, CMS' EHB regulations require coverage of habilitative services and devices, and specify that plans may not impose limits on coverage of habilitative services and devices that are less favorable than limits imposed on coverage of rehabilitative services and devices.[190]

Comment: Many commenters raised concerns related to mental health services. Commenters asked OCR to require both public and private payers to remedy the current inadequacies and inequities in mental health service reimbursement rates and policies, explaining that reimbursement rates have been historically lower for mental health services than physical health services. Commenters also identified a range of specific mental health benefit design inequities, including the need for intermediate-care facility coverage for high-use patients with non-urgent care needs to mobile crisis response that is on par to that of physical emergency response. Commenters also requested that the rule align with the mental health parity protections in the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

Response: OCR acknowledges commenters' concerns regarding coverage for mental health services. Mental health services may be needed by people who may or may not be individuals with disabilities under this rule. OCR will examine complaints alleging less favorable treatment for mental health coverage as compared to physical health coverage on a case-by-case basis to determine if the coverage discriminates against people with disabilities. Reimbursement rates and policies are subject to § 92.207 as part of a plan's benefit design, and thus must be provided in a nondiscriminatory manner. We also discuss reimbursement rates in the context of the integration provision under § 92.207(b)(6).

We decline to incorporate or align this rule with MHPAEA, as section 1557 is a distinct Federal civil rights law. We note that coverage limitations found to violate section 1557 may also be prohibited under MHPAEA.[191]

Comment: Commenters expressed concerns about issuers discriminating against enrollees based on age through certain benefit designs. Commenters provided examples of practices they believed to be discriminatory, such as issuers requiring an ASD diagnosis by a certain age to access coverage for ASD-related health care; not covering hearing aids for adults when otherwise covered for children; and imposing limitations on wheelchair and mobility device replacement for children that fail to align with how quickly children outgrow such devices. One commenter asked that OCR require issuers to attest that their pediatric benefit packages are comprehensive and age-appropriate by demonstrating that physical and mental health benefits do not have age, visit, or coverage limits that are not based on medical necessity or that are based on adult metrics. Commenters noted that plans that limit coverage to specific conditions or a child's capacity to attain a certain functional status will unfairly prevent many children with special health care needs from accessing critically important services.

Response: Section 1557 prohibits discrimination on the basis of age, consistent with the Age Act and its implementing regulations. The Age Act allows age distinctions under certain circumstances, including distinctions

[187] *Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 960 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–cv–01609–RAJ, 2022 WL 279028, at *8–9 (W.D. Wash., Jan. 31, 2022).

[188] *See, e.g.,* Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

[189] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022) (concluding that age limitations on hearing aid coverage are presumptively discriminatory under 45 CFR 156.125 when applied to EHB and there is no clinical basis for the age distinction). We note these regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[190] 45 CFR 156.110(a)(7) and 156.115(a)(5)(ii).

[191] The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110–343; 42 U.S.C. 300gg–26 (HHS); 29 U.S.C. 1185a (Department of Labor); 26 U.S.C. 9812 (Department of Treasury), and implementing regulations at 45 CFR 146.136 and 45 CFR 147.160, 29 CFR 2590.712, and 26 CFR 54.9812–1, respectively; The Departments of the Treasury, Labor, and HHS also published proposed rules on August 3, 2023 (88 FR 51552), to amend existing regulations and establish new regulations for the nonquantitative treatment limitation comparative analyses required under MHPAEA, as amended by the Consolidated Appropriations Act, 2021. The proposed rules would amend the existing rules to prevent group health plans and health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits from using nonquantitative treatment limits to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits; *see also* U.S. Dep't of Labor, U.S. Dep't of Health & Hum. Servs., U.S. Dep't of the Treasury, 2022 MHPAEA Report To Congress: *Realizing Parity, Reducing Stigma, and Raising Awareness: Increasing Access to Mental Health and Substance Use Disorder Coverage* (2022), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf*; U.S. Dep't of Labor, *Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA),* p. 38 (2020), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf*.

that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective [192] of a program or activity; are based on age-related factors that bear a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective; provide special benefits to the elderly or children; or are contained in a rule or regulation issued by the Department.[193] As a result, not all age-related distinctions in State or Federal law, including Department regulations, are prohibited by section 1557.[194] As noted above, these permissible age distinctions form part of the ''ground'' of discrimination prohibited under the Age Act, because they identify distinctions that either are not forbidden age discrimination, 42 U.S.C. 6103(b)(1)(A) (''reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity''), or are not age discrimination at all, *id.* section 6103(b)(1)(B) (''based upon reasonable factors other than age'').

When investigating a benefit design with an age distinction, OCR will first determine whether the distinction is permitted under the Age Act (and therefore section 1557). If it is not, OCR will then investigate the age distinction to determine whether it violates section 1557. As with other benefit design investigations, OCR's analysis will involve a fact-specific inquiry and will consider a covered entity's reason for the age distinction in its benefit design. The covered entity's justification must be a legitimate, nondiscriminatory reason, as discussed under § 92.207(c). For example, if an issuer is not able to provide a legitimate, nondiscriminatory reason to substantiate an age distinction in ASD coverage, such an age distinction would likely violate section 1557. We reiterate that this rule does not require a covered entity to provide coverage for all health services related to a particular disability or condition; rather, it requires covered entities to design their plan benefits in a nondiscriminatory manner. We note that covered entities may also be subject to relevant CMS EHB nondiscrimination regulations regarding presumptively discriminatory age distinctions.[195]

OCR does not agree that it is necessary to require a separate attestation related to pediatric benefit packages. As recipients of Federal financial assistance, issuers are required to submit an Assurance of Compliance with section 1557 under § 92.5, which attests that they will not discriminate on the basis of age, among other prohibited bases.

Comment: A commenter requested that OCR clarify the obligation of issuers and plan administrators to ensure that their staff, as well as the staff of any subsidiary entities with which they do business, receive explicit training on the relationship between benefit design choices and practices and activities that can amount to discrimination based on race, color, national origin, sex, age or disability.

Response: Covered entities are responsible for ensuring their staff, subrecipients, and subcontractors are compliant with section 1557. Section 92.9 requires covered entities to provide training to relevant employees on their section 1557 Policies and Procedures, and while we note that it is in a covered entity's best interest to ensure that relevant staff are adequately trained, we decline to specify additional training requirements at this time.

Comment: Commenters requested that the final rule expressly state that section 1557 prohibits proxy discrimination in benefit design, either in the preamble or regulation. Commenters expressed concern that absent express incorporation of proxy principles, covered actors may attempt to evade section 1557's nondiscrimination provisions. A commenter requested that the final rule incorporate established discrimination principles and noted that issuers continue to justify discriminatory plan designs by taking the position that health plans that target a particular medical service rather than a disability are neutral or uniform with respect to all enrollees. As an example, the commenter noted that plans restricting coverage of dialysis justify it as not being discriminatory against enrollees with end-stage renal disease. The commenter requested that the final rule declare that discriminatory plan designs that limit dialysis treatment are a form of prohibited disability discrimination under section 1557 due to the fact that dialysis services are a near perfect proxy for end-stage renal disease, according to the commenter.

Response: Proxy discrimination occurs when a policy or practice treats individuals differently on the basis of seemingly neutral criteria that are so closely associated with the disfavored group that discrimination on the basis of such criteria is, constructively, facial discrimination against the disfavored group.[196] Proxy discrimination is one of many basic civil rights theories available to OCR when investigating complaints under section 1557 and which courts have applied in cases alleging discrimination under section 1557.[197] Due to the fact-intensive nature of the analysis necessary, including determinations of whether a particular benefit design is discriminatory,[198] we decline to expressly include this theory of discrimination in the rule text. As we have noted above, all claims under this section will be evaluated on a case-by-case basis.

Comment: Some commenters noted that health insurance coverage and other health-related coverage may employ coverage limitations that are facially neutral and apply to all enrollees but have a disparate impact on a basis protected under section 1557. Specifically, commenters observed that these limitations and exclusions can have a particular discriminatory effect on individuals with disabilities who have chronic conditions and significant health needs.

Response: OCR utilizes all applicable causes of action when investigating potential discrimination under section 1557 consistent with relevant case law. For further discussion related to OCR's enforcement procedures, see § 92.301.

[192] 45 CFR 91.12(b) (Defining ''Statutory objective'' to mean ''any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.'').

[193] *See* 42 U.S.C. 6103(b); 45 CFR 91.12 through 91.14 and 91.17.

[194] *See, e.g.,* 42 U.S.C. 300gg; 45 CFR 147.102 (permitting premium rates charged by a health insurance issuer for health coverage offered in the individual or small group market to vary with respect to the particular plan of coverage by age, among other factors).

[195] *See, e.g.,* Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022) (providing examples of presumptively discriminatory benefit designs under CMS' EHB nondiscrimination regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets that include limitations on hearing aid coverage based on age, autism spectrum disorder coverage limitations based on age, and age limits for infertility treatment coverage when treatment is clinically effective for the age group). These regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[196] *Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 958 (9th Cir. 2020) (citing *Davis* v. *Guam,* 932 F.3rd 822, 837 (9th Cir. 2019)).

[197] *See, e.g., Schmitt* v. *Kaiser Found. Health Plan of Wash.* No. 2:17–cv–01611–RSL, 2018 WL 4385858 (W.D. Wash. Sept. 14, 2018), *aff'd in part, rev'd in part and remanded,* 965 F.3d 945 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–CV–01609–RAJ, 2022 WL 279028, at *1 (W.D. Wash. Jan. 31, 2022).

[198] *See, e.g., Schmitt* v. *Kaiser Found. Health Plan of Wash.,* No. 2:17–cv–01611–RSL, 2018 WL 4385858 (W.D. Wash. Sept. 14, 2018), *aff'd in part, rev'd in part and remanded,* 965 F.3d 945 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–CV–01609–RAJ, 2022 WL 279028, at *1 (W.D. Wash. Jan. 31, 2022).

Comment: Commenters requested that the final rule make clear the language in § 92.207(b), which addresses sex-related health services, includes the full spectrum of reproductive health services and treatments and medications for people with disabilities that may prevent, complicate, or end fertility or pregnancies.

Response: OCR appreciates the unique challenges faced by people with disabilities seeking reproductive health care. Section 1557 prohibits discrimination on prohibited bases regardless of the type of care an individual is seeking or receive. Therefore, we do not believe it is necessary to provide specific provisions related to each form of care an individual may seek.

Comment: Commenters requested that the final rule expressly state that infertility diagnoses, treatment, and services, including assisted reproductive technology, if offered, must be covered without regard to sexual orientation, gender identity, sex characteristics (including intersex traits), or any other protected basis. Commenters raised several examples of benefit design or coverage related to assisted reproductive technology that they stated should be prohibited as discriminatory against individuals based on their relationship status and sexual orientation. As examples, commenters cited requiring enrollees to use their spouse's sperm to fertilize their eggs for in vitro fertilization and requiring that single enrollees or those in non-heterosexual relationships pay out of pocket for a predetermined number of failed intrauterine insemination cycles before providing coverage when heterosexual couples do not have to meet the same standard. Commenters stated that issuers justify these types of benefit design features on outdated definitions of infertility. A commenter argued that in vitro fertilization coverage should include screening for genetic abnormalities that are unique to enrollees' lineage as a matter of reproductive justice and religious freedom.

Response: OCR agrees that to the extent plans cover infertility diagnosis, treatment, and services, including assisted reproductive technology, they must do so on a nondiscriminatory basis, including for same-sex couples. Due to the fact-intensive nature of the analysis necessary, determinations of whether a particular benefit design is discriminatory under this section will be evaluated on a case-by-case basis.

Comment: Commenters recommended that OCR add a new paragraph to § 92.207(b) affirming that denying or limiting coverage of, or coverage of a claim for, health services because they may prevent, cause complications to, or end fertility or pregnancies is prohibited. Commenters asserted this language would address discrimination by a State program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of a medically inaccurate assertion that the contraception causes an abortion, or a provider network that only includes facilities that refuse to provide certain types of contraception. Commenters emphasized that individuals are currently being improperly denied access to medications or treatments for care unrelated to abortion because the medicine is also used for abortion care.

Response: Denying access to specific medication or health services that may potentially be used for medication abortion purposes but are prescribed for reasons unrelated to abortion care may constitute discrimination under section 1557.[199] OCR finds it unnecessary to add any additional regulatory language to prohibit such discrimination on the basis of disability and sex. As noted above, simultaneous discrimination on multiple prohibited bases is important to account for and is prohibited by section 1557.

Comment: A commenter asked OCR to provide confirmation that while nothing in the regulation would require a covered entity to cover abortions, to the extent plans do cover abortions, they must do so on a nondiscriminatory basis.

Response: As the commenter stated, nothing in this rule requires the provision of any particular medical care, including abortion. To the extent plans offer coverage for termination of pregnancies and related services, they must do so on a nondiscriminatory basis.

Comment: Commenters recommended that OCR revise the regulatory text of proposed § 92.207(b)(4) and (5) to address sex discrimination related to pregnancy or related conditions by adding discrimination related to abortion, fertility care, and contraception. Some commenters requested that OCR specifically add ''termination of pregnancy, contraception, fertility care, miscarriage management, pregnancy loss, maternity care, other reproductive and sexual health services, or any health services'' to the prohibitions on exclusions, limitations, and cost sharing related to gender transition or other gender-affirming care in § 92.207(b)(4) and (5).

Response: OCR declines this suggestion. Section 92.207(b)(4) and (5) are not intended to list all types of potentially prohibited exclusions. The general prohibition on discriminatory limitations under § 92.207(b)(1) would apply to any exclusion or limitation related to all types of care that resulted in discrimination on the basis of sex.

Comment: Some commenters stated that they oppose § 92.207 to the extent it violates religious freedom and conscience protections. Other commenters stated that they opposed § 92.207 because it prevents plans from excluding coverage of all gender affirming care.

Response: Section 92.207 does not violate such protections because providers may rely on the protections of Federal religious freedom and conscience laws or choose to seek assurance of those protections from OCR under this final rule. With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' conscience or religious freedom, please refer to the preamble discussion of § 92.302. Additionally, we are revising § 92.207(c) to specify that nothing in this section precludes a covered entity from availing itself of protections described in § 92.3 and § 92.302. This modification is consistent with the revised language in § 92.206(c). As noted elsewhere in this preamble, and in § 92.3(c), insofar as the application of any rule requirement would violate applicable Federal protections for religious freedom and conscience, such application shall not be required.

Comment: Many commenters expressed strong support for the provisions in § 92.207(b)(3) through (5), citing the extensive discrimination faced by transgender people in the health insurance coverage and other health-related coverage context. Several legal service providers described their experiences assisting clients facing various types of discrimination in their health plans, even where State law or the plan terms provided some protection for gender-affirming care. Some commenters noted these provisions also addressed forms of discrimination commonly faced by intersex people. Commenters noted that the physical, mental health, and financial costs of such discrimination could be high, with individuals forgoing necessary care, facing extreme financial

[199] *See* U.S. Dep't of Health & Hum. Servs., *Guidance to the Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (Sept. 29, 2023), *https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.*

burdens, and experiencing distress when denied access to necessary medical care.

Both supporters and opponents of the Proposed Rule raised many of the same issues discussed in § 92.206(b)(4) (prohibiting categorical coverage exclusions on gender transition or other gender-affirming care) and (c) (discussing legitimate, nondiscriminatory reasons for denying or limiting care) above. As with § 92.206, some commenters asked OCR to define gender-affirming care or provide more detail about what types of care must be covered.

Response: OCR agrees that transgender and intersex people have long faced discrimination in the health insurance coverage and other health-related coverage context. Many of OCR's responses to the comments in § 92.206(b)(4) (prohibiting categorical coverage exclusions on gender transition or other gender-affirming care) and (c) (discussing legitimate, nondiscriminatory reasons for denying or limiting care) above are applicable to the comments in this section as well. For example, for the reasons we discussed above, we will not provide a definition of ''gender-affirming care'' in the regulation text.

Comment: Commenters noted that even plans without categorical exclusions will exclude certain types of gender-affirming care as ''cosmetic.'' Commenters noted that categorizing procedures as cosmetic when needed for gender-affirming care is contrary to established standards of care for the treatment of gender dysphoria and urged OCR to explicitly prohibit such procedure-specific exclusions. Some commenters further noted that plans will often consider these procedures on a case-by-case basis when not related to gender transition but will not do so when the care is related to gender transition.

Many commenters recommended deleting the word ''all'' from § 92.207(b)(4) to make clear that the exclusion of *any* gender-affirming care from coverage is prohibited. Some commenters stated that this change would be more consistent with § 92.207(b)(5), which more generally prohibits discriminatory limits on gender-affirming care coverage.

Response: OCR appreciates commenters' feedback and concern about forms of discrimination beyond broad categorical coverage exclusions. While we understand that some gender-affirming care exclusions are limited to the specific type of care at issue, we decline to revise the language of § 92.207(b)(4). Section 92.207(b)(5)'s general prohibition on limitations or restrictions on coverage for gender transition or other gender-affirming care reaches the narrower exclusions or restrictions on gender-affirming care.

We also decline to state that any denial of gender-affirming care will necessarily be discriminatory regardless of context or rationale. We will instead consider claims of discrimination raising non-categorical denials on a case-by-case basis. Where OCR receives complaints about such exclusions or restrictions, we will investigate on a case-by-case basis whether they constitute prohibited discrimination under § 92.207(b)(5) or any other applicable provision of the rule. Since section 1557 only prohibits discrimination and does not prescribe any specific standard of care, such denials will violate the final rule only where they entail discrimination on the basis of sex. As stated throughout this section, covered entities will have the opportunity to provide a legitimate, nondiscriminatory reason for such exclusions or restrictions.

Comment: Some commenters proposed striking the phrase ''if such denial, limitation, or restriction results in discrimination on the basis of sex'' from § 92.207(b)(5), stating that the elimination would make this provision clearer. Commenters viewed this phrase as confusing and redundant, as they stated that limiting or restricting coverage for services related to gender-affirming care is necessarily discriminatory. Another commenter noted the intersectionality of discrimination and stated that this language may be limiting.

Response: For the reasons discussed above, we disagree that any restriction impacting gender-affirming care will necessarily constitute prohibited discrimination. For example, if an insurance plan places restrictions on coverage for gender-affirming surgeries that are no more stringent than the restrictions placed on any other type of surgical care, those restrictions will not violate the rule. As such, we decline to make the deletion proposed by these commenters.

OCR agrees that the rule prohibits discrimination in the provision or coverage of gender-affirming care whether it is on the basis of sex or on the basis of race, color, national origin, age, or disability. That said, allegations about such discrimination are best brought under § 92.207(b)(1), as § 92.207(b)(5) is aimed at the types of denials or limitations on coverage that are based on a person's gender identity and are thus a form of sex discrimination.

Comment: Commenters noted that even plans without categorical exclusions of gender-affirming care may adopt barriers to accessing such care, such as more stringent pre-approval processes. The commenters noted that these requirements could result in transgender people ultimately not receiving necessary care or having to invest significant time and resources to navigate the barriers. Some commenters additionally noted the high mental health toll on individuals facing discriminatory limitations on medically necessary care.

Response: OCR appreciates the commenter's feedback and concern about the forms of discrimination transgender people encounter in seeking coverage for gender-affirming care but declines to revise § 92.207(b)(3) as suggested. Section 92.207(b)(5) prohibits limitations or restrictions on coverage for gender transition or other gender-affirming care.

Comment: Many commenters supported the provisions limiting issuers' ability to deny care based on a person's sex assigned at birth, gender identity, or gender otherwise recorded, noting that transgender, nonbinary, and intersex people can all face such discriminatory denials. Other commenters objected to these provisions, expressing concern that this would compel issuers to pay for care that was not medically necessary or appropriate for a given individual.

Response: Section 92.207(c) makes clear that a nondiscriminatory determination that care is not medically necessary based on a patient's anatomy or medical need is permissible. For example, this final rule would not prohibit a covered entity from denying coverage for preventive health services for a transgender patient where such care is not medically necessary, such as a prostate exam for a transgender man who does not anatomically have a prostate. In contrast, the rule may prohibit a covered entity from denying coverage for medically necessary preventive care for a transgender patient.

Comment: One provider group urged OCR to work with the Office of the National Coordinator for Health Information Technology (ONC) and electronic health record vendors to ensure that there are options for separately identifying a patient's gender identity and anatomy to reduce the risk of improper denials.

Response: OCR appreciates the suggestion that discriminatory denials could be reduced if the records systems used by providers, issuers, and other covered entities provide better options

for recording gender identity and sex characteristics. While minimum standards for record systems are not within the scope of the rule, we are committed to working with ONC and other relevant stakeholders to explore solutions to this issue.

Comment: Commenters noted that transgender people often have difficulty getting their health coverage to update their records to reflect their correct name and gender. Commenters noted that gender marker mismatches in health insurance records can result in denial of coverage for clinically appropriate care, and one commenter urged OCR to make clear that claims processing procedures that automatically deny coverage for care based on a perceived mismatch of sex or gender is a form of impermissible sex discrimination.

Response: OCR appreciates commenters' concerns about coverage denials due to a sex mismatch in claims processing procedures, which can result in transgender patients being denied coverage for a medically necessary and clinically appropriate services. However, we decline to categorically state that sex mismatch denials are always discriminatory. Instead, OCR will consider and investigate complaints raising this issue on a case-by-case basis under § 92.207(b)(3). While we refrain from categorically stating that initial sex mismatch or coding denials are prohibited under this rule, we caution that denials resulting in an undue delay or denial of services, such as repeated denials, could result in a finding of prohibited discrimination. For more information on OCR's view of this issue, please see the 2016 Rule preamble's discussion on computer systems with gender coding resulting in gender mismatches at 81 FR 31436.

Comment: With respect to cases where coverage for comparable treatments is relevant to the discrimination analysis, some commenters urged OCR to clarify that the question of what is comparable can be construed broadly, rather than parsing minor differences in broadly similar types of care.

Response: OCR declines to identify a bright line of how similar care must be to be considered comparable when such considerations are relevant to a discrimination claim, as there are many factors that may be relevant to this analysis, and our approach is case by case.

Comment: Commenters who addressed the integration requirement in § 92.207(b)(6) overwhelmingly supported the newly proposed provision, which clarifies the prohibition on having or implementing benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. Several noted the particular importance of this provision and access to community integration in light of the COVID–19 pandemic and the higher infection risks associated with congregate settings. A few commenters noted the role that discrimination on multiple bases may play with regard to community integration, highlighting the overrepresentation of people of color in institutional settings, and the relationship between access to effective communication and community integration. Numerous comments included examples of current practices that may violate the integration provision.

Commenters agreed that this provision should apply to both benefit design and implementation of a benefit design, including: coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management practices; medical management standards (including medical necessity standards); provider network design; provider reimbursement; standards for provider admission to participate in a network; benefits and service administration contracted to third parties, such as pharmacy benefit managers; and quality measurement and incentive systems. Many commenters requested that OCR clarify that the convenience or potential cost-saving of administering treatments in institutional settings are not legitimate, nondiscriminatory reasons for not providing comparable benefits in less restrictive settings.

Commenters suggested that providing coverage to qualified individuals with disabilities in the most integrated setting appropriate should not be done in a way that unnecessarily increases costs for all enrollees or compromises individual health benefits.

Response: We appreciate support for the inclusion of this provision. OCR recognizes the importance of providing and administering health coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities; we also recognize that discrimination on multiple bases heightens barriers and are committed to addressing allegations of discrimination on all bases protected under section 1557. As discussed in the Proposed Rule, 87 FR 47873, this provision encompasses both the benefit design of the benefit being offered by a covered entity as well as the indirect mechanisms that affect the implementation of the benefit design within a covered entity's control, such as utilization management practices, provider reimbursement, contracting out to third-party contractors such as pharmacy benefit managers, and quality measurement and incentive systems. OCR is not prescriptive in the list of potential mechanisms that could result in prohibited discrimination through implementation of a benefit design because it is a case-by-case analysis depending on the facts of each situation.

With respect to concerns about unnecessarily increasing costs to comply with this provision, OCR notes that institutional care is generally more expensive than community-based care and that increased cost alone is not necessarily a fundamental alteration.[200] However, concerns related to cost can be raised through a fundamental alterations defense.[201]

Comment: Nearly all commenters who addressed this provision agreed with the 2022 NPRM preamble language stating that requiring prior authorization, step therapy, or other utilization management when individuals access treatment in the community but not in an institution, would constitute discrimination if the discrepancy results in unnecessary segregation or a serious risk of unnecessary segregation. Commenters noted that these practices place additional terms and conditions on the receipt of certain benefits in integrated settings that are not in place within segregated or institutional settings, and that they can often delay care and cause unnecessary institutionalization. For example, commenters asserted that people with physical and sensory disabilities, complex medical needs, and people with psychiatric and mental disabilities are often required to try less expensive and often unsuccessful medication (*i.e.,* step therapy) before being able to access effective treatments in the community. If utilization management techniques are only required for community-based treatment and not for institutional care, commenters argued this may push individuals urgently in need of care into institutional setting so they can access treatment more quickly. In contrast, one commenter suggested that it may be clinically appropriate to distinguish between institutional settings and home and community-based settings (HCBS) through the use of medical management

[200] *Fisher* v. *Okla. Health Care Auth.,* 335 F.3d 1175, 1183 (10th Cir. 2003).

[201] *Id.* at 1182.

tools like prior authorization and step therapy due to closer monitoring by medical professionals in institutional settings.

Response: OCR shares commenters' concerns about the potential discrimination associated with the serious risk of institutionalization. The integration mandates of the ADA and section 504 apply to people with disabilities who are at serious risk of segregation or institutionalization, not only to people with disabilities who are currently in institutions.[202] For example, an individual could show sufficient risk of institutionalization such that it would constitute a violation of this provision if a covered entity's failure to provide community services or its cut to such services will likely cause a decline in health, safety, or welfare that result in the serious risk of institutionalization or segregation.

As articulated in the Proposed Rule, 87 FR 47873, step therapy and other utilization management practices that impose different standards on members or beneficiaries in the community than in institutional settings are discriminatory if the discrepancy results in unnecessary segregation or a serious risk of unnecessary segregation. Section 1557's incorporation of section 504's integration provision through § 92.101(b)(1) makes clear that serious risk of institutionalization is covered under section 1557 as well, given that the vast majority of courts have found section 504 and title II of the ADA prohibits actions, omissions, policies, and practices that place individuals at serious risk of unjustified isolation. Indeed, nearly every court of appeals to address the issue has held that the integration mandate of the ADA and section 504 apply not only to people with disabilities who are currently in institutions, but also to people with disabilities who are at serious risk of segregation or institutionalization.[203] As noted in *Fisher* v. *Oklahoma,* the integration mandate's ''protections would be meaningless if plaintiffs were required to segregate themselves by entering an institution before they could challenge an allegedly discriminatory law or policy that threatens to force into segregated isolation.'' [204] Likewise, section 1557's integration mandate would ring hollow if individuals were required to show that they have already had to submit to institutionalization in order to assert their right to receive services in the most integrated setting appropriate to their needs.

Further, even if a serious risk of unnecessary institutionalization was not an actionable claim in and of itself, it would still be appropriate for courts to grant relief to those at serious risk in order to prevent the unnecessary institutionalization prohibited by law.[205] For these reasons, the rule's integration provision explicitly prohibits benefit design that results in a serious risk of institutionalization.

Plans continue to be able to limit services, use utilization review standards, and employ other limitations to manage costs as long as they are not discriminatory in doing so.

OCR has revised the regulation text to clarify that the integration requirement under section 1557 extends to practices that result in the serious risk of institutionalization or segregation. We recognize that the question of what constitutes ''serious risk'' is a fact-based inquiry, which is why the Federal courts to have considered the question have provided only general guidance on determining risk rather than an exhaustive test.[206]

Comment: Several commenters strongly disagreed with the 2022 NPRM preamble language that stated that a State Medicaid program would generally not be required to provide a new benefit because that would fundamentally alter the nature of the program. Commenters noted that a State Medicaid program or other covered entity may have to expand its HCBS waiver programs or modify eligibility for particular services where necessary to satisfy the integration provision, and that there are many situations in which a State program has been required to create a ''new'' community-based benefit, where that benefit was previously only available in institutional settings. For example, commenters stated that a covered entity that provides for residential treatment for certain substance use disorder conditions and does not provide coverage of such services in appropriate community-based settings may need to create a ''new benefit'' by offering an existing institutional benefit in the community.

Response: After considering these comments, we clarify here that while a State Medicaid program is not required to create ''new'' programs to assist people with disabilities, nor are states required to provide a particular standard of care or level of benefits, covered entities must nevertheless adhere to section 1557's disability nondiscrimination requirements—including the integration requirement—with regard to the services they in fact provide. When a covered entity chooses to provide a service, it must do so in a nondiscriminatory fashion by ensuring access to that service in the most integrated setting appropriate to the needs of the qualified individual.[207] States may be required to offer services in an integrated setting that they have only been offering in segregated settings; that is not offering a ''new service,'' but instead is ensuring the service is offered in integrated settings and not just in segregated settings.[208]

[202] *See, e.g., Waskul* v. *Washtenaw Cnty. Cmty. Mental Health,* 979 F.3d 426, 460–62, (6th Cir. 2020) (''Plaintiffs may thus state a claim by sufficiently alleging that they are at serious risk of institutionalization''); *Steimel* v. *Wernert,* 823 F.3d 902, 911–12 (7th Cir. 2016) (agreeing that the mandate applies to ''persons at serious risk of institutionalization or segregation''); *Davis* v. *Shah,* 821 F.3d 231, 262–64 (2d Cir. 2016) (''We thus hold that a plaintiff may state a valid claim . . . by demonstrating that the defendant's actions pose a serious risk of institutionalization for disabled persons.''); *Pashby* v. *Delia,* 709 F.3d 307, 322 (4th Cir. 2013) (individuals state claims under the ADA and the Rehabilitation Act when ''they face a risk of institutionalization''); *M.R.* v. *Dreyfus,* 663 F.3d 1100, 1117–18 (9th Cir. 2011), *amended by* 697 F.3d 706 (9th Cir. 2012) (plaintiff must ''show that the challenged state action creates a serious risk of institutionalization''); *Fisher* v. *Okla. Health Care Auth.,* 335 F.3d 1175, 1181–82 (10th Cir. 2003) (plaintiffs who ''stand imperiled with segregation'' because of state action may state a claim under the ADA's integration mandate); *but see U.S.* v. *Miss.,* No. 21–60772, 2023 WL 6138536, at *5–*9 (5th Cir. Sep. 20, 2023) (rejecting the United States' at-risk *Olmstead* claim).

[203] *See supra* footnote 202 (citing cases).

[204] 335 F.3d 1175, 1181 (10th Cir. 2003).

[205] *See, e.g., U.S.* v. *W.T. Grant Co.,* 345 U.S. 629, 633 (1953) (explaining that ''[t]he purpose of an injunction is to prevent future violations'' and that such relief is appropriate where there is a ''cognizable danger of recurrent violation.'').

[206] For example, in *Davis* v. *Shah,* 821 F.3d 231, 262–63 (2d Cir. 2016), the court quoted DOJ, noting that ''a plaintiff 'need not wait until the harm of institutionalization or segregation occurs or is imminent' '' to bring a claim under the ADA. A plaintiff establishes a ''sufficient risk of institutionalization to make out an *Olmstead* violation if a public entity's failure to provide community services . . . will likely cause a decline in health, safety, or welfare that would lead to the individual's eventual placement in an institution.'' *See also Waskul* v. *Washtenaw Cnty. Cmty. Mental Health,* 979 F.3d 426, 462 (6th Cir. 2020) (finding ''declines in health, safety, or welfare'' as to sufficient to show plaintiffs were at serious risk of institutionalization).

[207] *See Olmstead,* 527 U.S. 581, 603 (1999); *see also Radaszewski* v. *Maram,* 383 F.3d 599, 609 (7th Cir. 2004) (citing *Olmstead,* 527 U.S. at 603 n. 14, for the principle ''that States must adhere to the ADA's nondiscrimination requirement with regard to the services they in fact provide'') (''While 'a State is not obligated to create new services,' it 'may violate Title II when it refuses to provide an existing benefit to a disabled person that would enable that individual to live in a more community-integrated setting.'").

[208] *See* U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.,* Question 8 (February 28, 2020), *https://www.ada.gov/olmstead/q&a_olmstead.htm* (stating that ''(p)ublic entities cannot avoid their obligations under the ADA and Olmstead by characterizing as a ''new

Continued

OCR clarifies that a program providing community-based services that are already available in institutional settings is not a new program for purposes of evaluating a fundamental alteration defense.[209] In addition, states may be required to offer services in an integrated setting that have only been offered in a segregated setting. Providing services beyond what a State currently covers under its Medicaid program may not be a fundamental alteration under § 92.205 (Requirement to make reasonable modifications), and existing nondiscrimination law, including section 504 and the ADA,[210] may require states to provide those services, under certain circumstances. In addition, to the extent that a benefit, including an optional benefit, is already provided in institutions as part of the State's program, the same or a substantially similar benefit must be offered in the community in a manner that does not incentivize institutional services over community services.

Comment: OCR received many comments in response to our request for comment on the application of the integration provision to State Medicaid programs. A number of comments related to Medicaid program designs required by title XIX of the Social Security Act. One commenter recommended that any action by a State Medicaid authority to reduce the existing scope of Medicaid-funded home and community-based long term services and supports, or to more strictly limit eligibility for them, that would have the effect of forcing people with disabilities who currently do, or could, live in their own homes and participate in unrestricted community activities into segregated, congregate, and/or institutional residential or day settings, or to cease their current level of community participation, on the basis of any general categorization of disability would be discriminatory under this provision.

Response: We appreciate the many comments highlighting potential issues related to community integration and State Medicaid programs. This rule does not impact the ability of states to target benefits under section 1915(c), section 1915(i), or section 1937 of the Social Security Act, consistent with Medicaid law. At the same time, the fact that a State chooses to use a Medicaid authority to target a particular disability population does not relieve a State of its obligations towards other populations. We will continue to work with our partners in CMS to ensure the robust provision of services in a nondiscriminatory manner to the maximum extent possible. We remind covered entities that obligations under the Medicaid statute are distinct from obligations under section 1557, and compliance with Medicaid requirements does not per se constitute compliance with section 1557.

Comment: A significant number of commenters raised concerns with ''use-in-the-home'' policies, where an insurance issuer will cover the provision of a benefit or service solely for use ''in the home.'' For example, commenters discussed that a covered entity might offer supplemental oxygen equipment for use in the home but decline to provide sufficient oxygen or equipment for an individual to access the broader community. Similarly, commenters noted that issuers might decline to cover medically necessary wheelchairs with functions that an individual needs to access the broader community outside their home. Commenters also provided examples of other kinds of medical diagnostic equipment, durable medical equipment, and home-use devices that are often not covered, but which would replace services provided in an institution and enable individuals to receive care in their home and community.

Commenters expressed concern that many State Medicaid programs, delegated managed care companies, and employer-sponsored private health plans have adopted the Medicare Mobility Assistive Equipment Coverage Policy [211] (a policy designed specifically to apply in the context of Medicare Part B) as their policy, despite what commenters see as the statutory differences between Medicare Part B and other authorities. Commenters contended that the unnecessary and unmandated adoption of such a policy in all programs unnecessarily restricts benefits to a low bar, denying people the ability to live in the most integrated setting possible.

Response: We appreciate the concerns raised by commenters. Each covered entity should review any legal authority governing the coverage they may provide to ensure that they are not interpreting it in a manner that results in discrimination. For example, Medicaid programs that impose homebound or ''in-the-home'' criteria that are not statutorily required under Federal law may be unnecessarily restricting services in the community in violation of civil rights laws. Where an in-the-home restriction is included in a statute, covered entities may not automatically deny coverage for any good or service that may also have use outside of the home, but must assess each claim to determine whether the denial will violate the most integrated setting requirement.

Comment: Many commenters expressed the need for § 92.207(b)(6), due to states increasingly turning to managed care plans to deliver Medicaid benefits. These commenters expressed concern that large issuers that administer a range of private employer plans and individual plans, as well as public Medicare and Medicaid plans, could employ uniform coverage policies across their plans that do not adequately support community integration. Commenters additionally noted that that Medicaid agencies should monitor whether Medicaid Managed Care Organizations (MCOs) are appropriately authorizing services in the community and that under current law states contracting with MCOs cannot escape liability when MCOs discriminate against people with disabilities.

Response: We appreciate the concerns raised by commenters. We recognize the increasing reliance on alternative payment models for the delivery or management of services to individuals with disabilities. The shift towards managed care in State Medicaid programs and other changes, such as quality incentives, quality assurance activities, and risk-sharing arrangements, requires addressing unnecessary segregation in these emerging models in this rule.

As we noted in the Proposed Rule, 87 FR 47873, covered entities designing contracts with MCOs, pharmacy benefit managers, or other third-party entities taking on financial risk for the delivery of health services should carefully scrutinize their capitation,

service'' services that they currently offer only in institutional settings.''); *see also Townsend* v. *Quasim,* 328 F.3d 511, 517 (9th Cir. 2003) (''Here, the precise issue is not whether the state must provide the long term care services sought by Mr. Townsend and the class members—the state is already providing these services—but in what location these services will be provided.'').

[209] *See Townsend,* 328 F.3d at 517 (''[c]haracterizing community-based provision of services as a new program of services not currently provided by the state fails to account for the fact that the state is already providing those very same services. If services were to constitute distinct programs based solely on the location in which they were provided, *Olmstead* and the integration regulation would be effectively gutted.'').

[210] While this final rule periodically references the ADA and section 504, the requirements under this rule are under section 1557, a separate legal authority. Accordingly, the integration requirements, like other requirements under this section 1557 rule, do not limit or impact the interpretation of integration requirements under the ADA and section 504.

[211] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *National Coverage Determination, Mobility Assistive Equipment (MAE)* (2005), *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=219.*

reimbursement, quality measurement, and incentive structures to ensure that they do not result in the unjustified segregation of individuals with disabilities or place individuals with disabilities at serious risk of institutionalization or segregation. When responsibility for services is shared across multiple entities, for example, under a managed care contract, both the State Medicaid agency and the contracted entity have obligations under this provision if they are both recipients of Federal financial assistance.

Comment: Many commenters discussed challenges related to mental health services, noting that the lack of available and funded community alternatives to institutional mental health care will continue to result in the institutionalization of individuals with serious mental illness, whether in hospitals, inpatient psychiatric facilities, prisons, or other secure facilities.

Many commenters voiced concern related to discharge planning, as people requiring intensive mental health services are often referred only to institutional or otherwise congregate care options, rather than comparably intensive services in community-based settings. Commenters recommended that OCR clarify that this can constitute a violation of the integration provision if it forces people with psychiatric disabilities to enter segregated settings in order to receive access to adequate services.

Other commenters discussed the disparity in access to community-based care for children who need mental health care.

Response: OCR appreciates the significant concerns related to the availability of community-based behavioral health services, particularly services to address youth mental health. With respect to discharge planning, a hospital or acute care provider that routinely discharges individuals with disabilities, including those with serious mental illness, to nursing homes, psychiatric residential treatment facilities, or other segregated care settings due to discharge planning procedures that do not assess for home-based support services or refer individuals to community-based providers may violate this provision. Covered entities are prohibited from implementing planning, service system design, and service implementation practices that result in the serious risk of institutionalization or segregation.

Comment: Several commenters provided insight into the relationship between community integration and reimbursement rates necessary to sustain a direct care workforce. Commenters explained that individuals receiving care in the community often fail to receive all of the hours of care for which they are approved due to a lack of provider capacity to fully staff the approved hours. Commenters noted that nurse's aides and other individuals who provide assistance in institutional settings are often paid at a higher rate than home health aides and other direct care professionals, resulting in an imbalanced direct care workforce. Commenters emphasized the importance of rate setting to incentivize HCBS.

Response: Reimbursement rates and network adequacy both constitute methods of program administration. As such, these are factors that OCR would consider as reimbursement practices or methods of administration related to this provision.

Comment: Commenters suggested additional guidance clarifying implementation of this provision, including incorporating DOJ's guidance on enforcement of the integration requirement under title II of the ADA describing how to provide the most integrated setting appropriate for an individual or group of individuals; [212] addressing the remedies available for violations of the integration provision; and explaining how OCR will undertake a fundamental alteration analysis. One commenter recommended incorporating the fundamental alteration defense into regulatory text. Commenters underscored the importance of setting a high bar for a fundamental alteration, noting that programs must alter an essential aspect of the health program or activity. Other commenters urged OCR to clarify how the fundamental alteration analysis applies to the integration provision, including whether and how OCR will incorporate DOJ guidance and case law related to the ADA's fundamental alteration defense for ADA title II entities. Commenters also requested clarification on whether covered entities will be required to establish an *Olmstead* integration plan [213] to raise the fundamental alteration defense, and if so, guidance related to that requirement.

Commenters also asked OCR to explain in future guidance how covered entities, including Medicaid programs, must coordinate community-based primary care and specialty mental health care and offer case management to avoid discrimination on the basis of disability and to avoid placing individuals with mental disabilities at serious risk of institutionalization.

Commenters further suggested guidance to covered entities explaining the specific HCBS that are essential to achieving compliance with the integration requirement, including as part of EHB. Commenters suggested that it would be discriminatory if EHB plans set higher reimbursement rates for a service or item for individuals in segregated settings rather than community-based settings; if rehabilitation services for physical conditions are covered, but not psychiatric rehabilitation services; and if a particular benefit (such as personal care services) is offered in greater amounts to individuals in segregated settings by virtue of the plan benefit design.

Finally, commenters encouraged OCR to develop joint guidance with DOJ on section 1557, section 504, and titles II, III, and IV of the ADA to ensure the rights of people with disabilities to access community integration in health care settings.

Response: We appreciate the comments requesting clarification through sub-regulatory guidance. We will consider future guidance after this rule has been finalized and are committed to our continued partnership with DOJ in developing shared guidance on civil rights requirements. The availability of the fundamental alteration defense is clear as drafted and so we decline to specifically incorporate this recommendation into regulation text. In this final rule, we clarify that a program is not required to provide coverage for a service in the most integrated setting appropriate to an individual's needs if it would fundamentally alter the program to do so.

Comment: Commenters, primarily representatives of the insurance industry, supported proposed § 92.207(c) that specified nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage

[212] U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.* (June 22, 2011), *https://www.ada.gov/olmstead/q&a_olmstead.htm.*

[213] Under the ADA, an *Olmstead* plan is a public entity's plan for implementing its obligation to provide individuals with disabilities opportunities to live, work, and be served in integrated settings. U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.* (June 22, 2011), *https://www.ada.gov/olmstead/q&a_olmstead.htm.*

requirements, such as medical necessity requirements, in an individual case. Commenters appreciated that OCR acknowledged that a covered entity's legitimate, nondiscriminatory reason for its actions may serve as a defense under this section.

Some commenters requested clarification that use of the phrase ''legitimate, nondiscriminatory reason'' not be construed in any way to limit the method of proof for any section 1557 claim to the *McDonnell Douglas* burden-shifting framework; that this method cannot be used to defend an express sex classification that causes injury; that the familiar but-for causation test applies to establishing a violation of section 1557; and that the *McDonnell Douglas* burden-shifting framework and legitimate nondiscriminatory reason framework apply to circumstantial evidence cases but not where there is direct evidence of discrimination.

Response: OCR appreciates commenters' support of this provision. As discussed throughout this section and in the Proposed Rule, in instances where there is not a facially discriminatory policy and OCR is investigating whether a particular action or practice is discriminatory under this rule, covered entities have the opportunity to defend the challenged action or practice by providing a legitimate, nondiscriminatory reason for its actions that is not pretext for discrimination. OCR will then evaluate whether the reason given by the covered entity is a pretext for prohibited discrimination. When considering whether a proffered reason is pretextual, OCR will consider, among other things, whether a denial of a health service is based on medical necessity standards or other reasonable medical management techniques that are not discriminatory, as discussed in more detail below.

To provide additional clarity about OCR's analysis when evaluating whether a covered entity's legitimate, nondiscriminatory reason is pretextual, OCR is revising § 92.207(c) to state that a covered entity's denial or limitation of a health service must not be based on unlawful animus or bias, or constitute a pretext for discrimination. This modification is consistent with the revised language in § 92.206(c). Under either section, in instances where there is no evidence of a facially discriminatory policy, covered entities may assert a legitimate, nondiscriminatory basis for actions that could otherwise give rise to the inference of discrimination. Consistent with general principles of civil rights law, OCR will consider such asserted bases but may also investigate to determine whether such asserted bases are pretextual and whether there is evidence that the challenged action was taken because of unlawful animus, bias, or other discriminatory factors.

In evaluating claims of discrimination, OCR relies on general nondiscrimination principles and longstanding civil rights case law. Such principles include, but are not limited to, the multi-factor test articulated in *Arlington Heights* and the *McDonnell Douglas* burden-shifting framework, which were discussed in detail in the Proposed Rule at 87 FR 47865. *Arlington Heights* sets forth a method of proof that utilizes different types of evidence that collectively may demonstrate that a covered entity acted, at least in part, because of a protected basis. The *McDonnell Douglas* burden-shifting framework is an inferential method of proof used to show that a covered entity treated similarly situated individuals differently because of a protected basis. Under *McDonnell Douglas,* where non-facial evidence of discrimination exists, a covered entity must articulate a legitimate, nondiscriminatory reason for its actions. The entity's legitimate, nondiscriminatory reason may refute the evidence of discrimination, unless it can be established that this reason is a mere pretext for prohibited discrimination. In response to the commenters' concerns about how § 92.207(c) may be interpreted inconsistently with the principles set forth in *McDonnell Douglas* and other civil rights principles, please see our response to the same comments under § 92.206 in which we affirm commenters' interpretations are correct—*McDonnell Douglas'* burden-shifting framework and legitimate nondiscriminatory reason framework apply to circumstantial evidence cases but not in cases where there is direct evidence of discrimination based on a facially discriminatory policy.

Comment: Some commenters appreciated OCR clarifying that medical management techniques based on clinical evidence are permitted, including the use of reasonable medical necessity and utilization management techniques based on clinical standards and evidence-based guidelines, when applied in a neutral manner. Commenters noted that medical management tools provide an important role in promoting quality care and reducing health care costs.

Other commenters raised concerns about medical necessity criteria and other medical management tools, noting that such tools may limit access to needed services and treatment. Commenters noted that discriminatory decisions often occur under the guise of medical necessity determinations. Some commenters argued that medical management practices such as prior authorization, step therapy, and durational or quantity limits are inherently discriminatory and inconsistent with patient health and safety. Many commenters strongly supported OCR clarifying that excessive use or administration of benefit utilization management tools that target particular disabilities could violate section 1557. Commenters asked OCR to expressly note the limitation on the use of utilization management tools in the text of the regulation.

Commenters asked OCR for examples of excessive medical management and suggested the following examples: requiring step therapy for new enrollees who are already on a working course of treatment; transferring management of particular medicines to niche vendors that apply more extensive medical management through specialty carve-out programs; requiring the use of off-label medications within step therapy; and imposing categorical prior authorization and step therapy requirements on most or all drugs required to treat a particular disease. Commenters noted that issuers apply such medical management techniques to discourage individuals with high-cost needs from enrolling in their plans. A commenter cited evidence that plans have restricted access to lower-cost brand drugs and generics when demand for those drugs attracts patients who have overall high health costs.[214] Other commenters noted that information about treatment limitations can be difficult to find for enrollees and cited evidence of issuers building arbitrary coverage denials into their business plans.[215] Commenters cited a study that found that more than half of step therapy policies developed by commercial health plans were more

[214] Michael Geruso et al., *Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges,* 11 a.m. Econ. J.: Econ. Pol. 2, 64–107 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8130799/.*

[215] Karen Pollitz et al., *Claims Denials and Appeals in ACA Marketplace Plans in 2021,* Kaiser Family Found. (2022), *https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/* (finding nearly 17 percent of in-network claims in non-group qualified health plans were denied in 2021; insurer denial rates varied widely around this average, ranging from 2 to 49 percent; about 14 percent were denied because the claim was for an excluded service, 8 percent were due to lack of preauthorization or referral, 2 percent were based on medical necessity, and 77 percent were classified as ''all other reasons'').

restrictive than recommended clinical guidelines.[216]

Some commenters requested that OCR revise the text of § 92.207(c) to state that, in addition to medical necessity requirements, covered entities may employ reasonable medical management techniques.

Response: OCR appreciates the variety of comments and recommendations put forth by commenters related to the rule's coverage of medical management techniques, including medical necessity standards and utilization management techniques.

OCR agrees that revising the regulatory text to reference reasonable medical management techniques would provide clarity and would be consistent with other provisions in the ACA and the Proposed Rule. Therefore, OCR is revising § 92.207(c) to state that applicable coverage requirements include reasonable medical management techniques, including medical necessity.

Further, as stated in the Proposed Rule, covered entities are not prohibited from employing reasonable medical management techniques as long as they are not discriminatory and are not otherwise prohibited under other applicable Federal and State law. 87 FR 47873–74. As just one example, covered entities participating in the Medicaid program under title XIX of the Social Security Act are not prohibited from implementing nondiscriminatory utilization management techniques, such as prior authorization.[217]

Under § 92.207(c), an issuer may assert a legitimate, nondiscriminatory reason for its denial or limitation of coverage of a health service that asserts the denial was based on medical necessity standards—or any other medical management technique. When assessing whether the challenged action was based on prohibited discrimination rather than on nondiscriminatory medical necessity standards, OCR will review a medical necessity determination only to make sure that it is a bona fide medical judgment, not conduct a review of the medical judgment underlying the medical necessity determination, but rather will assess whether the rationale for the denial was based on impermissible discriminatory considerations. In its review, OCR may require a covered entity to provide the following information: its medical necessity standards or guidelines; the clinical, evidence-based criteria or guidelines [218] relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination. As discussed previously, OCR will evaluate a covered entity's assertion that its actions were based on legitimate, nondiscriminatory reasons to determine if it is pretextual. Medical necessity determinations that are not based upon general medical judgments or based on clinical, evidence-based criteria or guidelines may be considered evidence of pretext for discrimination.

Similarly, as noted in the Proposed Rule, 87 FR 47872, we affirm that covered entities are not prohibited from using other reasonable medical management techniques, such as utilization management tools, when applied in neutral, nondiscriminatory manner and not otherwise prohibited under other applicable Federal and State law. Utilization management techniques include prior authorization,[219] step therapy (or ''fail-first''),[220] and durational or quantity limits.[221]

OCR shares commenters' concerns about potentially discriminatory practices related to medical management techniques and the negative impacts of excessive utilization management. As such, when relying on medical necessity requirements and other medical management techniques to deny coverage for a health service, covered entities must ensure that such tools are developed and applied in a neutral, nondiscriminatory manner. OCR would have concerns about guidelines that establish more restrictive requirements for certain diseases or conditions without a nondiscriminatory justification. In addition, OCR expects that limitations within such guidelines should be applied consistently with clinical standards within each patient population disease state, condition level, and diagnostic category to ensure equal clinical treatment across protected bases. That is, all patients diagnosed with a particular disease state must receive the same treatment that is deemed clinically appropriate, regardless of their race, color, national origin, sex, age, or disability.

We affirm that excessive use or administration of utilization management practices that target a particular condition that could be considered a disability or other prohibited basis under section 1557 could be discriminatory under this rule. OCR declines to state in preamble or regulatory text that specific practices are per se discriminatory under section 1557. As discussed throughout this section, OCR must conduct a fact-specific inquiry into allegations of discriminatory actions and consider a covered entity's proffered reason for the challenged action.

Comment: OCR received a number of comments discussing costs as a legitimate, nondiscriminatory reason for benefit designs under § 92.207(c). Commenters supported the rule allowing clinical evidence to support a benefit design and requested that OCR allow covered entities to use extraordinary costs as justification for certain benefit designs. Commenters stated that covered entities use utilization management controls, such as drug tiering, as part of their benefit design to keep coverage affordable. Commenters noted concerns that high-cost drugs or other services could lead to health plans becoming insolvent if they are unable to apply utilization management controls where all treatments for a particular condition are high cost, particularly when they are expensive new drugs or gene therapies. Commenters argued that issuers and plans must retain some flexibility in their approach to covering and paying for high-cost drugs and services. Commenters expressed concern that § 92.207 would prohibit covered entities from having utilization management controls on all or most drugs or services

[216] Kelly L. Lenahan et al., *Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans,* 40 Health Affairs 11, 1749–57 (2021), *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.00822?journalCode=hlthaff* (finding that plans applied step therapy in 38.9 percent of drug coverage policies, with varying frequency across plans (20.6–57.5 percent); 34.0 percent were consistent with corresponding clinical guidelines, 55.6 percent were more stringent, and 6.1 percent were less stringent).

[217] *See, e.g.,* 42 U.S.C. 1396r–8(d).

[218] *See also* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27296–300 (May 6, 2022) (discussing newly promulgated 45 CFR 156.125(a), which states ''[a] non-discriminatory benefit design that provides [EHB] is one that is clinically-based'').

[219] Medicare defines ''prior authorization'' as ''the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.'' 42 CFR 419.81 (Medicare definition of ''prior authorization'' for hospital outpatient department services). *See also* Ctrs. for Medicare & Medicaid Servs., *Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services Frequently Asked Questions (FAQs),* Q1 (Dec. 27, 2021), *https://www.cms.gov/files/document/opd-frequently-asked-questions.pdf.*

[220] Medicare defines ''step therapy'' for the Medicare Advantage Program as a ''utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.'' 42 CFR 422.2.

[221] Durational or quantity limits place limits on the frequency or number of benefits to be provided, such as limiting therapy visits to once per week or limiting prescription drug coverage to a 30-day supply of a medication.

that treat a particular condition or disease, regardless of their cost, and asked OCR to affirm that placing all treatments for a certain disease or condition in one tier may not in fact be discriminatory by default, but rather an appropriate benefit design due to the high cost of those particular items or services.

Conversely, other commenters asked OCR to clarify that covered entities cannot justify benefit designs that disfavor coverage for medically necessary services based on cost savings. Commenters noted that as costs of medications and therapies have increased, covered entities have significantly increased the use of utilization management, including adding arbitrary prior authorization processes not based in clinical evidence for new cancer therapies. They added that rare disease patients face the additional challenge of having no or few treatment alternatives if a preferred medication or therapy is not covered.

Response: OCR reiterates that § 92.207 does not prohibit a covered entity from engaging in reasonable utilization management techniques applied in a neutral, nondiscriminatory manner and that are not otherwise prohibited under other applicable Federal and State law. As noted above, excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate section 1557. Where there is an alleged discriminatory practice or action that is not based on a facially discriminatory policy, § 92.207(c) provides that the covered entity has the opportunity to provide a legitimate, nondiscriminatory reason for the practice. Covered entities are not restricted in what information they elect to provide to OCR as part of their justification for the challenged practice or action. OCR will carefully review a covered entity's proffered reason to ensure it is not pretext for discrimination.

OCR discussed previously that determinations on whether a particular benefit design feature is discriminatory, such as utilization management or drug tiering, will be made on a case-by-case basis. Accordingly, OCR declines to specify whether certain benefit design practices are per se discriminatory.

Comment: One organization raised concerns that OCR is asserting *de facto* authority over the relationship between health insurance and medical care, and that OCR is asserting that it has authority under section 1557 to regulate the practice of medicine and the structure of health insurance coverage according to its own determination of what is ''appropriate'' and ''nondiscriminatory,'' along with the authority to definitively determine what is, or is not, the current standard of medical care. The commenter further states that OCR may in the future assert and exercise similar claims of authority with respect to other medical practices, standards of care, or health insurance coverages.

Response: As previously discussed throughout this preamble, section 1557 was intended to prohibit discrimination in health insurance coverage and other health-related coverage, as the statute's plaint text makes apparent. Congress expressly granted the Secretary the authority to promulgate regulations to implement section 1557. 42 U.S.C. 18116(c). Therefore, OCR is acting within its statutory authority in promulgating this final rule to regulate health insurance coverage or other health-related coverage provided or administered by a recipient health insurance issuer or other covered entity. OCR disagrees with the commenter that this rule establishes a standard of medical care, or requires certain health insurance coverages. As specified in the preceding discussion, when assessing whether a challenged action was based on prohibited discrimination rather than on nondiscriminatory medical necessity standards, OCR will not conduct a general review of the medical judgment underlying the medical necessity determination, but rather will assess whether there is facial or other direct evidence of discriminatory intent or if a proffered rationale for the denial was pretext for discrimination. Further, this final rule does not require coverage of a particular health service; rather, it requires that the coverage being offered must be provided in a neutral and nondiscriminatory manner.

Comment: Commenters stated that issuers should provide transparent information on coverage details, utilization management practices, denial rates, and reasons for denials. Specifically, a commenter requested that this section be strengthened by implementing a requirement for health plans to disclose medical necessity determinations when care or coverage is denied based on medical necessity to individual enrollees. The commenter further suggested that OCR adopt the approach in the MHPAEA final rule, requiring disclosure of medical necessity criteria to potential beneficiaries or enrollees and the reasons behind denials of coverage or reimbursement. Commenters emphasized that disclosure would help providers and consumers to identify and challenge discriminatory denials of medically necessary care, which can be difficult to do when data regarding the coverage they need either does not exist or the issuer holds the data on details of coverage, denial rates, and reasons for denial.

Response: OCR agrees with commenters that transparency about medical management policies and coverage determinations and denials is useful information for the public, and we encourage issuers to disclose such information to all enrollees. OCR considered requiring issuers to affirmatively disclose certain plan information to the public, but we decline to do so at this time. We have determined that placing a transparency requirement on health insurance issuers covered under section 1557 would not be helpful on issuers if required in every situation, and because the scope and application of section 1557 is broader than, and imposes different requirements from, MHPAEA. We stress that OCR has the authority to request and receive information from a covered entity on the details of coverage, medical management policies, denial rates, and reasons for denials, among other things, when necessary to determine compliance with section 1557.[222] In addition, we note that appeals processes that subject individuals protected by section 1557 to excessive administrative burdens in accessing coverage benefits that other enrollees are not required to navigate when accessing coverage may be discriminatory under section 1557.

Comment: OCR received many comments on the use of value assessment methods in benefit design and pricing and coverage decisions, and their impacts on treatments for people with disabilities and older adults, particularly in access to prescription drugs and benefit design. Commenters suggested that some payers use these assessment methods to steer patients away from newer or more innovative treatments to less effective options. Commenters on this issue appreciated OCR's recognition in the Proposed Rule that these methods can have discriminatory impacts, though commenters did not provide uniform input about how to address these impacts.

Several commenters called for increased oversight of value assessment methods by OCR, and some called on OCR to ban the use of the quality-

[222] 45 CFR 92.303 (section 1557); 80.6 (title VI); 84.61 (section 504, incorporating title VI's § 80.6); 86.71 (title IX, incorporating title VI's § 80.6); 91.34 (Age Act).

adjusted life year (QALY) framework and similar methods. Commenters supporting a ban on the use of QALYs stated that these methods are inherently discriminatory because they assign a lesser numerical value to extending the lives of people with disabilities and older adults compared to people without disabilities or younger persons, especially when applied to benefit design or access to prescription drugs.[223]

Response: OCR recognizes that value assessment methods can be helpful tools in making decisions in various contexts within health care and are used widely. The use of value assessment methods that result in discrimination on the basis of race, color, national origin, age, disability and sex are prohibited under section 1557's general mandate of nondiscrimination. That is, where a value assessment uses methods that penalize patients or groups of patients on a ground protected by section 1557 and where such methods then result in limiting access to an aid, benefit, or service, they may violate section 1557. In response to commenters, we note that value assessment tools cannot be used to, to deny or afford an unequal opportunity to qualified individuals with disabilities or on the basis of age with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available. We further note that methods of value assessment are permissible so long as they do not discriminate in discounting the per-year value of life extension on the basis of age or disability under section 1557.

In addition, OCR has proposed a prohibition against the discriminatory use of value assessment methods in pending rulemaking under section 504. 88 FR 63409. Proposed § 84.57, which applies to recipients of Federal financial assistance from HHS, prohibits, directly or through contractual, licensing, or other arrangements, using any measure, assessment, or tool that discounts the value of life extension on the basis of disability to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available.

Given that many different measures exist for use in value assessment and may be applied in different ways, this discussion applies to evaluating any value assessment methodology rather than commenting on specific measures at this time. However, we appreciate the concerns raised by the commenters and will take them into account as OCR proceeds with future work on value assessment.

Comment: Many comments on value assessment also requested further development of new value assessment measures and the incorporation of input from patients with disabilities (and, per some commenters, their family members and providers) into value assessment schema. Commenters urged the Department to support the development and dissemination of these methodologies. Another commenter noted that cultural barriers existed in institutions that prevented the adoption of new metrics.

Response: OCR appreciates commenters' input and encourages and supports the development of such metrics and the incorporation of input from people with disabilities and other interested groups protected under section 1557, as reflected in research priorities elsewhere in the Department. Numerous research and grantmaking initiatives from the National Institutes of Health (NIH) and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) support this and similar efforts.[224] In addition, OCR notes that the National Council on Disability issued an updated policy brief released in November 2022.[225]

Benefit Design Analysis

The comments and our responses regarding benefit design are set forth below.

In the Proposed Rule, we discussed that OCR will apply basic nondiscrimination principles to the facts of the particular plan or coverage when analyzing allegations of discrimination under this section to determine if the challenged action is unlawful. We discussed that, consistent with general principles in civil rights law, covered entities will have the opportunity to articulate a legitimate, nondiscriminatory justification for an alleged discriminatory action or practice, and that OCR will scrutinize the justification to ensure it is not a pretext for discrimination.

Comment: Some commenters requested that OCR provide additional guidance explaining how it intends to investigate potential violations by health programs or activities engaged in providing or administering health insurance coverage or other health-related coverage and to ensure ongoing compliance with Federal law. Commenters urged OCR to establish clear, predictable standards that covered entities can rely upon when designing their plans and that will ensure OCR's ''case-by-case'' analysis does not result in only retroactive reviews of existing plans or lead to arbitrary results.

Another commenter noted that if OCR will not provide presumptively discriminatory benefit design examples, OCR should provide more information to educate covered entities about what OCR interprets to be best practices other than the information, corrective plans, and resolution agreements it stated it would publish on its website in the 2016 Rule. The commenter urged OCR to publicly publish deidentified information on each and every investigation that it pursues, including the specific actions purported to be discriminatory by a covered entity, the alleged basis of discrimination, and OCR's resolution of the complaint so that covered entities can educate themselves on best practices and actions that OCR may deem to be discriminatory.

Response: We appreciate the comments requesting further specificity regarding OCR's analysis when investigating potential violations under this section. We agree that providing clarity to covered entities promotes compliance and reduces prohibited discrimination. Each potentially discriminatory action involves unique

[223] These concerns were also highlighted in testimony at a recent Congressional hearing on proposed legislation to ban the use of QALYs in all Federal health programs. *See Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities: Hearing on H.R. 467, H.R. 498, H.R. 501, and H.R. 485 Before the Subcomm. on Health of the H. Comm. on Energy & Com.,* 118th Cong. (2023) (statement of Kandi Pickard, President & CEO, Nat'l Down Syndrome Society), *https://d1dth6e84htgma.cloudfront.net/Witness_Testimony_Pickard_HE_02_01_2023_065c903370.pdf?updated_at=2023-01-30T21:38:38.787Z* (speaking on her support of Protecting Health Care for All Patients Act, H.R. 485, 118th Cong. (2023)).

[224] Funding Opportunity Announcement, U.S. Dep't of Health & Hum. Servs., Nat'l Insts. of Health, *NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Cohort (U54 Clinical Trial Optional)* (December 8, 2020), *https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-20-022.html*; U.S. Dep't of Health & Hum. Servs., Adm. for Cmty. Living, *Disability and Rehabilitation Research Projects (DRRP) Program, https://acl.gov/programs/research-and-development/disability-and-rehabilitation-research*; U.S. Dep't of Health & Hum. Servs., Nat'l Insts. of Health, *All of Us Research Program, https://allofus.nih.gov/*.

[225] Nat'l Council on Disability, *Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions* (2022), *https://www.ncd.gov/report/alternatives-to-qaly-based-cost-effectiveness-analysis-for-determining-the-value-of-prescription-drugs-and-other-health-interventions/*.

facts and circumstances that must be independently investigated on a case-by-case basis before OCR can determine whether a challenged action is considered discriminatory under this section, particularly considering that each covered entity's reason for engaging in the challenged action may be specific to that covered entity and the circumstances surrounding its decision process. For example, when determining whether a challenged design feature is discriminatory, OCR considers the benefit design of the plan as a whole, whether similar limitations or restrictions are placed on other types of health services, and whether the covered entity consistently relies on neutral, nondiscriminatory criteria when developing the design feature, among other things. Therefore, OCR reaffirms the investigative approach set forth in the Proposed Rule, 87 FR 47875, whereby OCR's determination of whether a challenged action is discriminatory is necessarily a fact-specific, case-by-case analysis dependent on the facts of the particular situation. When analyzing whether an action violates this section, OCR will apply basic nondiscrimination principles to the facts of the particular health insurance coverage or other health related coverage, consistent with civil rights case law. This includes the opportunity for covered entities to articulate a legitimate, nondiscriminatory justification for an alleged discriminatory action, which OCR will scrutinize to ensure it is not a pretext for discrimination. Where a covered entity's justification relies upon medical standards or guidelines, we note that such standards or guidelines may be subject to additional scrutiny if they are not based on clinical, evidence-based criteria or guidelines. For more information related to OCR's consideration of a covered entity's legitimate, nondiscriminatory reason, please see previous discussion under § 92.207(c).

OCR reiterates that this rule does not require a covered entity to provide coverage for any particular health service in its health insurance coverage or other health-related coverage when provided in a nondiscriminatory manner; however, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

Regarding our analysis when investigating potential discrimination in the benefit design of excepted benefits and short-term, limited duration insurance (STLDI), we provide additional information below in the discussion under this section on *Scope of Application to Health Insurance and Health-Related Coverage (Including Excepted Benefits and STLDI).*

OCR acknowledges that the nature of our complaint-driven investigative process results in OCR reviewing existing plans and making determinations on the benefit designs of existing plans. However, OCR's case-by-case analysis is necessary in order to consider the fact-specific nature of each challenged action and to apply relevant case law to each situation. OCR investigates each allegation in a consistent manner and treats all complainants and covered entities evenly.

We appreciate commenters' suggestions to provide more information to educate covered entities about what OCR interprets to be best practices; OCR will consider issuing such guidance in the future. To educate both the public and covered entities, OCR posts its resolution agreements on its website and issues press releases when cases are resolved, and we intend to continue this practice.

Comment: Commenters recommended that OCR specify in the final rule that a nondiscriminatory benefit design is one that is clinically based. While expressing support for OCR considering clinical guidelines and standards of care when evaluating plan benefit designs, these same commenters also cautioned that OCR should not exclusively rely on clinical guidelines and journal articles in its analysis of discriminatory design because clinical guidelines may perpetuate racial bias and health disparities, and entities could cite a single peer-reviewed article as a shield to escape valid claims of discriminatory benefit design.

Response: An analysis of whether a benefit design is discriminatory under this rule is a fact-specific inquiry that will be made in accordance with general civil rights principles and applicable case law. As discussed under § 92.207(c), covered entities may provide a legitimate, nondiscriminatory reason as a defense to a potentially discriminatory coverage determination. A covered entity has latitude to submit any legitimate reason for its actions as long as it is not discriminatory or pretext for discrimination. However, if the justification given is not based on clinical, evidence-based criteria or guidelines, OCR will consider that evidence of pretext. When a covered entity submits a justification that relies upon medical standards or guidelines, OCR may conduct additional investigation to ensure the justification is not pretextual, including a review on whether the standards or guidelines are or are not based on clinical, evidence-based criteria or guidelines. OCR's review of a covered entity's justification will not rely solely on a covered entity's provision of one piece of literature but will consider a variety of factors, as discussed in detail above under §§ 92.206(c) and 92.207(c). We further note that OCR will not conduct a general medical review of the medical judgment undergirding the determination.

Comment: Commenters noted that OCR could ensure higher quality health care for all enrollees through stronger oversight and regulation. These commenters urged OCR not to rely solely on complaints and to engage in proactive oversight by affirmatively reviewing covered entities' plan designs.

Response: We agree that robust enforcement of section 1557 is critical to ensure individuals' ability to receive medically necessary health services, unencumbered by discriminatory conduct. OCR will employ all available means of investigating health insurance coverage and other health-related coverage under this rule, including through compliance reviews and complaint investigations.

Comment: Commenters requested that OCR clarify how it will coordinate with State and Federal agencies that establish specific plan requirements and approval processes. Commenters noted that many facets of benefit design are heavily regulated by other agencies within the Department, including CMS' regulation of nondiscriminatory plan design in EHB and qualified health plans, retail pharmacy network adequacy of Medicare Part D plans, and benefit coverage requirements under Medicare Advantage and Medicaid. Commenters suggested that OCR should not enforce a discrimination claim if the underlying design is accepted by the plan's regulator and should defer enforcement action to existing review processes where appropriate. Some commenters also suggested that the Department should establish a safe harbor for health insurance issuers to comply with section 1557 in cases where there are State law interactions to avoid creating multiple or duplicative standards.

Response: OCR acknowledges commenters' concerns about harmonization in the regulation and enforcement of benefit design requirements across State and Federal laws. We note that covered entities offering health insurance coverage and other health-related coverage, such

Medicaid or qualified health plans in the Exchanges, are subject to a host of other laws and regulations, at both the State and Federal level. OCR does not view a covered entity's compliance with other State or Federal laws, which were adopted under different requirements and for different purposes, to be determinative in all cases of a covered entity's compliance with section 1557, unless otherwise specified in this rule.[226] OCR commits to coordinating with other Federal agencies as appropriate to avoid inconsistency and duplication in enforcement efforts and will consider issuing guidance in coordination with other agencies, such as CMS, after publication of the rule. We will give consideration to a covered entity's compliance with other Federal laws when those requirements overlap with section 1557's requirements and will work closely with covered entities when compliance with this final rule requires additional action. That said, as the lead enforcement agency for section 1557, OCR maintains sole authority to determine a covered entity's compliance with this final rule.

Comment: Commenters requested clarity on which covered entity is liable for potentially discriminatory plan benefit designs when several covered entities provide or administer elements of the benefit design. Commenters requested that OCR state that all entities, including third party administrators, benefits advisers, and consultants, that participate in discriminatory plan design with respect to group or individual insurance plans are covered entities under section 1557. A commenter requested that benefits advisers or consultants working with employers to design self-funded group health plans specifically should be considered a covered entity presumptively where the employer, the plan, or the third party administrator receives Federal financial assistance. The commenter noted concern that such advisers and consultants are a driving force behind discriminatory plan design and should be put on notice that their conduct is subject to section 1557 in many circumstances. A commenter requested that OCR make clear that any entity itself covered by section 1557 violates the statute by outsourcing the implementation or design of discriminatory plans to entities that might themselves not be covered by the statute.

Response: OCR clarifies that in situations where multiple covered entities provide or administer elements of a discriminatory benefit design, all of the entities may be found liable under section 1557. In the discussion of the definition of ''Federal financial assistance'' in § 92.4, we explained that both the direct recipient and subrecipient (or subcontractor) are responsible for complying with applicable civil rights laws. We also note that covered entities are responsible for the conduct of their subcontractors and cannot outsource or contract away their civil rights obligations by entering into contractual arrangements with subcontractors. The responsibility of third party administrators is discussed later in this section. As noted, this final rule does not apply to employment practices. *See* § 92.2(b).

Comment: Commenters expressed concern that the proposed regulation may unintentionally limit covered entities' ability to develop effective programs and initiatives to close care gaps and address unique needs to reduce health disparities. Commenters explained that they currently conduct individual outreach to members of a subgroup through care management processes, invest in social determinants of health interventions, tailor marketing to subgroups to address particular health concerns, provide plans that restrict enrollment to special needs individuals with specific chronic conditions, and develop targeted quality programs and chronic care management programs to reduce health disparities for their members. A commenter noted that issuers take those actions to more efficiently provide care to particularly vulnerable populations without an intent to discriminate. Another commenter noted that if health plans are required to provide services that address chronic care, social determinants of care, or other similar programs ''equally'' to all enrollees rather than ''equitably'' target services to those in need based on health or socioeconomic condition, plans will be limited in their ability to provide appropriate services and scale and sustain these programs. To address these concerns, commenters requested that OCR clarify in the final rule that actions taken to reduce health disparities and those designed to improve health for specific populations are not discriminatory for purposes of section 1557. Commenters also recommended that OCR consider an approach similar to language in the Department's Group Health Insurance Market regulations prohibiting prohibition on discrimination based on health status that explicitly permits group health plans and health insurance issuers to treat individuals with adverse health conditions more favorably. 45 CFR 146.121(g).[227]

Response: We appreciate commenters raising this concern and applaud efforts to mitigate and address health disparities. Nothing in this rule prohibits programs designed to improve health outcomes for specific populations so long as the programs do not discriminate on the basis of race, color, national origin, age, sex, or disability. For example, programs could be developed using social determinants of health or other metrics that serve to identify underrepresented individuals that are not based on protected bases under section 1557. To illustrate, a ''Special Needs Plan'' is a specialized Medicare Advantage coordinated care plan that exclusively enrolls ''special needs individuals,'' who are not limited to individuals with disabilities, and do not violate section 1557.[228] In addition, covered entities are permitted and encouraged to develop programs that address health disparities related to a person's age. Under the Age Act and section 1557, age distinctions in programs that provide special benefits to older adults or children are permitted. 45 CFR 91.17 (Age Act); 92.101(b)(1) (section 1557, incorporating 45 CFR 91.17).

Scope of Application to Health Insurance Coverage and Other Health-Related Coverage (Including Excepted Benefits and STLDI)

In the 2022 NPRM, we sought comment on excepted benefits and short-term, limited-duration health insurance (STLDI), and the Proposed Rule's application to these products. Consistent with the definition of ''health program or activity'' under § 92.4, we proposed that the rule would apply to all the operations of any covered entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage. 87 FR 47875–76.[229] As an example, we explained that an issuer participating in the Exchange and thereby receiving Federal financial assistance would be covered by the rule for its qualified health plans offered on the Exchange, as well as for its health

[226] *E.g.,* 45 CFR 92.203, which requires covered entities to comply with certain accessibility requirements in the ADA.

[227] In this final rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[228] *See* sections 1859(b)(6), 1859(f)(2)–(4) of the Social Security Act (42 U.S.C. 1395w–28(b)(6), (f)(2)–(4)).

[229] However, per § 92.2(b), this rule does not apply to employers with regard to their employment practices, including the provision of employee health benefits.

plans offered outside the Exchange, including, for example, large group market plans,[230] grandfathered plans,[231] grandmothered plans,[232] excepted benefits,[233] and STLDI,[234] as well as for its operations related to acting as a third party administrator for self-insured group health plans. 87 FR 47876.

The comments and our responses regarding the scope and application to all operations of a covered health insurance issuer and to excepted benefits and STLDI specifically are set forth below.

Comment: Several commenters, including those representing the health insurance industry and some State insurance regulators, raised concerns about how the Proposed Rule's application to all operations of a recipient health insurance issuer would result in covering an issuer's other operations and lines of business that do not receive Federal financial assistance, including, for example, plans sold off the Exchange, grandfathered plans, grandmothered plans, employer plans, excepted benefits, STLDI, third party administrator activities and pharmacy benefit manager activities. Commenters noted that these plans are treated separately under the ACA and are not subject to some or all of the ACA's health insurance market reforms. Commenters suggested that plans that do not receive Federal financial assistance should not be subject to section 1557. Comments about particular types of plans are discussed in turn below.

Commenters argued the Proposed Rule's application was too broad and went beyond Congressional intent and urged OCR to retain the 2020 Rule's approach that the rule cover a health insurance issuer's operations only to the extent the operations directly receive Federal financial assistance.

In addition, commenters argued that applying the rule to a covered issuer's operations that do not receive Federal financial assistance would create an unlevel playing field among health insurance issuers that accept Federal funding and those that do not, placing those that receive Federal funding at a competitive disadvantage. For example, commenters stated that issuers that do not receive Federal financial assistance may underwrite excepted benefits or STLDI by age or sex, or exclude higher cost health care services, which may result in non-covered entities offering lower-cost coverage to a pool of individuals whose coverage is less costly, while the pool of individuals under a covered entity's coverage could be costlier, leading to higher premiums. Commenters also argued that covered entities would be subject to increased compliance costs to which competitors are not subject. For example, these commenters stated that compliance with the rule's nondiscrimination notices would result in tremendous costs to which non-covered entities are not subject. Some commenters argued that this competitive disadvantage could discourage issuers from participating in the Exchanges.

A few commenters that supported the proposed application to all an issuer's operations also raised concerns that the rule would create an unlevel playing field that would disadvantage plans that support Federal programs like Medicare and Medicaid while giving an unfair competitive advantage to competitors that are not required to comply with nondiscrimination requirements. To level the playing field, these commenters and others suggested that OCR work with other Federal agencies and develop a tri-Department rule with the Departments of Labor and the Treasury to subject all health plans to similar nondiscrimination and accessibility requirements.

A number of commenters, including some members of Congress, supported the broad application of the rule to an issuer's other operations and argued the 2020 Rule's approach is contrary to Congress's intent in passing the ACA to prohibit discrimination in health care. Commenters argued that a private insurance company receiving financial assistance from the Federal Government should not be allowed to engage in discriminatory practices in its other lines of business. Commenters observed that issuers offering plans that receive Federal financial assistance, such as qualified health plans or Medicare Advantage plans, often also offer plans that do not receive Federal financial assistance. Noting that many of these other types of plans are not currently subject to any or all nondiscrimination requirements under the ACA's health insurance market reforms, these commenters argued that the Proposed Rule's broad application will increase protections from discriminatory practices for individuals enrolled in those plans.

Response: OCR appreciates the concerns raised by some commenters regarding the Proposed Rule's application to all operations of a recipient health insurance issuer; however, these concerns do not abrogate a recipient's obligation to comply with section 1557. Under the definition of ''health program or activity'' at § 92.4, a recipient of Federal financial assistance that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage is covered under this rule for all of its operations. Section 1557 applies to ''any health program or activity, *any part of which* is receiving Federal financial assistance,'' 42 U.S.C. 18116(a) (emphasis added). As we explain in detail under the discussion of the definition of ''health program or activity'' in § 92.4, it is reasonable to infer that Congress intended the term ''health program or activity'' to be interpreted broadly and to include all of that entity's operations if the entity that receives Federal funding is principally engaged in the provision or administration of health insurance coverage or other health-related coverage.[235]

[230] 42 U.S.C. 300gg–91(e)(3); 45 CFR 144.103.

[231] 42 U.S.C. 18011; 45 CFR 147.140.

[232] Grandmothered plans are certain non-grandfathered health insurance coverage in the individual and small group market that are not considered to be out of compliance with certain specified market reforms under certain conditions. *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[233] 42 U.S.C. 300gg–21(b), 300gg–63, and 300gg–91(c); 45 CFR 144.103, 146.145(b), and 148.220(b). The Departments of HHS, Labor, and the Treasury share interpretive jurisdiction over the definition of ''excepted benefits''. We cite to HHS regulations but note that the Departments of Labor and the Treasury have parallel statutory and regulatory citations.

[234] Short-term limited duration insurance is a type of health insurance coverage that is generally exempt from the provisions of title XXVII of the PHS Act because it is specifically excluded from the definition of ''individual health insurance coverage'' in the PHS Act. See 42 U.S.C. 300gg–91(b)(5). Short-term limited duration insurance is currently defined in Federal regulations as health insurance coverage issued under a contract that is effective for less than 12 months, and, taking into account renewals or extensions, has a duration of no longer than 36 months in total. 45 CFR 144.103. Short-term limited duration insurance is defined by the Departments of HHS, Labor, and the Treasury (Tri-Departments). The Tri-Departments issued a Notice of Proposed Rulemaking on Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; and Tax Treatment of Certain Accident and Health Insurance that would revise the definition of ''Short-Term Limited-Duration Insurance'' to limit the length of the initial contract period to no more than three months and the maximum coverage period to no more than four months, taking into account any renewals or extensions. 88 FR 44596 (July 12, 2023). In this final rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[235] *See, e.g., Fain* v. *Crouch,* 545 F. Supp. 3d 338, 342–43 (S.D.W. Va. 2021) (finding '''health program or activity' under Section 1557 necessarily includes health insurance issuers'' and holding that defendant health plan was, ''by virtue of its acceptance of federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio''), *rehearing*

In response to comments that this obligation might cause a competitive disadvantage with entities that do not accept Federal funds, this obligation is consistent with statutory text as set forth by Congress, as discussed above. Further, the risk of competitive disadvantage is low given that the majority of health insurance issuers offer some type of product that receives Federal financial assistance, such as Medicare Advantage plans, Medicare Part D prescription drug plans, Medicaid managed care plans, and qualified health plans through the Exchanges.[236] In any event, by accepting the benefit of Federal funds, a recipient is prohibited from discriminating in its health programs and activities under section 1557, as discussed previously under the definition of ''health program or activity.'' Any recipient of Federal financial assistance from the Department is subject to this same requirement and prohibited from discriminating in its health programs and activities, including all of its operations when principally engaged, as set forth in this final rule.

Section 1557 does not authorize OCR to require a health plan or insurance issuer not otherwise subject to section 1557 to comply with the statute. Whether the Department could issue a rule, under different authority, with the Departments of Labor and the Treasury, to apply similar nondiscrimination and accessibility standards to all health plans or health insurance issuers, is outside the scope of this rule.

We further address comments about particular types of plans and their coverage under this final rule in various comment responses below.

Comment: Some commenters requested that grandfathered and grandmothered plans should be exempt from the rule because they are not subject to many of the ACA's provisions. These plans benefit consumers, commenters stated, by allowing them to maintain affordable existing coverage as long as it continues to meet their needs. Commenters argued that applying section 1557 to these plans would be inconsistent with the longstanding regulatory treatment of the plans. Further, commenters argued that the costs of complying with section 1557, including but not limited to notice and tagline requirements, could result in increased costs for issuers, which would be passed on to consumers, and could lead to a decision to discontinue plans.

Response: OCR understands commenters' concerns and acknowledges that grandfathered and grandmothered plans are not subject to many of the ACA's provisions. However, the statutory text of the grandfathered health plan provision [237] indicates that Congress did not intend to exclude them from dection 1557. The statute sets forth the specific provisions of the PHS Act that apply to grandfathered plans and then provides that except for those provisions, ''this subtitle and subtitle A (and the amendments made by such subtitles) shall not apply'' to grandfathered plans. 42 U.S.C. 18011(a)(2). ''This subtitle'' refers to subtitle C of title I of the ACA, while ''subtitle A'' refers to subtitle A of title I of the ACA, both of which contain market reforms. Section 1557 is in subtitle G of title I of the ACA and therefore is not one of the subtitles that Congress specified should not apply to grandfathered health plans.

Grandmothered plans [238] were not established in the ACA or the PHS Act; they are not exempt from the ACA or the PHS Act by statute or regulation. Rather, CMS specified that it will not take enforcement actions against grandmothered plans that are out of out of compliance with certain specified ACA market reforms under certain conditions (CMS Non-Enforcement Policy).[239] The CMS Non-Enforcement Policy has been in place since 2013 [240] and has provided relief from the same ACA market reform provisions continuously since that time.[241] Section 1557 has never been one of the provisions for which enforcement relief was provided; therefore, grandmothered plans are not exempt from section 1557.

When offered by a recipient health insurance issuer, grandfathered and grandmothered plans would be covered under the rule as part of the issuer's operations when the issuer is principally engaged in the business of providing or administering health insurance coverage or other health-related coverage. If OCR were to receive a complaint about a grandfathered plan or grandmothered plan, OCR would carefully consider the facts and circumstances of the challenged action or practice. As discussed throughout this section, the health insurance issuer may provide a legitimate, nondiscriminatory reason for the action or practice. Further, in cases of alleged disability discrimination, covered entities may also prove that modifying a plan to comply with section 1557 would result in a fundamental alteration to their health program or activity.

Comment: A commenter requested clarification on how the rule would apply to Medicare Employer Group Waiver Plan (EGWP) participants.

Response: EGWPs are types of Medicare Part C (Medicare Advantage) plans [242] or Medicare Part D prescription drug plans [243] that qualify for waivers of certain Medicare regulations because they are offered exclusively to the employees, former employees, members or former members of an employer, union or labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof). Entities that receive funding through the Department's Medicare Part C or Medicare Part D program are subject to the rule as recipients of Federal financial assistance. This includes entities providing Medicare

en banc granted, No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721).

[236] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio Data and System Resources* (2022), *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[237] Grandfathered health plans were established by Congress in title I of the ACA to permit the continuation of coverage for certain plans in effect as of the date of enactment of the ACA (March 23, 2010) in which individuals were enrolled at that time. 42 U.S.C. 18011; 45 CFR 147.140. Grandfathered health plans are statutorily subject to only certain market reforms in the ACA, 42 U.S.C. 18011(a)(3)–(5), and thus are not subject to certain market reforms related to nondiscrimination, such as fair health insurance premiums and EHB. To maintain grandfathered status, plans cannot make certain changes to the terms of the plan or coverage. Specifically, certain changes to benefits, cost-sharing requirements, and contribution rates will cause a plan or coverage to relinquish its grandfather status.

[238] Grandmothered plans are certain non-grandfathered health insurance coverage in the individual and small group market that are not considered to be out of compliance with certain specified market reforms under certain conditions, including those related to nondiscrimination, such as fair health insurance premiums, the prohibition of preexisting condition exclusions or other discrimination based on health status with respect to adults (except with respect to group coverage), the prohibition of discrimination based on health status (except with respect to group coverage), and EHB.

[239] *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[240] *See* Letter from Gary Cohen, Director, Ctr. for Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Servs., to Insurance Commissioners (Nov. 14, 2013), *https://www.cms.gov/cciio/resources/letters/downloads/commissioner-letter-11-14-2013.pdf.*

[241] *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[242] 42 U.S.C. 1395w–27(i); 42 CFR 422.106.

[243] 42 U.S.C. 1395w–132(b); 42 CFR 423.458.

Advantage plans or Medicare Part D plans, including EGWPs, or qualified retiree prescription drug plans (as defined at 42 CFR 423.882) (also known as RDS plans). Because employers and other plan sponsors are not subject to this rule with regard to their employment practices, pursuant to § 92.2(b), an employer or other plan sponsor would not be liable for discrimination related to these plans under this rule. This applies even if an employer directly contracts with CMS to offer a Medicare Advantage or Part D plan as an EGWP and receives Federal financial assistance for that EGWP.[244] In circumstances where an employer offers an ''800 series'' EGWP through a Medicare Advantage organization or Part D plan sponsor,[245] the health insurance issuer or entity offering the EGWP would be subject to the rule for the EGWP plan due to receipt of either Medicare Part C or Part D funding.

Comment: One commenter requested clarification as to whether self-funded non-Federal Governmental plans, such as municipal plans, that opt out of certain Federal market reforms are covered under this rule if they receive funds from the Department directly or indirectly.

Response: A self-funded non-Federal Governmental plan is a governmental plan established or maintained by a non-Federal Governmental agency, such as a State, county, school district, or municipality, for its employees.[246] As with any other type of group health plan coverage, a non-Federal Governmental plan would be subject to this rule if it directly or indirectly receives Federal financial assistance from the Department. The non-Federal Governmental agency sponsoring the employee health benefit plan would be excluded from liability under this rule an employer or plan sponsor, as applicable, pursuant to § 92.2(b).

Comment: Commenters requested that the rule clarify when group health plans are subject to the rule.

Response: A group health plan is subject to this rule if it is a recipient (or subrecipient) of Federal financial assistance as set forth under § 92.2(a)(1). We address the rule's applicability to group health plans in more detail in the discussion above under §§ 92.1 (Applicability) and 92.4 (definition of ''health program or activity'').

Comment: Several commenters expressed concerns with the rule's proposed application to excepted benefits as part of a covered health insurance issuer's operations and urged OCR to exclude excepted benefits from the rule. Commenters argued that the rule's coverage of excepted benefits is inconsistent with Congressional intent and likely subject to legal challenge. These commenters explained that excepted benefits are statutorily defined benefits that Congress has long recognized as distinct from traditional health insurance coverage by excluding them from health insurance and group health plan coverage mandates under the PHS Act, ERISA, and the Internal Revenue Code, as long as they meet certain requirements.[247] Commenters argued that the ACA retained this exclusion and that Congress therefore intended excepted benefits to be excluded from the ACA. To further demonstrate Congressional intent to exclude excepted benefits, commenters stated that since Congress first recognized excepted benefits in 1996 as part of HIPAA by incorporating their provisions into the PHS Act, ERISA, and the Internal Revenue Code, Congress has had several opportunities to redefine excepted benefits or to impose new requirements on them in subsequent laws, including the ACA, but it has not chosen to do so.[248]

While acknowledging that section 1557 does not explicitly exclude excepted benefits, commenters asserted that OCR cannot use its regulatory authority to impose new requirements that are inconsistent with the carefully crafted statutory provisions governing excepted benefits where Congress has clearly chosen not to do so. As support, commenters cited to *Central United Life* v. *Burwell,* 827 F.3d 70 (D.C. Cir. 2016). Commenters stated the court in *Central United* struck down a Department rule that revised the requirements related to fixed indemnity excepted benefit insurance in the individual market as an unconstitutional exercise of regulatory authority because the ACA maintained the HIPAA excepted benefit exemption for these benefits and the law did not authorize the Department's proposed requirement. *Central United,* commenters argued, illustrates that nothing in the ACA changes the excepted benefits governing statutes and demonstrates that agencies must adhere to the boundaries set forth in Federal statute.

Commenters stated that the ACA is entirely focused on comprehensive medical coverage, while excepted benefits are not intended to serve as such coverage. They maintained that excepted benefits are not used to finance the delivery of health care services but are meant to provide benefits for a wide variety of costs associated with accidents or illnesses not covered by comprehensive medical insurance, or to defray costs that are not fully covered by comprehensive medical coverage. For example, commenters stated that some of these products, such as dental and vision plans and Medicare supplemental insurance (Medigap), can cover additional benefits not included in comprehensive medical plans. Commenters stated that noncoordinated excepted benefits, such as fixed indemnity excepted benefits and specified disease excepted benefits coverage, must pay benefits regardless of whether the medical event triggering benefits is covered under another plan. Commenters stated that while comprehensive medical insurance coverage is regulated through HIPAA or the ACA, excepted benefits are subject to separate long-standing and extensive State regulatory regimes whereby Congress and State policymakers have consistently maintained excepted benefits are not meant to be a type of comprehensive health insurance that pays for medical benefits, and therefore, commenters argue, should not be within the purview of the ACA, including section 1557.

Commenters further expressed concerns that applying the rule to excepted benefits could severely disrupt the market for these benefits and may drive competitors out of the market,

[244] CMS may contract directly with an employer, union or labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) for the entity to offer a Medicare Advantage plan or Part D plan to its employees, former employees, members or former members. 42 U.S.C. 1395w–28(i) and 1395w–132(b); 42 CFR 422.106(d) and 423.458(c).

[245] In these situations, a Medicare Advantage organization or a Part D plan sponsor contracts with CMS to offer the Medicare health or drug plan and separately contracts with the employer, union or labor organization, or trustee of a fund established by one or more employers or labor organizations (or combination thereof) for the Medicare Advantage organization or Part D plan sponsor to offer an EGWP. For more information about direct contract and ''800 series'' EGWPs, *see generally* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Managed Care Manual, Chapter 9—Employer/Union Sponsored Group Health Plans* (2013), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c09.pdf.*

[246] 42 U.S.C. 300gg–91(d)(8)(A)–(C); 45 CFR 144.103. For more information on self-funded, non-Federal Governmental plans, *see* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Self-Funded, Non-Federal Governmental Plans, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/nonfedgovplans.*

[247] Title XXVII of the PHS Act; part 7 of ERISA; chapter 100 of the Internal Revenue Code.

[248] For example, the Mental Health Parity Act of 1996; Newborns' and Mothers' Health Protection Act of 1996 (NMHPA); Genetic Information Nondiscrimination Act of 2008 (GINA); Paul Wellstone and Pete Domenici Mental Health Parity and Equity Additional Act of 2008 (MHPAEA); Michelle's Law (2008); ACA (2010); and No Surprises Act (2020).

ultimately increasing health care costs and premiums and reducing product choice for consumers and employers, and thereby reducing access to care. Commenters also asserted that applying the rule to excepted benefits could result in increased costs that are passed onto consumers as increased premiums, which could result in individuals dropping coverage due to lack of affordability and thereby result in reducing access to care, particularly in dental plans where consumers are highly price sensitive when selecting coverage.

Conversely, many other commenters supported applying the rule to excepted benefits as part of an issuer's operations. Commenters noted that excepted benefits are under-regulated and not otherwise subject to nondiscrimination requirements. Commenters argued this would provide comprehensive nondiscrimination protections for individuals enrolled in excepted benefits, particularly individuals with disabilities who face barriers to accessing care.

Response: OCR appreciates the breadth of comments received and the concerns raised. Excepted benefits are statutorily defined benefits that are exempt from the Federal consumer protection and market reforms applicable to comprehensive coverage under title XXVII of the PHS Act, part 7 of ERISA, and Chapter 100 of the Internal Revenue Code (hereinafter the Federal consumer protections and market reform requirements applicable to comprehensive coverage). Some excepted benefits are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage in all circumstances, such as coverage only for accident, workers' compensation or similar coverage, disability income coverage, and coverage for on-site medical clinics. 42 U.S.C. 300gg–21(b), 300gg–63(a), and 300gg–91(c)(1).

Other types of coverage, known as limited excepted benefits, are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage when the benefits are offered under a separate policy, certificate or contract of insurance, or are otherwise not an integral part of the plan. 42 U.S.C. 300gg–21(c)(1), 300gg–63(b), and 300gg–91(c)(2). Examples of limited excepted benefits include certain limited scope vision insurance and limited scope dental insurance (though stand-alone dental plans sold through the Exchange are subject to certain qualified health plan requirements),[249] and long term care insurance.

Another type of coverage, known as independent, noncoordinated excepted benefits, are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage when certain conditions are met. 42 U.S.C. 300gg–21(c)(2), 300gg–63(b), and 300gg–91(c)(3). This category of excepted benefits includes coverage only for a specified disease or illness (such as cancer-only policies) and hospital indemnity or other fixed indemnity insurance.

The final type of excepted benefit coverage is supplemental excepted benefits. Benefits are supplemental excepted benefits only if they are provided under a separate policy, certificate, or contract of insurance and are Medicare supplemental health insurance (also known as ''Medigap''), coverage supplemental to the coverage provided under 10 U.S.C. chapter 55 (also known as TRICARE supplemental programs), or similar supplemental coverage provided to coverage under a group health plan. 42 U.S.C. 300gg–21(c)(3), 300gg–63(b), and 300gg–91(c)(4).

Excepted benefits offer more limited coverage than, and are generally not intended to be an alternative to or replacement for, comprehensive coverage. These products are not subject to the Federal consumer protections and market reform requirements applicable to comprehensive coverage when applicable criteria are met. As we stated in the 2016 Rule, 81 FR 31431, and the 2022 NPRM, 87 FR 47875, and restate here, the fact that excepted benefits are exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage, including the ACA's consumer protections and market reforms, and are not intended to serve as comprehensive coverage does not justify their exclusion from section 1557.[250] In addition, section 1557 does not limit its protections only to health programs and activities that are themselves subject to other provisions of the ACA or that are comprehensive coverage, but also applies to all operations of any covered entity that is principally engaged, as defined under the term ''health program or activity'' in § 92.4. Further, section 1557 is an independent provision, which Congress did not codify in the PHS Act or co-locate in the ACA with the ACA's market reforms. Further, section 1557 uses the broad term ''health program or activity,'' in contrast to elsewhere in the ACA where Congress specifically made distinctions between various types of insurance. If Congress had intended to limit section 1557's reach to only certain types of insurance in the PHS Act or to carve out excepted benefits from the scope of section 1557, it could have done so.

OCR is mindful of comments raised about potential market disruption and reduced health care options for the public. However, as we discussed previously in the definition of ''health program or activity'' under § 92.4, commenters did not provide sufficient evidence to support this contention. Further, we note that when OCR has determined that a particular plan is discriminatory under this final rule, a covered entity may provide a legitimate, nondiscriminatory reason for the plan's benefit design. This could include evidence that compliance with § 92.207 would result in making the plan unaffordable to the extent the covered entity could no longer offer the plan. When such a reason is proffered, OCR will carefully consider the evidence presented by the covered entity in making our determination as to whether the reason is legitimate and not pretext for discrimination. In the case of alleged disability discrimination, covered entities may also prove that modifying a plan to comply with section 1557 would result in a fundamental alteration to their health program or activity.

For these reasons, we are not excluding excepted benefits from requirements established in this final rule. If a recipient health insurance issuer is principally engaged in the provision or administration of health insurance coverage or other health-related coverage, all of its operations are covered, including its provision of excepted benefits. Further, we note that a principally engaged issuer would not be covered under this rule for its excepted benefits subsidiary if the issuer can prove that the subsidiary is legally separate from its federally funded activities.[251]

Commenters' reliance on *Central United* to argue that this rule exceeds OCR's regulatory authority by imposing new requirements that are inconsistent

[249] *See, e.g.,* 45 CFR 155.1065 and 156.150.

[250] We further note that none of the statutory provisions that establish the exemption for these products from the PHS Act Federal consumer protections and requirements applicable to comprehensive coverage extend beyond the requirements in title XXVII of the PHS Act. *See* 42 U.S.C. 300gg–21(b)–(c), 300gg–63, and 300gg–91(c).

[251] For more information on how OCR will analyze such claims, see discussion of subsidiary liability under the definition of ''health program or activity'' in § 92.4 and under the *Application to Third Party Administrators* in this section.

with statutory provisions regarding excepted benefits is misplaced. In *Central United,* the court invalidated the requirement at 45 CFR 148.220(b)(4)(i) that an individual must attest to having minimum essential coverage prior to purchasing fixed indemnity excepted benefits coverage in the individual market. The court held that imposing that requirement went beyond what Congress required under the PHS Act. 827 F.3d at 74. The PHS Act statutes at issue in *Central United* contain statutory language specifically addressing excepted benefits, while section 1557 does not expressly mention or address excepted benefits. Further, Congress could have but did not extend the exemption under the PHS Act for these products to section 1557.[252] OCR therefore maintains that this rule's interpretation and application to all operations of a recipient health insurance issuer when principally engaged, including an issuer's excepted benefits, is the best reading of the section 1557 statutory language, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance.*'' 42 U.S.C. 18116(a) (emphasis added).

Comment: A few commenters raised concerns with the sufficiency of the Proposed Rule's discussion on excepted benefits. These commenters asserted the Proposed Rule did not adequately explain why subjecting excepted benefits to the rule is necessary or appropriate. Commenters stated that the regulatory text does not address excepted benefits and that the preamble discussion does not explain how the rule would apply to excepted benefits. Thus, according to commenters, there was insufficient notice for public comment, which they assert would likely subject the final rule to legal challenge as violative of the Administrative Procedure Act. These commenters argued OCR should issue a new Proposed Rule with comment period that explains how OCR intends to address excepted benefits and provides additional clarity on how the rule will apply to excepted benefits, taking into account the specific nature and legal structure of such products that Congress made statutorily distinct from major medical products. Commenters also objected to the Proposed Rule's investigative approach to evaluate claims of discrimination on a case-by-case basis, with one commenter arguing the case-by-case approach indicated a ''regulation-by-audit scheme.''

Response: We disagree that the Proposed Rule failed to adequately provide notice and opportunity to comment on OCR's reasoning regarding the applicability of section 1557 to all operations of a recipient health insurance issuer that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage. We fully discussed OCR's legal authority and reasoning regarding this scope of coverage in the Proposed Rule's discussion of the definition of ''health program or activity'' under § 92.4. 87 FR 47844–45. We also disagree that the Proposed Rule did not provide notice to the public of the terms or substance of how OCR intends to address excepted benefits for purposes of applying section 1557. In the preamble to the Proposed Rule, we clearly stated that all operations of a covered issuer principally engaged would include its other plans, explicitly mentioning excepted benefits. 87 FR 47875–76. Further, in the Proposed Rule, 87 FR 47875, we described the subject and the issues involved in how OCR will analyze claims of discriminatory benefit design by specifically stating that we acknowledged the unique nature of these products as being exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage, and discussed how OCR proposes to investigate such plans by considering the nature, scope, and contours of the specific plan at issue and evaluating on a case-by-case basis an alleged discriminatory design feature in light of the entity's stated coverage parameters.[253] We also reiterated that covered entities have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice. As discussed throughout this section and in the Proposed Rule, OCR's analysis for investigating a potentially discriminatory benefit design—as well as for all OCR investigations—is necessarily a fact-specific, case-by-case analysis. This is true for allegations related to benefit design features in all plans, including major medical coverage as well as excepted benefits.

Comment: Some commenters raised concerns specific to Medicare supplemental health insurance (known as ''Medigap''), which is an excepted benefit, and requested that the rule not apply to such plans.

Commenters argued that applying section 1557 to Medigap plans would be inconsistent with Congress's intent and the interlocking Federal-State regulatory framework set forth by Congress. A commenter noted that when Congress wants to alter this regulatory scheme, it speaks clearly,[254] and because Congress made no such specific reference to Medigap when enacting section 1557, Congress intended Medigap to be beyond the scope of section 1557. Commenters discussed that Medigap is highly standardized coverage comprehensively regulated under both Federal and State law over which issuers have little discretion with respect to plan benefit design.[255] Commenters explained that Federal law prescribes ten different types of Medigap benefit packages, with each offering a different set of standardized benefits.[256] Commenters noted that Congress established a Federal-State regulatory framework that prescribes the benefits, eligibility, and rating methodologies permissible for Medigap plans, with States establishing State-specific requirements for Medigap policies sold in their State. For example, a commenter noted that State laws may regulate Medigap plans in several ways, such as premium rating based on age, sex/gender, or medical underwriting, with some states requiring sex/gender rating; Medigap eligibility criteria based on an individual's age, disability, or end-stage renal disease, with some States specifying that Medigap plans are not available to such individuals; and State-specific standardized Medigap plans over which issuers have no control with respect to benefit design, communications, or other factors.

Commenters stated that Medigap is commonly underwritten after an initial open enrollment period to prevent adverse selection, and that Medigap

[252] *See* 42 U.S.C. 300gg–21(b)–(c) and 300gg–63. *See also* the conforming amendments in section 1563(a) of the ACA.

[253] *Cf. Easley by Easley* v. *Snider,* 36 F.3d 297, 301–05 (3d Cir. 1994) (examining the ''essential nature of the program'' as intended by the state when determining that a state's Attendant Care Program did not discriminate against individuals with mental disabilities under the ADA by excluding adults with disabilities who were not mentally alert).

[254] For example, the commenter noted that Congress revised the Medigap statute when it wanted to expressly apply section 104 of the Genetic Information Nondiscrimination Act to Medigap. Public Law 100–360, 102 Stat. 683, sec. 221 (1988) (codified in 42 U.S.C. 1395ss).

[255] *See* 42 U.S.C. 1395ss, 42 CFR 403.200 through 403.258; *see also* Nat'l Ass'n of Ins. Comm'rs, *NAIC Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act, MO–651–1* (2022), *https://content.naic.org/sites/default/files/model-law-651.pdf.*

[256] *See* 42 U.S.C. 1395ss. *See also* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare,* 11 (2023), *https://www.medicare.gov/publications/02110-medigap-guide-health-insurance.pdf.*

issuers are generally limited to competing along two dimensions: price and customer service.[257] Commenters argued that subjecting Medigap to section 1557 could result in adverse selection that could force covered issuers to leave the Medigap market, resulting in reduced consumer choice, higher Medigap premiums, and lower quality of service for seniors.

If the final rule does not exclude Medigap from section 1557, commenters requested at minimum that the rule specify that covered issuers are not responsible for possible discriminatory benefit designs, decisions, or actions that are a result of complying with a Federal or State requirement, including State-approved commercial underwriting practices.

Response: OCR appreciates the concerns raised by commenters about Medigap, which is a statutorily defined excepted benefit.[258] Medigap is a type of private supplemental health insurance coverage designed to cover cost-sharing gaps in original Medicare, such as deductibles, coinsurance, and copayments.[259] Medigap is regulated by both Federal and State law. 42 U.S.C. 1395ss. Congress standardized Medigap plans to establish standard plan designs.[260] While the plan benefits are standardized, the premiums and availability of the plans may vary by issuer depending on Federal and State law requirements. Medigap plans are statutorily prohibited from medical underwriting based on health status or imposing preexisting condition exclusions under certain circumstances, including during a six-month Medigap open enrollment period that begins when an individual turns 65 and enrolls in Medicare Part B and other specific times when guaranteed issue rights are available, 42 U.S.C. 1395ss(s), after which they are generally not prohibited from such practices under Federal law. States may enact their own State-specific requirements on Medigap, including whether the plans are guaranteed issue and whether the premiums may be rated based on age, health status, sex, or other factors.[261] In addition, while there generally is no Federal Medigap open enrollment period during which time Medigap plans must be sold to individuals with disabilities under the age of 65, some States may require it.[262]

Like other excepted benefits, Medigap is not designed to serve as comprehensive coverage and does not receive Federal financial assistance. As an excepted benefit, Medigap plans would be subject to the rule in the same fashion as other excepted benefits: if a Medigap plan is offered by a recipient health insurance issuer that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage as specified under the definition of ''health program or activity'' in § 92.4, the Medigap plan would be subject to the rule as part of the issuer's operations.

That said, we acknowledge commenters' concerns about State law requirements that might result in benefit design features that could violate section 1557. When investigating a discriminatory design feature in a Medigap plan, OCR will evaluate the covered entity's legitimate, nondiscriminatory reason for the challenged feature. If the reason is based on a Federal or State law requirement, OCR will take this information into account when evaluating the context of the challenged design feature and will work with the covered entity to achieve compliance to help ensure that issuers do not leave the Medigap market or lower quality of products for consumers; however, section 1557 would preempt a State law Medigap requirement—or any other excepted benefit requirement—that compelled conduct prohibited by section 1557 as applied to a recipient health insurance issuer subject to section 1557.

Comment: Many commenters supported the Proposed Rule's application to STLDI as part of a principally engaged covered entity's operations. Commenters argued that the proposed broad application is crucial to protect against discrimination in these products.

Commenters stated that STLDI plans are marketed, often misleadingly and fraudulently, as an alternative to comprehensive coverage, but have significant gaps that lead to high out-of-pocket costs and little financial protection for consumers.[263] Commenters stated that STLDI plans are under-regulated and use a lax regulatory environment to market and sell products that can harm individuals, especially those with complex health needs. For example, a commenter stated that a person with cancer would pay anywhere from $23,000 to $100,000 in out-of-pocket expenses during the first six months following diagnosis under an STLDI plan.[264]

Commenters discussed that STLDI plans charge higher prices based on an applicant's age, sex, or disability and exclude or severely limit coverage for benefits related to preexisting conditions, prescription medications, mental health, and preventive services for women, contraception, and maternity care, all of which adversely impact individuals with disabilities, women, and individuals who are or who may become pregnant.[265] Commenters suggested that the plans appear to be designed to discourage enrolling women of child-bearing age and that one study revealed that all plans reviewed discriminated against women through various practices, including gender rating and coverage exclusions.[266] Commenters stated that including

[257] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medigap (Medicare Supplement Health Insurance), https://www.cms.gov/Medicare/Health-Plans/Medigap* (stating that ''the only difference between medigap policies sold by different insurance companies is the cost.'').

[258] Referred to as ''Medicare supplemental health insurance'' under 42 U.S.C. 300gg–91(c)(4); 45 CFR 144.103, 146.145(b)(5), and 148.220(b)(5).

[259] Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 2 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[260] Omnibus Budget Reconciliation Act of 1990, H.R. 5835, Pub. L. 101–508, pt. 5, Nov. 5, 1990, 104 Stat. 1388, *https://www.congress.gov/bill/101st-congress/house-bill/5835. See also* Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 5–7 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[261] *See, e.g.,* Cristina Boccuti et al., Kaiser Family Found., *Medigap Enrollment and Consumer Protections Vary Across States,* pp. 8–13 (2018), *https://files.kff.org/attachment/Issue-Brief-Medigap-Enrollment-and-Consumer-Protections-Vary-Across-States.*

[262] *See* 42 U.S.C. 1395ss(s)(2)(A). *See also* Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 3 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[263] *See, e.g.,* Sabrina Corlette et al., *Urban Inst., The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses* (2019), *https://www.urban.org/sites/default/files/publication/99708/moni_stldi_final_0.pdf.*

[264] *See, e.g.,* Gabriela Dieguez & Dane Hansen, Milliman, *The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,* p. 13 (2020), *https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf.*

[265] *See, e.g.,* H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view*; Dania Palanker & Emily Curran, Commonwealth Fund, *Limitations of Short-Term Health Plans Persist Despite Predictions That They'd Evolve* (2020), *https://www.commonwealthfund.org/blog/2020/limitations-short-term-health-plans-persist-despite-predictions-theyd-evolve*; JoAnn Volk et al., Commonwealth Fund, *Trump Administration Promotes Coverage That Fails to Adequately Cover Women's Key Health Care Needs* (2020), *https://www.commonwealthfund.org/blog/2020/trump-administration-promotes-coverage-that-fails-to-cover-womens-key-health-care-needs.*

[266] H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk,* 61, 74 (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view.*

coverage under section 1557 for these plans is particularly important for individuals with disabilities, including those with HIV, hepatitis, and mental health and substance use disorder disabilities who are harmed by discriminatory practices, such as including more frequent application of prior authorization and fail-first protocols and denials of medically necessary services.

Because STLDI plans are not subject to traditional oversight of their provider networks, commenters stated that the plans may be designed in a way that limits care for LGBTQI+ people, individuals with disabilities, older individuals, individuals with LEP, or people of color.[267] In addition, commenters observed that STLDI plans retroactively cancel coverage and are not guaranteed renewable, leaving people with serious health conditions without coverage and often unable to enroll if the denial occurred outside of an ACA open enrollment period.[268]

One insurance industry commenter raised detailed concerns about applying the rule to STDLI in its discussion opposing the rule's application to excepted benefits. The commenter argued that similar to arguments above regarding excepted benefits, Congress excluded these products from most of the ACA's requirements and that applying the rule to these products would create a competitive disadvantage for covered entities that must comply with section 1557 as compared to non-recipient competitors that can offer lower-cost coverage due to the ability to vary premium rates on the basis of factors otherwise prohibited under section 1557 or exclude higher cost benefits. The commenter also argued recipients would be subject to greater costs due to compliance with section 1557's procedural requirements.

Response: OCR appreciates commenters' support and shares the concerns raised by commenters about the misleading and deceptive practices of some issuers of STLDI plans. STLDI is excluded from the definition of ''individual health insurance coverage'' under the PHS Act.[269] As a result, it is generally exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage offered in the individual market, such as the prohibition on discrimination based on health status, 42 U.S.C. 300gg–4, the prohibition of preexisting condition exclusions, 42 U.S.C. 300gg–3, and the prohibition on lifetime and annual dollar limits on EHB, 42 U.S.C 300gg–11, among others. These plans were traditionally not designed to serve as comprehensive coverage and were intended to fill temporary coverage gaps when an individual was transitioning between comprehensive coverages. *See* 81 FR 38020, 38032 (June 10, 2016).[270]

OCR acknowledges the commenter's concerns about competitive disadvantage and compliance costs. However, as discussed previously, the risk of competitive disadvantage is low given that the majority of health insurance issuers offer some type of product that receives Federal financial assistance, and by accepting the benefit of Federal funds, a recipient is prohibited from discriminating in its health programs and activities under section 1557. For the same reasons set forth above explaining why this rule applies to a principally engaged recipient issuer's excepted benefits, STLDI would be covered under this final rule as part of a recipient issuer's operations if the issuer is principally engaged as set forth in the definition of ''health program or activity'' at § 92.4. That Congress excluded STLDI from the PHS Act definition of individual health insurance coverage does not exclude such coverage from section 1557. Congress could have but did not extend the exemption for these products to section 1557. section 1557 applies to ''health programs or activities'' and contains no exceptions for certain types of plans or coverage, nor is it limited to plans or coverage that are subject to other provisions in the ACA. OCR therefore maintains that this rule's interpretation and application to all operations of a recipient health insurance issuer when principally engaged, including an issuer's products, is the best reading of the section 1557 statutory language, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance.*'' 42 U.S.C. 18116(a) (emphasis added).

Application to Third Party Administrators

In the Proposed Rule, we discussed that an issuer's or other entity's operations related to third party administrative services also would be subject to the rule when the issuer receives Federal financial assistance and is deemed to be principally engaged in the provision or administration of health insurance coverage or other health-related coverage as set forth in the definition of ''health program or activity'' under § 92.4. 87 FR 47876–77. We stated that we will engage in a fact-specific analysis to evaluate whether a third party administrator is appropriately covered under section 1557 as a recipient of Federal financial assistance in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance.

When investigating complaints relating to third party administrators that are appropriately covered under section 1557, we stated that OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the plan sponsor or with the covered third party administrator. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, we stated that OCR will process the complaint against the third party administrator because it is the entity responsible for the decision or other action being challenged in the complaint. We also stated that OCR will pursue claims against the covered third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. Where the alleged discrimination relates to the benefit design of self-insured group health plan coverage that did not originate with the third party administrator, but rather with the plan sponsor, OCR will refer the complaint to the Equal Employment Opportunity Commission (EEOC) or DOJ for potential investigation. We discussed that we would refer complaints related to the Federal Employees Health Benefits (FEHB) Program, the Federal Employees Dental and Vision Insurance Program (FEDVIP), or the Federal Long Term

[267] *See, e.g.,* H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view.*

[268] *See, e.g.,* Gabriela Dieguez & Dane Hansen, Milliman, *The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,* p. 11 (2020), *https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf.*

[269] 42 U.S.C. 300gg–91(b)(5) defines ''individual health insurance coverage'' to mean ''health insurance coverage offered to individuals in the individual market, *but does not include short-term limited duration insurance.*'' (Emphasis added.)

[270] *See also,* U.S. Dep't of Health & Hum. Servs., *Short-Term Limited Duration Insurance: Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance,* Proposed Rule, 88 FR 44596 (July 12, 2023) (proposing to narrow the definition of ''short-term limited duration insurance'' to mean health insurance coverage that has an expiration date that is ''no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total''.)

Care Insurance Program (FLTCIP) to the Office of Personnel Management (OPM).

The comments and our responses regarding coverage of third party administrator activities are set forth below.

Comment: Several commenters supported the rule's application to third party administrators as part of the operations of a principally engaged recipient health insurance issuer. Commenters stated that issuers often serve as third party administrators and the rule's application to an issuer's third party administrator activities will help achieve health equity, improve health outcomes, and ensure that all individuals can access health care without unnecessary barriers. Commenters stated that third party administrators play an outsized role in administering and designing health coverage for millions of people enrolled in self-funded employer group health plan coverage,[271] which may contain discriminatory provisions prohibited by section 1557.[272] Commenters discussed how third party administrators do more than simply process claims. These commenters stated that, similar to issuers, third party administrators make significant decisions about critical health plan features and often design benefits, formularies, payment structures, and networks; conduct prior authorization; and establish and evaluate other clinical coverage criteria. One commenter stated that third party administrators rely on their own clinical criteria, which may result in discriminatory denials of coverage despite the plan providing coverage generally. For example, the commenter discussed that where a self-funded plan might provide coverage for gender-affirming care, the third party administrator might rely on its own clinical criteria to categorically exclude coverage for certain types of gender-affirming care.

Other commenters opposed the rule covering third party administrators. These commenters argued the rule should exclude third party administrators from the scope of the final rule and that section 1557's application should not extend beyond the legal entity that provides or offers the ''health program or activity.'' Several commenters argued that the rule's coverage of third party administrators would create an unlevel playing field and result in a competitive disadvantage for health insurance issuers that accept Federal financial assistance. For example, commenters argued the administrative costs of complying with section 1557, such as the nondiscrimination notice requirements, would place covered third party administrators at a competitive disadvantage with non-covered third party administrators that are not subject to the same requirements. Commenters asserted that third party administrators generally do not receive Federal financial assistance and argued that applying section 1557 to third party administrators would result in subjecting all their clients to section 1557's requirements when neither the client nor the third party administrator receives Federal financial assistance. Commenters argued this would create a disincentive for clients to engage a third party administrator that is subject to section 1557 and so would create an unlevel playing field between third party administrators covered by section 1557 and those that are not. Commenters further suggested this could result in entities deciding not to participate in federally funded or conducted programs, such as the Exchanges.

One commenter asserted OCR did not explain the need for this proposed change from the 2020 Rule, which does not cover an issuer's third party administrator activities, and that the uncertainty of how the rule will apply to covered third party administrators would likely result in higher third party administrator charges to employers, which would be passed through to enrollees.

Response: We appreciate the diversity of comments received on our proposal to apply section 1557 to third party administrators when certain criteria are met. The final rule applies to all the operations of a recipient principally engaged in the provision or administration of health insurance coverage or other health-related coverage, including its third party administrator activities, as discussed in detail previously under the definition of ''health program or activity'' under § 92.4. This position is also supported by a decision of the District Court for the Western District of Washington, which held that third party administrators operated by health insurance issuers are subject to section 1557 even if the third party administrators do not receive Federal financial assistance.[273] In addition, a third party administrator could be covered under the rule if it is a subrecipient of Federal financial assistance. We also note that where a third party administrator is not covered under section 1557, a covered entity that contracts with a third party administrator, such as a health insurance issuer or group health plan, may be liable for the third party administrator's actions as a subcontractor. Please see the earlier discussion on subrecipients and contractors in the sections on Application, § 92.2, and the definition of ''Federal financial assistance,'' § 92.4.

We acknowledge commenters' concerns that this may result in a competitive disadvantage for health insurance issuers that accept Federal financial assistance. This argument, however, is not unique to health insurance issuers or their third party administrator activities. Any covered entity that accepts Federal funding from the Department knowingly agrees to comply with section 1557 and other civil rights laws that apply to recipients of Federal financial assistance.

Comment: Some commenters were opposed to the rule holding a third party administrator liable for plan benefit designs even if the discriminatory terms originated with the third party administrator. Commenters stated this approach was inconsistent with the 2016 Rule's approach that a third party administrator was liable only where the third party administrator was ''responsible for the decision or action . . . as the decision-making entity.'' 81 FR 31432. These commenters requested that OCR clarify that a third party administrator will be held responsible for actions only when it is the entity that controls whether or not the action must be taken. Commenters argued that third party administrators should not be liable for plan benefit designs simply because a third party administrator suggested or helped develop the benefit design ultimately chosen by the group health plan because the third party administrator is not the decision-making entity that adopted the benefit design. Accordingly, commenters argued that third party administrators should not be held responsible for administering benefits based on benefit design decisions made solely by a plan sponsor and urged OCR to clarify that the rule will not apply to third party

[271] Commenters noted that 64 percent of workers in the United States receive health coverage through self-insured employer plans. Gary Claxton et al., Kaiser Family Found., *Employer Health Benefits 2021 Annual Survey,* p. 9 (2021), *https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf.*

[272] *See, e.g.,* Anna Kirkland et al., *Transition Coverage and Clarity in Self-Insured Corporate Health Insurance Benefit Plans,* 6 Transgender Health 4, 214 (2021), *https://www.liebertpub.com/doi/full/10.1089/trgh.2020.0067* (showing that employer plans had three times as many categorical exclusions for gender-affirming health care).

[273] *See C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8 (W.D. Wash. Dec. 19, 2022).

administrators in cases where a plan sponsor adopts a potentially discriminatory plan design that the third party administrator played no role in selecting.

Commenters also noted that, under ERISA, third party administrators generally must administer self-insured plans according to the plans' terms. 29 U.S.C. 1104(a)(1)(D). These commenters asserted that a third party administrator should not be liable for the benefit design of a plan, including utilization management techniques, when it is administering the plan consistent with the plan terms as adopted by the group health plan or plan sponsor. Otherwise, commenters argued, the rule would effectively hold a third party administrator responsible for decisions made by another entity, namely, the plan's named fiduciary or plan administrator. Commenters further stated that ERISA does not require the third party administrator to be responsible for plan terms, but does require the plan sponsor to have a ''named fiduciary'' that has ultimate control over the plan's operation.[274] A commenter argued it would be unreasonable for OCR to take the position that a third party administrator is legally obligated under section 1557 to violate its obligation under ERISA to honor its contract with the plan sponsor and honor the plan's terms.

Commenters also argued that covering third party administrators is contrary to Congressional intent. Commenters stated that under ERISA, Congress made the group health plan responsible for the benefits it chooses to provide, and that OCR should not shift that responsibility to third party administrators through section 1557. These commenters argued that had Congress intended for third party administrators to be subject to section 1557, it would have said so clearly.

In contrast, several commenters expressed support for the rule that would make a covered third party administrator liable when the discriminatory plan feature originated with the third party administrator. These commenters asserted that third party administrators cannot insulate themselves from liability by arguing that ERISA requires a group health plan to be administered according to its terms (including by a third party administrator contracted by a plan sponsor). ERISA, commenters noted, does not exempt group health plans or their service providers (including third party administrators) from complying with other Federal laws, like section 1557.[275] These commenters, citing to case law,[276] argued that third party administrators should be held liable under section 1557 for discriminatory plan administration and when discriminatory plan terms originate with the third party administrator, even when the plan sponsor subsequently adopts the plan designed by the third party administrator and maintains control over its terms. Commenters noted that many large health insurance issuers design and market self-funded plans to plan sponsors and contract to serve as third party administrators.[277] Commenters noted that third party administrators are largely responsible for designing plans except for those offered by the most sophisticated employers. Commenters stated that issuers administer the self-funded plans using the same coverage policies that they use in their fully insured plans, and therefore the discriminatory terms in self-funded plans are often directly traceable to and redressable by third party administrators.

Some commenters suggested that third party administrators should be liable for administering a plan with discriminatory benefit design features even when the plan design did not originate with the third party administrator. Commenters argued that third party administrators that agree to administer discriminatory plans play a role in discriminating against protected individuals and should not be given immunity when administering plans with discriminatory designs.

Response: OCR carefully considered the variety of views expressed by commenters relating to the liability of a third party administrator covered under this rule. We agree with commenters that a third party administrator should not be held responsible for discriminatory plan design features over which the third party administrator exercised no control.

We disagree with commenters that believe a covered third party administrator should not be liable for discriminatory benefit design features that originated with the third party administrator simply because the plan sponsor is ultimately the entity responsible under ERISA for adopting the plan and maintaining control over its terms. Our interpretation is consistent with case law, which has held that a third party administrator may be liable for discriminatory plan terms that originated with the third party administrator, notwithstanding the fact that the plan sponsor subsequently adopted the plan and maintained control over the terms.[278] Further, as commenters noted, health insurance issuers operating as third party administrators often design the plans that they offer to self-insured group health plans and offer standard plan design options, often to small and midsize employers while only offering flexibility in the plan design to larger employers.[279]

We recognize that ERISA requires group health plans to be administered consistent with the terms governing the plan, as long as the terms are consistent with the provisions of the same

[274] *See, e.g.,* Dep't of Labor, *Meeting Your Fiduciary Responsibilities* (2021), *https://www.dol.gov/node/63375.*

[275] *See* 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . .'').

[276] *Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017).

[277] Blue Cross Blue Shield of N.D., *Self-Funding, Alternative Financial Arrangements for Group Benefit Plans,* p. 1 (2019), *https://www.bcbsnd.com/content/dam/bcbsnd/documents/brochures/employers/29300143_BND-Self-Funding-Brochure.pdf* (''Groups with 26 or more employees enrolled have a choice of several standard design plan options available. There is additional flexibility for custom designed benefit plans for groups with more than 50 employees enrolled.''); UnitedHealthcare, *UMR, https://www.uhc.com/employer/employer-resources/umr* (stating UMR, UnitedHealthcare's third party administrator, ''serve[s] over 5 million members with custom plan designs, cost-containment solutions and innovative services'').

[278] *See, e.g. Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017) (concluding that enrollee in a self-insured employer-sponsored plan could establish Article III standing for a claim of discrimination under section 1557 to sue a third party administrator where ''the plan and its allegedly discriminatory terms originated with [the third party administrator]—not with [the employer],'' and if the third party administrator provided the employer ''with a discriminatory plan document, . . . notwithstanding the fact that [the employer] subsequently adopted the plan and maintained control over its terms''); *C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *7, *9 (W.D. Wash. Dec. 19, 2022) (holding that ''third party administrators can be liable under Section 1557 based on discriminatory terms in a self-funded plan even if the third party administrator provided the plan document 'notwithstanding the fact that the [plan sponsor] subsequently adopted the plan and maintained control over its terms''' (quoting *Tovar,* 857 F.3d at 778)); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (holding that a third party administrator may be liable under section 1557 for damages arising from discriminatory terms in a self-insured, employer-sponsored health plan where the harm suffered ''was proximately caused by [the third party administrator's] designing and providing to [the self-insured plan] the discriminatory provisions in the plan'').

[279] *See, e.g.,* Blue Cross Blue Shield of N.D., *Self-Funding, Alternative Financial Arrangements for Group Benefit Plans,* p. 1 (2019), *https://www.bcbsnd.com/content/dam/bcbsnd/documents/brochures/employers/29300143_BND-Self-Funding-Brochure.pdf* (''Groups with 26 or more employees enrolled have a choice of several standard design plan options available. There is additional flexibility for custom designed benefit plans for groups with more than 50 employees enrolled.'').

subchapter in ERISA.[280] ERISA then provides in the same subchapter that it is not to be construed to impair or supersede other Federal laws, including regulations issued under such laws.[281] This rationale finds support in the cases that have held that ERISA's requirement that a plan's terms must be administered as written must not be construed to invalidate or impair section 1557.[282]

For these reasons, we affirm our general approach as discussed in the Proposed Rule at 87 FR 47876–77. When OCR investigates a potentially discriminatory action or plan design related to a self-insured group health plan coverage administered by a covered entity acting as a third party administrator, OCR will take into account the party responsible for the alleged discriminatory conduct. Recognizing that third party administrators might not be responsible for the benefit designs of the self-insured group health plan coverage that they administer, OCR does not intend to enforce this rule against a third party administrator for a plan design that it did not design and over which it has no control. Where the discriminatory terms of the plan originated with the covered third party administrator rather than with the plan sponsor, the third party administrator could be liable for the discriminatory design feature under section 1557.

Accordingly, when analyzing a claim against a covered third party administrator, OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the third party administrator, group health plan, or the plan sponsor. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, OCR will process the complaint against the covered third party administrator because it is the entity responsible for the decision or other action being challenged. For example, if a covered third party administrator applies a plan's neutral, nondiscriminatory utilization management guidelines in a discriminatory way against an enrollee, OCR will proceed against the covered third party administrator as the entity responsible for the decision. In addition, OCR will pursue claims against a covered third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. For instance, if a covered third party administrator develops standard plan designs that it offers to employers, the covered third party administrator is liable for any discriminatory design feature in the plans because the plans originated with the third party administrator. Where the alleged discrimination relates to the benefit design of self-insured group health plan coverage that did not originate with the covered third party administrator, but rather with the plan sponsor or the group health plan, and where the third party administrator played no role in the development of the plan's benefit design, OCR will refer the complaint to the EEOC or DOJ for potential investigation.

As discussed in the Proposed Rule at 87 FR 47877, as part of OCR's enforcement authority, OCR has the option of referring or transferring matters to other Federal agencies with jurisdiction over the entity. Accordingly, OCR will transfer matters to the EEOC or DOJ where OCR lacks jurisdiction over an employer responsible for the benefit design of employer-sponsored group health plan coverage. OCR will refer to OPM complaints alleging discrimination in the FEHB Program (including the Postal Service Health Benefits Program), FEDVIP, and FLTCIP. This Rule does not determine how or whether any other agency will investigate or enforce any matter referred or transferred by OCR.

As part of OCR's analysis, we will also engage in a fact-specific inquiry to evaluate whether a third party administrator is appropriately covered under section 1557 in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance, as discussed in more detail below.

Comment: Commenters requested that OCR provide additional clarity on the circumstances under which OCR would hold a third party administrator liable under the rule. Commenters stated that plan sponsors and third party administrators may place blame on each other for the discriminatory features. Another commenter said that a self-insured plan sponsor could direct a third party administrator on the goals or parameters of the design it seeks or refer the third party administrator to other plan designs and request that the third party administrator develop a plan design in accordance with those parameters. The commenter argued that in these cases, where the third party administrator is not the decision-making entity that ultimately controls and determines whether to implement the design or feature, it should not be liable under section 1557 for that design or feature.

Response: If a third party administrator is a covered entity under section 1557, it is responsible for ensuring that its actions do not discriminate on the basis of race, color, national origin, sex, age, or disability. Where a covered third party administrator plays a role in designing benefits for self-insured group health plan coverage, it must not do so in a manner that results in discrimination on a prohibited basis. This is so even if the plan sponsor requests that the covered third party administrator develop a certain plan design that includes a discriminatory feature. For example, if a plan sponsor requested that a covered third party administrator develop a plan design that excluded all enrollees of a certain race, there would be no question that a third party administrator could not design such a plan without violating section 1557. This is true for any other discriminatory design feature that would violate section 1557. In these cases, while the plan sponsor may be the entity requesting the particular design feature for a group health plan, the covered third party administrator would still be liable as the entity that designed such a plan, notwithstanding the plan sponsor's request.

Comment: Several commenters requested that OCR provide clarity on the rule's application to pharmacy benefit managers. Many commenters argued that pharmacy benefit managers, similar to third party administrators, make significant decisions about critical health plan features and should be liable when they are responsible for discriminatory formulary benefit designs. Commenters noted that plan sponsors often defer to the expertise of pharmacy benefit managers. Commenters opposed to the rule's application to third party administrators argued that pharmacy benefit managers similarly should not be liable under the

[280] 29 U.S.C. 1104(a)(1)(D) (''[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . in accordance with the documents and instruments governing the plan *insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.*'' (emphasis added)).

[281] 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.'').

[282] *See, e.g., C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8, 10 (W.D. Wash. Dec. 19, 2022) (holding that ERISA's requirement at 29 U.S.C. 1104(a)(1)(D) to administer a plan's terms as written ''is subservient to Section 1557, outlawing discrimination, which is dominant''); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (''The Court will not construe ERISA to impair Section 1557. Nothing in Section 1557, explicitly or implicitly, suggests that TPAs are exempt from the statute's nondiscrimination requirements.'').

rule when a pharmacy benefit manager was not responsible for designing the plan benefits that were adopted by the plan sponsor, similar to their arguments above against holding third party administrators liable under the rule.

Response: We discuss the rule's applicability to pharmacy benefit managers in the discussion under § 92.4 regarding the definition of ''health program or activity.'' Pharmacy benefit managers are health programs or activities and would be covered under the rule if they receive Federal financial assistance. A pharmacy benefit manager that does not directly receive Federal financial assistance would also be covered under the rule if it is part of the operations of a recipient that is principally engaged in the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, as set forth under the definition of ''health program or activity'' at § 92.4.[283]

If a pharmacy benefit manager is subject to section 1557 as part of the operations of a principally engaged recipient, we agree with commenters that the pharmacy benefit manager's liability under the rule would be similar to that of a covered third party administrator. Both entities contract with other parties, such as issuers or sponsors of self-insured group health plan coverage, to administer health benefits to plan enrollees. They may design plan benefits, formularies, payment structures, networks, and conduct utilization management. Therefore, if OCR receives a complaint about a covered pharmacy benefit manager, OCR will evaluate the liability of the pharmacy benefit manager consistent with the analysis set forth above for third party administrators. That is, OCR will determine whether responsibility for the challenged action lies with the covered pharmacy benefit manager or the plan sponsor.

Comment: One commenter requested that OCR clarify that administrative actions such as developing documents or preparing policy booklets for clients, alone, would not constitute third party administrator liability for discriminatory plan design features.

Response: We affirm that such administrative actions would not violate this rule to the extent the covered third party administrator is merely relaying information to enrollees consistent with the underlying plan terms that the third party administrator played no role in developing.

Comment: Some commenters requested that the rule clarify that an entity covered by section 1557 cannot outsource the implementation or design of discriminatory plans to entities that are not covered by the rule. Another commenter requested that OCR clarify that any third-party company may be liable under section 1557 when discriminatory plan terms originate with, or are managed by, the third-party company. For example, the commenter stated that third-party specialty benefits programs may promote or manage discriminatory specialty medication programs.

Response: A covered entity that outsources the implementation or benefit design of discriminatory plans remains liable under this rule for any discriminatory plan terms. Under the discussion of the definition of ''Federal financial assistance'' in § 92.4, we clarify that covered entities are responsible for the conduct of their subcontractors and cannot outsource or contract away their civil rights obligations by entering into contractual arrangements with subcontractors.

A third-party company that develops or manages discriminatory plans on behalf of a covered entity would only be liable under section 1557 to the extent the third-party company is a recipient or subrecipient of Federal financial assistance from the Department, including if the third party is part of a principally engaged recipient's operations.

Comment: Commenters requested that OCR clarify when liability under section 1557 extends across affiliated companies. Some commenters expressed concern that third party administrators and pharmacy benefit managers would automatically be deemed to be covered entities under the rule solely because they are related to an entity that received Federal financial assistance. These commenters requested that the final rule provide the same clarification that was in the 2016 Rule to clarify that a third party administrator (or pharmacy benefit manager[284]) is unlikely to be covered under the rule where they are ''a legal entity that is truly independent of an issuer's other, federally funded, activities.'' 81 FR 31433.

Other commenters expressed concern that third party administrators and pharmacy benefit managers could use complex corporate structures to distinguish separate lines of business to evade compliance with section 1557.[285] These commenters requested that OCR provide greater clarity on when liability under section 1557 extends across affiliated companies.

Response: As discussed in the 2016 Rule, 81 FR 31433, OCR will conduct a case-by-case analysis to determine whether a third party administrator or pharmacy benefit manager is appropriately subject to section 1557 as part of the operations of a recipient covered entity in situations where the third party administrator or pharmacy benefit manager is legally separate from an issuer or other covered entity that receives Federal financial assistance. This fact-specific analysis will rely on principles developed in longstanding civil rights case law, such as the degree of interrelatedness between or among entities, including the degree of common ownership and control between or among entities.[286] OCR will also examine whether the purpose of the legal separation was to avoid liability or avoid the application of civil rights law requirements—that is, whether it is intended to allow the entity to continue to administer discriminatory health insurance coverage or other health-related coverage.[287] As indicated in the 2016 Rule, a third party administrator or pharmacy benefit manager is unlikely to be covered by this final rule where it is a legal entity that is truly independent

[283] *See, e.g., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 12–23 (N.D. Cal., Aug. 5, 2022) (relying on section 1557, the 2016 Rule, and the incorporated civil rights statutes to conclude that the complaint plausibly alleged that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[284] The 2016 Rule did not address pharmacy benefit managers.

[285] *Cf., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 15 (N.D. Cal., Aug. 5, 2022) (''To ignore the overall interrelationship among the entities which, in the case at bar, design and implement the allegedly discriminatory program and permit the CVS interrelated entities to escape responsibility would exalt form over substance and impair the effectiveness of the anti-discrimination provision of the ACA.'').

[286] *See, e.g., Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.,* 69 F.3d 1235, 1240–42 (2d Cir. 1995) (title VII); *Valesky* v. *Aquinas Acad.,* 2011 U.S. Dist. LEXIS 103791, No. 09–800 (W.D. Pa. Sept. 14, 2011) (title IX); *Russo v Diocese of Greenberg,* 2010 U.S. Dist. LEXIS 96338, No. 09–1169 (W.D. Pa. Sept. 15, 2010) (title IX, section 504); *Margeson* v. *Springfield Terminal Railway Co.,* 1993 U.S. Dist. LEXIS 12243, No. CIV.A. 91–11475–Z (D. Mass. Aug. 24, 1993) (section 504); *See also Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 12–23 (N.D. Cal., Aug. 5, 2022) (relying on section 1557, the 2016 Rule, and the incorporated civil rights statutes to conclude that the complaint plausibly alleged that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.)

[287] *Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 941 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA).

of an issuer's other, federally funded activities. We also address subsidiary liability under the discussion of § 92.4's definition of ''health program or activity.''

Comment: One commenter urged OCR to consider whether stop-loss coverage sold by a covered third party administrator to an employer results in discrimination on the basis of disability prohibited under section 1557. The commenter stated that stop-loss coverage uses techniques that target group members with high medical needs. The commenter asserted this could result in stop-loss coverage penalizing employers when a covered individual needs intensive treatment for a disabling condition.

Response: Stop-loss insurance provides coverage for the benefit of the employers, plan sponsors, or group health plans to cover financial liability for such entities to provide protection against catastrophic or unpredictable losses, and does not provide coverage for individuals. Stop-loss insurance that does not discriminate against individuals on the grounds protected under section 1557 does not implicate this final rule.

Comment: A few commenters expressed concern that the rule's application to covered third party administrators does not account for situations where the third party administrator is administering plans for religious employers. Commenters argued the rule could impose a burden on an employer's religious beliefs. Another commenter further argued that it could cause the employer to be exposed to liability for a claim of employment discrimination. The commenter explained that § 92.207 prohibits covered entities, such as a covered third party administrator, from providing a health-coverage related product that aligns with the beliefs and practices of religious employers. The commenter argued this results in a burden on the employer's religion because such religious employers cannot obtain a health coverage-related product that is illegal for covered entities to provide. If such an employer were to obtain a group health plan that was consistent with its faith, the commenter argued that the employer is at risk of liability due to OCR's position that it will transfer complaints alleging discrimination by an employer to the EEOC, which will review the employer's plan to determine if it is discriminatory under title VII of the Civil Rights Act.

Response: As discussed throughout this section, a health insurance issuer or third party administrator subject to section 1557 is prohibited from discriminating on the basis of race, color, national origin, sex, age, or disability in its provision or administration of health insurance coverage or other health-related coverage, and is also able to seek assurance of a religious exemption consistent with § 92.302(b). As specified in § 92.2(b), section 1557 does not apply to an employer or a plan sponsor with regard to its employment practices, including the provision of employee health benefits. A religious employer is able to obtain health insurance coverage or administration of its self-funded group health plan coverage from any entity not subject to section 1557, which would fall outside of the application of this rule.

Network Adequacy

The comments and our responses regarding network adequacy are set forth below.

Comment: Commenters appreciated OCR's attention to network adequacy and its acknowledgement that certain provider networks may constitute discriminatory benefit design under section 1557. Commenters stated that discriminatory provider networks profoundly affect the accessibility and quality of care for vulnerable populations. One commenter expressed concern that OCR has limited interest in complaints about access to care stemming from provider networks because the preamble in the Proposed Rule emphasized that health plans have discretion over benefit design and did not explicitly mention provider networks. A commenter recommended that OCR amend the proposed § 92.207(b)(2) to expressly reference provider networks as a type of design feature that falls within the scope of prohibited discriminatory activities.

Response: OCR acknowledges the importance of network adequacy in ensuring nondiscriminatory access to health care while also recognizing covered entities' autonomy in developing their provider networks as part of their benefit design packages, consistent with existing State and Federal network adequacy and other laws, including section 1557.[288] OCR will accept complaints related to provider networks and will investigate allegations of discrimination on a case-by-case basis. OCR declines to amend § 92.207(b)(2) because we believe the regulatory text is clear as written and does not require further clarification. As previously discussed, the term ''benefit design'' encompasses an array of features, including provider networks, and OCR intends to interpret it broadly.

Comment: Commenters urged OCR to include examples of discriminatory network design while articulating several practices that they believed to be violations of section 1557. Some network design practices commenters characterized as discriminatory included low reimbursement rates that lead to lower provider participation, arbitrary limits to in-network providers, limiting the participation of safety-net providers, insufficient providers with accessible medical equipment, narrow pharmacy networks, and performance requirements related to cost or other outcome and quality measures. Commenters argued that all of these practices prevent access and may be used by covered entities to dissuade enrollees with high health needs from enrolling in plans.

Response: OCR appreciates commenters providing examples of how network plan designs might have discriminatory impacts on vulnerable populations. While we agree that certain network plan designs and practices, such as excluding all or most providers that specialize in treating certain conditions, may be discriminatory under section 1557, we will not establish minimum network adequacy standards in this rulemaking. As discussed in the Proposed Rule, 87 FR 47877, covered entities employing network plan designs may be subject to network adequacy standards governed by State and Federal law. For example, CMS regulations establish network adequacy requirements for qualified health plans, Medicare Advantage plans, and Medicare Part D prescription drug plans, and require states to develop and enforce network adequacy standards for their contracted Medicaid managed care plans. *See* 87 FR 47877. Many of these regulations establish specific requirements that must be satisfied, such as inclusion of certain types of providers and time and distance standards. Recognizing that network adequacy is regulated by other Departmental regulations, as we noted in the 2016 Rule, and again note here, it is outside the scope of section 1557 to establish uniform or minimum network adequacy standards.

Comment: Commenters asserted that discriminatory network design practices lead to excessive, and often insurmountable, administrative burdens

[288] Network plans offer medical care through a defined set of providers under contract with the issuer. *See* 42 U.S.C. 300gg–91(d)(10); 45 CFR 144.103 (defining ''network plan'' as ''health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer'').

for enrollees. Commenters also stated that provider network appeals processes can be opaque, arbitrary, and ultimately a tool to deny access to necessary care that meet the definition of a disability under the ADA. Commenters expressed concern over the increase in ''phantom networks,'' plans that list providers as in-network when they are not actually accepting patients, particularly for mental health providers. For example, commenters cited a recent study that showed that 60 percent of the mental health providers in the Oregon Medicaid managed care network were not actually accepting patients.[289] Commenters expressed frustration in discovering that certain in-network providers are unable or unwilling to address multiple co-occurring disabilities or general medical care for people with disabilities.

Response: Plan designs that subject individuals protected by section 1557 to excessive administrative burdens to access coverage benefits that other enrollees do not have to navigate to access coverage may be discriminatory under section 1557. Section 92.207(b) prohibits covered entities from discrimination ''in providing *or administering*'' (emphasis added) health insurance coverage or other health-related coverage.

Comment: Commenters requested strict monitoring and enforcement of provider network compliance with section 1557. A commenter suggested that OCR include scrutiny of provider networks via regular compliance reviews in addition to investigating complaints. To determine whether a certain network design is discriminatory, a commenter urged OCR to consider access measures such as medication adherence, uptake of innovative therapies, and complaints and appeals regarding delayed or denied access to specialists and drugs. A commenter requested that OCR provide greater scrutiny to the impact of provider network consolidation, especially those involving religiously affiliated institutions, in creating discriminatory impacts on health care recipients.

Other commenters stated that OCR should not establish network adequacy standards, as they believe that discrimination through network adequacy is sufficiently addressed by other State and Federal agencies as well as the National Association of Insurance Commissioners, National Committee for Quality Assurance, and URAC (formerly Utilization Review Accreditation Commission). Commenters noted that as network requirements increase, providers and facilities demand increased reimbursement rates, additional contracts for other member or system facilities, and specific network tier placement. Commenters asked OCR to consider limiting provider contracting practices such as ''all-or-nothing'' contracting and anti-tiering clauses. They noted that such practices harm consumers by increasing provider leverage and driving up health care costs.

Response: While we will not establish minimum network adequacy standards in this rulemaking, we emphasize that to ensure compliance with section 1557, covered entities must develop their networks in a nondiscriminatory manner. When determining whether an entity has violated this section, OCR will conduct a fact-intensive investigation to determine whether the challenged network excludes individuals from participation in or denies them the benefits of the plan, or otherwise discriminates against them on the basis of race, color, national origin, sex, age, or disability. This analysis will include evaluating whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt its provider network. As noted in the Proposed Rule, OCR is cognizant that a variety of factors may affect a covered entity's provider network design.[290] If OCR determines that a network design is discriminatory, covered entities will be expected to provide a neutral, nondiscriminatory reason for the network design that is not a pretext for discrimination.

Concerns around provider consolidation are out of the scope of this regulation; however, OCR acknowledges that as providers consolidate, there may be increased or novel concerns around discriminatory provider network design and impact to access to care for protected classes.

Medical Diagnostic Equipment

In the Proposed Rule, 87 FR 47836, OCR noted that individuals with mobility disabilities experience challenges accessing preventative, primary, and specialty care due to inaccessible medical diagnostic equipment (MDE). OCR sought comment on the extent to which a lack of accessible MDE within a provider network limits or denies access to care for individuals with disabilities. OCR also requested comment on whether it should incorporate the U.S. Access Board's Medical Diagnostic Equipment Standards (MDE Standards) as enforceable standards and whether a lack of accessible MDE constitutes discriminatory benefit design or network inadequacy.

Comment: OCR received many comments urging OCR to adopt the MDE Standards, created pursuant to section 510 of the Rehabilitation Act, in the final rule. These commenters stated that inaccessible MDE leads to poor health outcomes for people with disabilities, mainly because inaccessible MDE results in individuals with disabilities receiving less preventative care, including mammograms and cervical screenings, compared to their counterparts without disabilities.[291] One commenter also noted that this lack of preventative care, and ensuing poor health outcomes, could also place people with disabilities at unnecessary risk for institutionalization. Finally, these commenters urged OCR to state that the denial of services to individuals with disabilities due to inaccessible MDE is discrimination under other Federal disability rights laws, including section 504 and the ADA.

One commenter recommended that OCR require covered entities to ensure that within 30 days of the publication of the final rule, all newly purchased or replaced MDE comply with the MDE Standards. The commenter also recommended that OCR require all covered entities that use MDE to ensure that within two (2) years of the publication of this rule, all of their MDE meets the MDE Standards. A different commenter recommended that OCR use a similar approach to that required by the 2010 ADA Standards for Accessible Design, 75 FR 56236 (Sep. 15, 2010), where accessible MDE would be purchased to replace older equipment as needed.

Response: OCR appreciates the numerous comments requesting that the final rule require covered entities to comply with the MDE Standards. OCR agrees that when individuals with disabilities are denied appropriate preventative health care due to the

[289] Jane M. Zhu et al., *Phantom Networks: Discrepancies Between Reported and Realized Mental Health Care Access in Oregon Medicaid,* 41 Health Affairs 7, 1016 (2022), *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.00052.*

[290] Such factors include ''the geographic location of the service area, the number of available providers and specialists in the service area, reimbursement rates, the number of providers willing to contract with the payer, and the overall design of the plan as it relates to premiums.'' 87 FR 47877. We note that the importance of geographic limitations may be reduced due to the industry growth in virtual care and ease of medical travel, where clinically appropriate.

[291] *See* Nat'l Council on Disability, *Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities* (2021), *https://www.ncd.gov/assets/uploads/reports/ncd_medical_equipment_report_508.pdf.*

inaccessibility of MDE, they are placed at increased risk of poor health outcomes and potentially institutionalization. As noted, section 504, the ADA, and section 1557 all prohibit covered entities from discriminating against people with disabilities by denying them appropriate health care services. Requiring covered entities to comply with the MDE Standards would be one method to ensure that people with certain disabilities receive appropriate health care services, while allowing for greater patient autonomy.

On September 14, 2023, OCR issued an NPRM proposing updates to the Department's section 504 regulations.[292] OCR proposed specific accessibility standards, scoping requirements, and time periods for compliance for MDE used by recipients of Federal financial assistance in that NPRM.[293] Accordingly, while OCR recognizes the importance of ensuring that all people, regardless of disability status, receive effective preventative care, we will not address the MDE Standards in the regulatory text of this rulemaking.

Comment: Many commenters noted that while the MDE Standards were published in 2017, many providers, including recipients of Federal financial assistance, have failed to abide by the standards and acquire accessible MDE. As evidence, some commenters point to the data collected by the State of California concerning the prevalence of accessible MDE among providers, which they state indicates that the majority of California providers do not have accessible MDE.[294] These commenters note that until a Federal regulation creates specific requirements, accessible MDE will not be used by the majority of providers. Finally, commenters noted that even if providers acquire accessible MDE, they still must ensure that their staff are able to use the MDE effectively in order for people with disabilities to benefit.

Response: OCR recognizes that in the absence of an enforceable standard that requires providers to acquire MDE with specific features, providers may not acquire accessible MDE. This may be due in part to the cost of accessible MDE exceeding the cost of non-accessible MDE and the durability of existing MDE. OCR also agrees that if a provider acquires accessible MDE, such as an adjustable exam table, but does not ensure that staff can effectively use the table and assist patients with transfers, patients with disabilities will not benefit. For the MDE Standards to be effective, providers must also know how to use accessible MDE. OCR will continue to enforce existing nondiscrimination obligations and, as noted above, is in the process of rulemaking to adopt enforceable standards for accessible MDE under section 504.

Comment: Numerous commenters requested that OCR consider expanding on the existing MDE Standards. Some commenters requested that OCR create new standards specific to individuals with visual impairments, sensory limitations, or cognitive disabilities. Some commenters also requested that OCR expand the MDE Standards to non-diagnostic medical equipment in addition to MDE, with others, requesting that OCR determine the scoping requirements that covered entities would have to follow under the MDE Standards.

Response: OCR appreciates commenters' suggestions. Because we are not requiring providers to abide by the MDE Standards in this rulemaking, we will not determine whether to expand the MDE Standards beyond diagnostic equipment, create new standards unique to individuals with other disabilities, or determine the scoping requirements of the MDE Standards. However, we will consider these recommendations and note that regardless of whether medical equipment is diagnostic, a covered entity must make its health programs and activities accessible to individuals with disabilities.

Comment: Numerous commenters stated that because of inaccessible MDE, many patients with disabilities have been asked to bring someone with them to appointments in order to help them transfer onto MDE. The commenters state that it is never appropriate to require this of a patient.

Response: Existing Federal civil rights laws, including section 504, title II of the ADA, and the existing section 1557 implementing regulation, forbid providers from requiring a patient with a disability to bring their own aide or support person to an appointment to assist them with transfers. Any person who has been required by a provider to bring another person to an appointment to assist with transfers is encouraged to file a complaint with OCR.

Comment: One commenter stated that the use of accessible MDE could be considered a reasonable modification for persons with disabilities as required by existing disability rights laws.

Response: Providing accessible MDE is one method that providers can use to ensure that a patient with a disability is able to access a provider's programs and activities. A provider would likely violate Federal disability discrimination laws like section 504, the ADA, and section 1557 if the health programs and activities they provide, including preventative and diagnostic care, are not accessible to people with disabilities.

Comment: One commenter stated that while requiring covered entities to obtain and use accessible MDE would be beneficial to people with disabilities, in certain circumstances it may be sufficient for a covered entity without accessible MDE to offer transportation to another covered entity with accessible MDE.

Response: While a provider acquiring and using accessible MDE so that its patients with disabilities are able to receive health care in its offices is preferrable, there may be specific situations where it is appropriate for the provider to offer transportation to another facility that has accessible MDE.

Comment: Many commenters stated that they consider accessible MDE to raise both network adequacy and benefit design implications. They believed that a lack of accessible MDE leads to a lack of in-network care and a lack of network adequacy, which they alleged to be discriminatory. They stated that benefit design could be used to embed accessible MDE requirements. They also stated that accessibility should also be considered in conjunction with time and distance standards to determine network adequacy.

Response: OCR appreciates commenters raising these important opinions concerning how the presence of accessible MDE affects network adequacy and benefit design. While OCR has decided not to explicitly address accessible MDE in this rulemaking, we refer commenters to the discussion of network adequacy and benefit design under this section.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the nondiscrimination in health insurance coverage and other health-related coverage provision at § 92.207 as proposed, with modification. We have revised § 92.207(b)(6) to clarify that the integration requirement extends to practices that result in the serious risk of institutionalization or segregation. We have revised § 92.207(c) to strike the text following ''legitimate,

[292] 88 FR 63392 (Sept. 14, 2023).

[293] 88 FR 63392, 63511 (Sept. 14, 2023) (proposed subpart J).

[294] Nancy R. Mudrick et al., *Presence of Accessible Equipment and Interior Elements in Primary Care Offices,* 3.1 Health Equity 275 (2019), *https://dredf.org/wp-content/uploads/2019/10/Presence-of-Accessible-Equipment-and-Interior-Elements-in-Primary-Care-Offices.pdf.*

nondiscriminatory reason for'' and now the text prohibits ''denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements including reasonable medical management techniques such as medical necessity requirements.'' This section also provides that ''such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.'' We have also made conforming edits to include ''or any combination thereof'' to the list of prohibited bases of discrimination found § 92.207(a) and (b)(1) and (2).

Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

In § 92.208, OCR proposed to prohibit covered entities from discriminating on the basis of sex in their health programs and activities with respect to an individual's marital, parental, or family status. The 2016 and 2020 final rules did not include a similar provision. This is not a new concept, however, as it is similar to the Department's title IX implementing regulations. *See* 45 CFR 86.40(a). Section 92.208 provides that, in determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.[295]

The comments and our responses regarding § 92.208 are set forth below.

Comment: Many commenters supported the inclusion of § 92.208 because it provides clarity for patients and providers and brings OCR into alignment with other nondiscrimination practices set by section 1557, ensuring that all vulnerable groups receive the same level of civil rights protections. Several commenters mentioned that this change aligned with the title IX regulation, which has, since 1975, explicitly interpreted sex discrimination to encompass discrimination on the basis of current, potential, or past parental, family, or marital status that treats persons differently on the basis of sex. Commenters also raised other civil rights statutes, like the Civil Service Reform Act that is applicable to Federal employees, which explicitly includes protections based on marital status.[296]

Response: OCR agrees that including this provision brings regulations in line with other civil rights laws that recognize policies that treat people differently on the basis of sex in applying rules related to marital, parental, or family status,[297] as discrimination on the basis of sex, particularly, and as stated in the Proposed Rule's preamble, the Department's longstanding acknowledgment of this interpretation of title IX, at 45 CFR 86.40(a).

Comment: Numerous commenters supported proposed § 92.208. Some of these commenters explained that taking marital, parental, or family status into account has engendered arbitrary policies at medical facilities that create barriers to accessing health care, which can result in harmful and inequitable treatment of individuals. Many commenters stated that this provision will help alleviate the denial of care some women experience because they are single, unmarried, childless, or not in the presence of a male partner or husband when they are seeking, for instance, birth control.

Response: OCR agrees that absent the prohibition on taking sex into account in marital, parental, or family status, covered entities may adopt arbitrary policies that could create unnecessary inequities and result in harmful health outcomes. Section 92.208 prohibits discrimination that applies different policies and procedures based on sex in the context of marital, parental, or family status; it does not, however, prohibit discrimination on the basis of marital status alone (*i.e.,* single, divorced, widowed, etc.). As discussed in the 2022 NPRM, OCR encountered complaints, in the course of its enforcement work, where covered entities applied different policies for married men and married women. For example, OCR has settled cases against covered entities with policies of automatically assigning a male spouse as the guarantor when a female spouse received medical services, while not automatically assigning a female spouse as the guarantor when a male spouse received medical services. 87 FR 78878.

Comment: Many commenters supported the protections against discrimination on the basis of sex in the context of marital, parental, and family status contained in § 92.208 because of their impact on same-sex couples and the varying types of discrimination that this group experiences, including past experiences of discrimination on the basis of marital, parental, and family status alone. For example, some commenters said that these protections are critical because, although many same-sex couples live in committed relationships, they are less likely to be married, largely due to laws that until recently prohibited same-sex marriage. These protections, commenters argued, help to insulate LGBTQI+ individuals who have experienced discrimination in many health care settings, such as hospitals where they have been denied visitation rights and authority to make medical decisions impacting their loved ones' health conditions. Many commenters highlighted that these forms of discrimination were well documented during the AIDS crisis, when longtime partners were regularly denied hospital visitation rights and lacked adequate protections, even for discrimination based solely on marital status. For similar reasons, some commenters stated that this provision would protect families headed by same-sex couples, who may be denied the right to make medical decisions for their children. These commenters noted, that in the health care context, the involvement of family and external support systems can improve health outcomes, management of chronic illnesses, and continuity of care.

Response: OCR agrees that the prohibition on taking an individual's sex into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status can be critical in health care settings involving medical decision-making and visitation rights, particularly for same-sex couples. Section 92.208 prohibits a covered entity from implementing a policy related to marital, parental, or family status that treats individuals differently on the basis of sex (*e.g.,* male spouses of women can make medical decisions for their children but non-male spouses of women cannot, or allowing visitation rights for a married heterosexual couple but denying visitation rights to a married same-sex couple), but it does not prohibit covered entities from making distinctions based upon their marital status alone (*e.g.,* applying different rules to married and nonmarried individuals that do not distinguish based on an individual's sex).

Comment: Other commenters also discussed the impact that the protections contained in proposed

[295] This final rule does not preclude the application of Federal laws regarding eligibility criteria for certain Federal programs under CMS.

[296] *See* Public Law 95–454, sec. 101, 92 Stat. 1111, 1113–14 (Oct. 13, 1978), codified at 5 U.S.C. 2301(b).

[297] The term ''family status'' used in this rule is distinct from any defined terms in other rules, including ''familial status'' as defined in the Fair Housing Act, 42 U.S.C. 3601 *et seq.*

§ 92.208 have on same-sex couples seeking fertility treatments. They stated that these protections are needed because some health insurance coverage or other health-related coverage include in vitro fertilization (IVF) treatments as a covered benefit for heterosexual married couples, but not for same-sex married couples. Some commenters highlighted how, in their view, institutional policies' definition of ''infertility'' lead to such a discriminatory practice. This establishes what commenters describe as an impossible standard for same-sex couples to meet when seeking fertility treatment and coverage.

Response: OCR understands that not all covered health insurance issuers offer fertility coverage or treatments. However, those that do must offer such benefits in a nondiscriminatory manner. For example, a covered health insurance issuer that offers fertility coverage or treatments for married different-sex couples could not deny the same coverage or treatments to married same-sex couples. section 1557's prohibitions of discrimination apply across all covered health programs and activities.

Comment: Other commenters who supported the inclusion of § 92.208 stated that these protections are important because they help ensure nondiscrimination against a wide range of family structures.

Response: OCR reminds commenters that this section prohibits discrimination on the basis of sex when applying rules related to marital, parental, and family status, and is not to be conflated with prohibition against discrimination on the basis of these statuses alone. Thus, policies and procedures that include conditions or limitations tied to these statuses would not run afoul of this rule unless they applied differently based on the sex of the individuals.

Comment: Some commenters supported § 92.208 because in their view, a medical practice cannot refuse a female patient solely because she has a female spouse or partner, as this could constitute a denial on the basis of association.

Response: OCR agrees that a medical practice may not refuse to see a prospective female patient based solely on the fact that the patient has a female spouse if they otherwise accept married individuals into their practice. This is because the refusal would be based on the sex of the prospective patient and would therefore constitute sex discrimination related to marital status. And, as noted in the Proposed Rule, a denial based on a female patient having a female spouse or partner would also constitute discrimination on the basis of association, which is specifically addressed in § 92.209, as the refusal would be based on the sex of an individual with whom the patient is known to have a relationship or association. 87 FR 47880.

Comment: Many commenters opposed the inclusion of § 92.208, stating that if Congress meant to include ''marital, parental, or family status'' in section 1557 it would have done so, just as it did in part in the Equal Credit Opportunity Act (ECOA) (including ''marital status'') and the Fair Housing Act (FHA) (including ''familial status''). These commenters contended that adding these protections would make the addition of marital and familial status a mere surplusage to the text of the ECOA and FHA, and that it would include additional terms to their application despite neither statute explicitly including the additional terms. Some commenters who opposed the provision also stated that OCR needs to account for the additional costs of including these changes, especially as it may impact religious institutions that provide marital counseling services.

Response: OCR disagrees that clarifying these protections under section 1557 impacts either the ECOA or FHA.[298] While these statutes bar discrimination on the basis of an individual's marital or familial status *per se,* § 92.208 bars discrimination on the basis of sex as it relates to marital and family status. As discussed in the 2022 NPRM, 87 FR 47878, this final rule's interpretation is consistent with a parallel, longstanding prohibition included in the Department's title IX implementing regulations, 45 CFR 86.40(a). OCR has consistently interpreted the scope of section 1557's prohibition on the ground of sex consistently with the scope of title IX's prohibition of discrimination on the ground of sex, which includes discrimination within the context of marital, parental, or family status.[299] This provision will apply similar standards already enforced by OCR, and we do not anticipate additional costs for covered entities, including religious institutions beyond the costs already captured in the Regulatory Impact Analysis below for recipients to seek assurances of religious and conscience exemptions under § 92.302(b).

Discrimination on the Basis of Pregnancy-Related Conditions

In proposing § 92.208, OCR stated its view that it could be beneficial to include a provision that would specifically prohibit discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination, and sought comment on how to include such a provision in the final rule. 87 FR 47879. This proposal was specifically requesting comment on a stand-alone provision, separate from the inclusion of ''pregnancy or related conditions'' in § 92.101(a)(2)'s inclusion of the term. Including such a provision at § 92.208 would mirror its placement to those of the Department's title IX implementing regulations at 45 CFR 86.21(c), 86.40, 86.52(b), and 86.57. The 2016 Rule explicitly included ''pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions'' in former § 92.4. While the 2020 Rule did not include any definition of ''sex discrimination,'' it indicated that section 1557 would be enforced consistent with title IX and its implementing regulations, which includes these terms. For the reasons explained below, we decline to add ''pregnancy or related conditions'' to § 92.208.

The comments and our responses regarding this request for comment are set forth below.

Comment: Many commenters supported the inclusion of a provision that includes pregnancy-related conditions as a prohibited form of discrimination on the basis of sex. Numerous commenters discussed that pregnancy-related conditions are inherently linked to sex because discrimination on that basis affects an individual's ability to make decisions about their reproductive health and life, and affects individuals' ability to be equal and participating members of society.

Response: OCR appreciates these comments and agrees that clarifying that discrimination on the basis of sex includes pregnancy-related conditions, as § 92.101(a)(2)(ii) (''discrimination on the basis of sex includes . . . pregnancy or related conditions'') does, is critical to ensuring that individuals are protected against this form of sex discrimination. OCR also agrees that discrimination on the basis of

[298] *Cf. Conn. Nat'l Bank* v. *Germain,* 503 U.S. 249, 253 (1992) (courts must give effect to statutes with overlapping coverage ''so long as there is no 'positive repugnancy' between the two'').

[299] As discussed in the 2022 NPRM, 87 FR 47878, OCR has resolved complaints against covered entities with policies of automatically assigning a male spouse as the guarantor when a female spouse received medical services, while not automatically assigning a female spouse as the guarantor when a male spouse received medical services. *See* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Sex Case Summaries: Summary of Selected OCR Compliance Activities, https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/sex-discrimination/index.html.*

pregnancy or related conditions can negatively affect an individual's ability to make decisions about their reproductive health and life, and their ability to be equal and participating members of society.

Comment: Many commenters who supported the inclusion of pregnancy-related conditions discussed the need for clarity in light of the Supreme Court's decision in *Dobbs.* Commenters contended that pregnancy-related conditions should be included in the definition of ''sex discrimination'' because it would reinforce covered entities' legal obligations under section 1557, and would allow OCR to address related discrimination more holistically and inclusively.

Commenters maintained that pregnancy protections are critical in light of total or near-total abortion bans in some States after the *Dobbs* decision. Commenters explained that this legal uncertainty warrants clarity and explicit protections for pregnancy-related conditions, including termination of pregnancy, because patients and providers have been left uncertain and fearful of their ability to provide care, are subjected to additional scrutiny, and face the possibility of criminal prosecution and civil litigation in States that have limited reproductive health care options.

Response: OCR affirms that under section 1557, covered entities may not discriminate against individuals for their pregnancy-related decisions, past, present, or future. OCR declines to add in additional protections outside of the scope of this rule. At the same time, the ACA itself provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A).[300] HHS will comply with this provision.

Comment: Some commenters discussed privacy concerns involving HIPAA, as some providers have worried that medical privacy may be compromised when patients seek care or information, even if unrelated to abortion. Commenters argued for the need to include pregnancy-related protections under section 1557 so that patients are not discriminated against for their pregnancy-related decisions, past, present, or future.

Response: OCR appreciates the privacy concerns raised by these commenters. OCR affirms that under section 1557, covered entities may not discriminate against individuals for their pregnancy-related decisions, past, present, or future, including where the patient discloses the information or where such information is contained in medical records. Indeed, HIPAA was enacted to protect such sensitive patient health information from being disclosed without the patient's consent or knowledge. Separately, OCR is considering revisions to the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information related to reproductive health care. *See HIPAA Privacy Rule To Support Reproductive Health Care Privacy,* notice of proposed rulemaking, 88 FR 23506 (Apr. 17, 2023).

Comment: Other commenters urged OCR to address pregnancy-related conditions but to do so elsewhere in the rule, either in the provisions on what constitutes discrimination on the basis of sex (§ 92.101(a)(2)), equal program access on the basis of sex (§ 92.206(b)), or nondiscrimination in health insurance coverage (§ 92.207(b)). These commenters explained that confining the discussion of the pregnancy-related conditions to § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status) risked a narrow interpretation and application of the prohibition, and could lead providers to consider this prohibition to be limited in context and scope. Commenters emphasized that pregnancy-related protections are relevant to a wide range of conduct beyond the context of marital, parental, or familial status and should not exclude individuals who are single. Commenters also raised that pregnancy-related discrimination applies to a broad scope of protected services, such as the decision to access certain reproductive health care services (*e.g.,* contraception), as well as denials of reproductive services and insurance coverage. Many commenters suggested that OCR include pregnancy-related conditions in a standalone provision, because OCR could then further clarify the interplay between section 1557 and other Federal statutes or regulations related to termination of pregnancy that may apply to covered entities.

Response: OCR appreciates these comments. In the 2022 NPRM, OCR considered including additional details regarding discrimination on the basis of ''pregnancy or related conditions'' in § 92.208 to mirror its placement to the Department's title IX implementing regulations at 45 CFR 86.21(c), 86.40, 86.52(b), and 86.57. However, having considered the comments received, OCR concluded that the rule is better served by leaving ''pregnancy or related conditions'' in § 92.101(a)(2), which outlines the scope of discrimination on the basis of sex. The Department believes § 92.101(a)(2)—which addresses forms of sex discrimination generally—is a better location, so as to not suggest that discrimination based on pregnancy or its related conditions is limited to instances of discrimination involving only marital, parental, or family status.

Comment: Many commenters supported the inclusion of pregnancy-related conditions, but suggested additional changes to the rule, including explicit descriptions of what pregnancy or related conditions encompasses. Several commenters encouraged OCR to add language establishing that pregnancy-related conditions specifically include pregnancy termination, childbirth, false pregnancy, ectopic pregnancy, miscarriage, and recovery, including any refusal of service or procedure based on any other protected basis under the rule.

Response: OCR agrees that protections for ''pregnancy or related conditions'' are critical and affirms that covered entities may not discriminate against individuals based on pregnancy or related conditions under section 1557. However, additional language to identify what the term ''pregnancy or related conditions'' means is not necessary given that the regulatory language is not intended to be exhaustive as explained above. As noted in the NPRM, OCR understands the term as including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom, which are the ''grounds'' prohibited under title IX.[301] 87 FR 47878.

Comment: Some commenters opposed the inclusion of pregnancy-related conditions. One commenter cautioned OCR to not rely on the *Dobbs* decision or its effects as a basis for prohibiting discrimination on pregnancy-related conditions, including pregnancy termination. Some commenters stated *Dobbs* held that the regulation of abortion was returned to the States, and thus, OCR cannot propose a provision that is inclusive of abortion, which would be contrary to Congressional and judicial prohibitions. Other commenters, despite acknowledging

[300] The application of this final rule to covered entities with conscience or religious freedom objections are discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[301] 45 CFR 86.40(a).

that the title IX regulations have since 1975 included ''pregnancy and related conditions'' (which includes termination of pregnancy), argued that because the term ''termination of pregnancy'' is not defined in the title IX regulations, the term should not be adopted here. A commenter suggested that OCR either not include ''termination of pregnancy'' as a pregnancy-related condition or clarify that ''termination of pregnancy'' does not include abortion because abortion is not morally equivalent to pregnancy or childbirth and should not be treated as such. Some commenters who opposed including pregnancy-related conditions argued that if the final rule includes such a term, OCR must account for its impact.

Response: OCR appreciates comments regarding the inclusion of ''pregnancy or related conditions,'' including those concerns related to *Dobbs.* OCR is not promulgating this rule in response to *Dobbs,* which addressed the question of whether the Constitution provides a right to abortion. This rule does not purport to interpret the Constitution, nor does it address whether States may regulate or ban abortions. Indeed, we emphasize that section 1303 of the ACA specifically states that ''[n]othing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.'' 42 U.S.C. 18023(c)(1). Pursuant to that provision, this rule should not be read to override any such State abortion laws. OCR reiterates that a covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the care, based on a professional or business judgement about the scope of services it wishes to offer, or for any other nondiscriminatory reason.

This rule implements section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities by incorporating the ''grounds prohibited under'' title VI, title IX, the Age Act, and section 504. Under title IX, discrimination based on pregnancy has been understood to constitute sex discrimination since 1975. Consistent with this long-standing interpretation, OCR will consider complaints of sex discrimination, including discrimination based on pregnancy or related conditions, on a case-by-case basis, and it will look to title IX and section 1557 case law to determine whether discrimination on the basis of sex has occurred. OCR is unaware of any instance in which a covered entity has been required to provide an abortion under title IX, title VI, the Age Act, or section 504.

Consistent with this understanding of the incorporated statutes, the relevant case law, and historical practice, OCR emphasizes that a covered provider's decision not to provide abortions is not itself sex discrimination, under section 1557. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. As noted above, a covered provider that generally offered abortion care could violate that prohibition if, for example, it generally offers or provides abortions to patients but refused to offer or provide an abortion to a particular patient because of that patient's race or disability. But a covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason.

Comment: Many commenters stated that *Dobbs* prevents OCR from protecting access for abortion care through its proposed definition of sex, because the Supreme Court held there is no constitutional right to an abortion and returned the issue to the States. Other commenters also stated that, because *Dobbs* returned the issue of abortion to the States, OCR cannot create regulations that would create conflicts with State laws banning or restricting abortion. Additionally, these commenters raised section 1303 as another basis under which the ACA prohibits OCR from issuing regulations that preempt State laws regarding abortion.

Other commenters raised the view that *Dobbs* reaffirmed *Bray* v. *Alexandria Women's Health Clinic,* 506 U.S. 263 (1993), which held that opposition to abortion does not constitute animus against women. They contend that OCR cannot therefore define sex to include pregnancy termination. Commenters also stated that *Dobbs* established that there is no compelling government interest in promoting abortion, and therefore OCR has no authority to promulgate rules in support of abortion. A few commenters expressed that under the ''major questions'' doctrine, OCR cannot set an abortion policy such as prohibiting discrimination on the basis of pregnancy termination without explicit authorization from Congress.

Response: OCR appreciates the commenters' concerns and their interpretation of *Dobbs.* The *Dobbs* opinion did not address title IX or section 1557. *Dobbs* nowhere prohibits OCR from issuing regulations or promulgating rules under its statutory authorities. Indeed, under section 1557, HHS is charged by Congress with the elimination of discriminatory barriers in the administration and provision of a diverse range of health programs and activities.

As OCR has previously stated, this rule does not establish a Federal policy requiring or promoting abortion services. Although OCR has concluded that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision, see § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status), as we note throughout this preamble, OCR emphasizes that a covered provider's decision not to provide abortions does not itself constitute discrimination in violation section 1557. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities.

It bears emphasis that nothing in the ACA, including section 1557, has ''any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). In addition, nothing in the ACA, including section 1557, preempts or has any effect on State laws regarding ''the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions'' as provided in section 1303 of the ACA, 42 U.S.C. 18023(c)(1).

OCR's interest is protecting individuals against prohibited forms of discrimination under section 1557 when accessing the range of health programs and activities covered under the statute. OCR also disagrees that the ''major questions'' doctrine is implicated by its promulgation of rules that protect individuals from discrimination on the basis of sex consistent with the manner in which the term has long been interpreted in the title IX context.

Comment: Many commenters stated that *Dobbs* had—and continues to have—a significant impact that warrants section 1557's protections against

discrimination on the basis of pregnancy or related conditions. Many commenters discussed that *Dobbs* limited access to abortion nationwide and created a complex web of State laws that ban or severely restrict access to care. These commenters stated that certain communities, including people of color, people with low incomes, immigrants, young people, people with disabilities, and LGBTQI+ individuals are most likely to face legal barriers to accessing abortion care, including an increased threat of arrest and prosecution in States hostile to abortion.

Many commenters also posited that States' efforts to restrict access to abortion have resulted in further challenges to accessing other reproductive health care, including contraception, fertility care and treatment, and miscarriage or early pregnancy loss management. Commenters cited examples from multiple States where women experiencing miscarriages have been denied care even as their pregnancy-related complications threaten their health and lives.

Response: OCR understands commenters' concerns regarding the negative health impacts stemming from the *Dobbs* decision, including on those with pregnancy-related conditions. We emphasize, as we have repeatedly throughout this preamble, that this rule is neither a response to *Dobbs* nor affected by that decision. This rule rests on the application of section 1557's nondiscrimination prohibition, and the longstanding interpretation of title IX's prohibition on sex discrimination to include discrimination on the basis of pregnancy and related conditions.

Comment: Many commenters raised concerns about access to prescriptions related to contraception, miscarriages or early pregnancy loss, and medication abortion. Commenters also raised concerns about access to drugs prescribed to treat conditions like chronic disease or illness that are unrelated to abortion, but may have the effect of terminating a pregnancy. Some commenters explained that pharmacists are fearful about dispensing medications that could terminate a pregnancy even when the medication is not prescribed for the purpose of abortion, and in some instances, pharmacists have refused to fill prescriptions in certain States that have banned abortion.

In States that have banned abortion, commenters noted that physicians, health care providers, and pharmacists fear they will be criminally prosecuted under State law, leading to denials or delays in lawful access to medications to treat conditions unrelated to abortion. For instance, many commenters explained that certain drugs prescribed to treat health conditions such as cancer, arthritis, ulcers, autoimmune diseases, or other chronic conditions are being denied or limited because they can result in termination of a pregnancy. Specifically, commenters relayed that some treatments for conditions such as breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression involve drugs that are being denied because of an indirect potential relationship with pregnancy termination.

Similarly, many commenters requested clarification that section 1557's prohibitions on discrimination protect access to contraception in the retail pharmacy setting. They raised concerns and described instances where individuals are denied access to hormonal contraception at a pharmacy that provides other forms of contraceptives. Some commenters opined that a pharmacy's refusal to provide prescribed medication to enable IUD (intrauterine device) insertion, or to treat an incomplete miscarriage, should be considered a section 1557 violation.

Commenters were concerned that such discrimination is not only sex and disability discrimination, but also creates additional and unnecessary barriers to prescription drugs that people need to live and maintain their health. For example, many commenters discussed that people with disabilities are increasingly denied or subjected to barriers to obtaining methotrexate, which is a prescription drug used to treat cancer and autoimmune conditions, because of the drug's potential effects on pregnancy. Many commenters explained that a pharmacist's refusal to fill an individual's prescription or a pharmacist's decision to not stock a specific drug or class of drugs inevitably harms persons with disabilities and women, especially those experiencing miscarriages and early pregnancy loss. They stated that women are also more likely than men to have autoimmune diseases for which many of these drugs are prescribed.

Response: OCR appreciates comments relating to access to lawfully prescribed and medically necessary medications. To start, OCR notes that, on September 29, 2023, after the close of the comment period for this rule, OCR issued revised guidance to pharmacies that supersedes the guidance referred to by some commenters.[302] If a covered entity denies or delays lawful access to medications to support persons with disabilities, treat cancer, or treat an autoimmune condition, that refusal could violate section 1557 if, for example, the refusal is on the basis of a prohibited ground, such as the person's race, age, disability, or sex. But, as OCR clarified in its updated guidance to the nation's pharmacies, section 1557 does not require pharmacies to fill prescriptions for medication for the purpose of abortion, nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion.[303] OCR provided several examples in the guidance, in which denying lawfully prescribed medication to customers may violate civil rights laws.[304] For example, where a treating physician diagnoses a miscarriage complicated by a uterine infection and orders an antibiotic to treat a patient's chills, fever, and vaginal bleeding, a pharmacy that refuses to provide the antibiotic because of concern that subsequent care may include an abortion may be discriminating on the basis of sex. OCR will evaluate and apply all applicable statutory protections, including relevant religious freedom and conscience protections, on a case-by-case basis.

In addition, the ACA is hardly silent on the issue of abortion. It contains an elaborate set of rules for when and how a qualified health plan may refuse or be prohibited from providing or paying for certain abortions. See 42 U.S.C. 18023(a)–(b). It further specifies that State laws regarding abortion are not preempted and that ''nothing in this act shall be construed to have effect on federal laws regarding—(i) conscience protections; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay

[302] *See* U.S. Dep't of Health & Hum. Servs., *Guidance to the Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies,* (Sept. 29, 2023), *https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.* On April 5, 2024, the court in *State of Texas* v. *Becerra et al.,* No. 7:23–cv–00022–DC, Order for S.J., ECF No. 69 (W.D. Tex.), held that the revised guidance mooted plaintiffs' legal challenge to the superseded guidance.

[303] *See* U.S. Dep't of Health & Hum. Servs., *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (September 29, 2023), *https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html* (''nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion'').

[304] *Id.*

for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' *Id.* at 18023(c).

Comment: OCR sought comment on the title IX abortion neutrality provision's inclusion and on other possible readings of that provision. Although OCR also sought comment on whether the Department should align its title IX regulation regarding the abortion neutrality provision of title IX with the 2000 ''Common Rule'' version of that regulatory provision that more than 20 agencies have long adopted,[305] no comments addressed this specifically. Many commenters supported OCR's proposal to not import the language of title IX's abortion neutrality provision into section 1557's final rule. Doing so, they contended, would undermine and be contrary to OCR's implementation of section 1557, which is to eliminate barriers and expand access to health care and coverage. These commenters discussed how abortion is a critical form of health care and patients seek or need to terminate a pregnancy for a wide variety of reasons.

Response: OCR's determination to not incorporate title IX's abortion neutrality provision is based on our conclusion that doing so is not required and unnecessary as the ACA itself speaks to this issue. The ACA provides that nothing in the statute, including section 1557, has ''any effect on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). By contrast, the ACA does not contain specific language directing the incorporation of title IX's abortion neutrality provision. That section 1557 does not require its incorporation is therefore the better reading of the statute with regard to title IX. We reiterate, moreover, that this rule does not—and indeed, cannot—create a right to abortion; it operates only to prohibit discrimination on specific prohibited grounds.

Comment: Several commenters highlighted the differences between section 1557's coverage of health care from title IX's coverage of education because the decision to receive health care from a particular provider is often driven by factors, including geographic location, cost, insurance coverage, the type of care being sought, and the urgency of that care. Many other commenters stated that importing title IX's abortion neutrality provision would allow denials of care that can directly harm patients, including putting at risk a patient's life or health.

Response: OCR agrees with commenters that health care is fundamentally different from education. And although section 1557 incorporates ''the ground prohibited under'' title IX and the ''enforcement mechanisms provided for and available under'' that statute, 42 U.S.C. 18116(a), it does not incorporate title IX's other provisions. Title IX's abortion neutrality provision does not purport to define what constitutes prohibited sex discrimination under title IX—the ''ground prohibited'' under that statute—and it is not an enforcement mechanism; it provides only that nothing in title IX shall be construed to require or prohibit any person or entity to provide or pay for abortion or related benefit or service.

Congress made clear that the ACA, including section 1557, would have no effect on several specific Federal laws protecting individuals and entities that refuse to provide abortions. *See* 42 U.S.C. 18023(c)(2)(A). The ACA itself restates provisions of longstanding Federal law by making clear in 18023(c)(2)(A) that ''nothing in this act shall be construed to have effect on federal laws regarding—(i) conscience protections; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' These provisions reiterate existing Federal restrictions on abortion. For example, the Weldon Amendment forbids funds appropriated to HHS from being ''made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.'' [306] The Coats-Snowe Amendment forbids discriminating against an entity that refuses to undergo training in performance of or referrals for abortions.[307] The Church Amendment forbids requiring any individual ''to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions.'' [308] It also provides that an entity's receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act ''does not authorize any court or any public official or other public authority to require . . . such entity to . . . make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions.'' [309] The Church Amendments also prohibit discrimination against health care personnel related to their employment or staff privileges because they ''performed or assisted in the performance of a lawful sterilization procedure or abortion.'' [310] The same nondiscrimination protections also apply to health care personnel who refuse to perform or assist in the performance of sterilization procedures or abortion.[311] In addition, some of HHS's programs and services are specifically governed by abortion restrictions in the underlying statutory authority or program authorization.[312] The ACA also contains a variety of ''special rules'' that apply specifically to

[305] *See* 65 FR 52869 (Aug. 30, 2000); *see also, e.g.,* 28 CFR 54.235(d)(1) (DOJ regulation). The agencies that have adopted the Common Rule include: Agency for International Development, 22 CFR part 229; Corporation for National and Community Service, 45 CFR part 2555; Department of Agriculture, 7 CFR part 15d.; Department of Commerce, 15 CFR part 8a; Department of Defense, 32 CFR part 196; Department of Energy, 10 CFR part 1040; Department of Homeland Security, 6 CFR part 17; Department of Housing and Urban Development, 24 CFR part 3; Department of the Interior, 43 CFR part 41; Department of Justice, 28 CFR part 54; Department of Labor, 29 CFR part 36; Department of State, 22 CFR part 146; Department of Transportation, 49 CFR part 25; Department of the Treasury, 31 CFR part 28; Department of Veterans Affairs, 38 CFR part 23; Environmental Protection Agency, 40 CFR part 5; Federal Emergency Management Agency, 44 CFR part 19; General Services Administration, 41 CFR part 101–4; National Aeronautics and Space Administration, 14 CFR part 1253; National Archives and Records Administration, 36 CFR part 1211; National Science Foundation, 45 CFR part 618; Nuclear Regulatory Commission, 10 CFR part 5; Small Business Administration, 13 CFR part 113; and Tennessee Valley Authority, 18 CFR part 1317.

[306] Consol. Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, section 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024). *See also, e.g., id.* sections 506–07, 138 Stat. 460, 703 (Hyde Amendment provisions).

[307] 42 U.S.C. 238n(a).

[308] 42 U.S.C. 300a–7(d).

[309] 42 U.S.C. 300a–7(b)(2)(A).

[310] 42 U.S.C. 300a–7(c)(1); *see also* U.S. Dep't of Health & Hum. Servs., *Guidance on Nondiscrimination Protections under the Church Amendments, https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html.*

[311] 42 U.S.C. 300a–7(c)(1).

[312] *See, e.g.,* title X of the PHS Act, 24 U.S.C. 300a–6; section 1303(b)(4) of the ACA, 42 U.S.C. 18023.

abortion coverage and services.[313] Each of these laws continues to apply and is not affected by this rule. Accordingly, it is not necessary to incorporate title IX's abortion neutrality provision.

OCR emphasizes that a covered provider's decision not to provide abortions or abortion coverage does not itself constitute discrimination in violation section 1557. As described above, section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. As such there may be nondiscriminatory reasons for a provider not to offer abortion care or coverage. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason.

Comment: Many commenters who supported OCR's proposal noted that section 1557 does not require incorporation of title IX's abortion neutrality provision because if Congress wanted to include such a provision, it would have done so either by explicitly referencing title IX's abortion neutrality provision or by including text matching 20 U.S.C. 1688. Commenters suggested that silence on the incorporation or importation of title IX's abortion neutrality provision is not an oversight on the part of Congress, but instead an intentional decision, as Congress legislates with knowledge of the basic rules of statutory construction.

Many commenters stated that the Congressional drafters of section 1557 did not pick and choose among the multiple title IX exceptions, including those specific to military training, admissions decisions, and membership practices of certain tax-exempt organizations, and that there is no justification for OCR to do so either. They maintained that the statute only references title IX for the prohibition of sex discrimination. Commenters also said there was no need to import title IX's abortion neutrality provision given the availability of existing Federal statutory protections for covered entities and individuals who object to the provision, payment, or referral of abortion services. Many commenters noted that OCR proposed a process in which a covered entity could seek an exemption based on conscience or religious conflicts. These commenters argued that, where permitted by relevant Federal laws, such analysis by OCR would also account for any potential harm to third parties.

Response: For the reasons we set forth above, OCR maintains that importing title IX's abortion neutrality provision in this rule is not legally required by the statute.

Comment: Other commenters who supported not importing the title IX abortion neutrality provision suggested that the final rule should include the Proposed Rule's discussion that EMTALA protects emergency care for pregnancy-related conditions, including termination of pregnancy. Some commenters expressed that the final rule should make clear that section 1557 incorporates section 1303(d) of the ACA, 42 U.S.C. 18023(d), which states that nothing in title I of the ACA relieves any health care provider from providing emergency services as required by EMTALA.

Response: OCR does not enforce EMTALA and directs commenters to the discussion of EMTALA under § 92.3. OCR notes that the 2022 NPRM's discussion of EMTALA does not alter any requirements under section 1557, EMTALA's existing obligations, or the Department's previous guidance regarding EMTALA. Nothing in this rule changes or otherwise affects any health care provider's obligations with respect to EMTALA, including with respect to the rights, remedies, procedures, or legal standards available to individuals and entities under section 1303(c) of the ACA.

Comment: Many commenters objected to OCR's proposal that it was not required to import title IX's abortion neutrality provision in this rule. These commenters argued that the provision must be included to explicitly address that section 1557 and its implementing regulations are abortion neutral. Some commenters maintained that the 2022 NPRM's request for comment on whether ''it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination,'' 87 FR 47879, constituted an ''abortion mandate'' that would discriminate against providers and covered entities who object to abortion. Some commenters stated that the inclusion of ''pregnancy or related conditions'' as a form of sex discrimination without importing title IX's abortion neutrality provision would strip providers of their ability to object to pregnancy terminations. Some commenters acknowledged that other Federal laws exist to protect religious freedom and conscience, but nevertheless expressed concerns that absent the provision's adoption of title IX's abortion neutrality provision, health care providers and entities with religious objections would be left without protections and would be forced to provide, cover, pay, or refer for abortion services.

Response: OCR appreciates commenters' concerns, but for the reasons stated above, we disagree. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide, pay for, cover, or refer for abortions based on religious or conscience objections to performing the procedure. OCR also intends to enforce and comply with all applicable religious freedom and conscience protections, including section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, RFRA, and other applicable religious freedom and conscience laws. We have added a procedure for recipients whereby they may rely on such protections or seek assurance of those protections, if they wish. See § 92.302.

Comment: Other commenters who objected to the Department's position contended that, on the one hand, OCR was relying on title IX's regulations to prohibit discrimination on pregnancy-related conditions, while, on the other hand, ignoring title IX's statutory abortion neutrality provision and religious exception. These commenters argued that OCR is arbitrarily and capriciously picking and choosing which provisions of title IX to implement. They stated that, under title IX, declining to provide or pay for any service related to abortion is not treated as prohibited sex discrimination and therefore it cannot be that the same action, under section 1557, could constitute prohibited sex discrimination. Several commenters argued that the abortion neutrality provision, unlike title IX's exceptions, is a rule of construction that applies to all of title IX, including the statute's prohibition on sex discrimination, and thus OCR must incorporate the provision into any section 1557 implementing regulations.

Response: OCR appreciates commenters' concerns. As we explained above, however, section 1557 incorporates some, but not all, parts of title VI, title IX, the Age Act, and section 504. Specifically, section 1557 incorporates the ''ground'' of discrimination and the ''enforcement mechanisms'' under the referenced statutes, including title IX. Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations and case law.

[313] *See* 42 U.S.C. 18023(b).

But section 1557 does not incorporate provisions of title IX or that statute's regulations that do not define or interpret what constitutes a ground of discrimination or an enforcement mechanism. Those provisions include the religious exception and the abortion neutrality provision. This reading gives meaning to every term in section 1557, while recognizing that although the statute incorporates parts of other civil rights statutes, each statute addresses distinct issues and contexts. Title IX's abortion neutrality provision is a rule of construction as to what acts can be required of recipients under title IX, but nothing in the provision states that it construes what constitutes a ground of prohibited discrimination. In section 1557, Congress was explicit in the limited incorporation of title IX when it listed only the ground to be prohibited by itle IX and the enforcement mechanisms that apply, and the title IX abortion neutrality provision is not an enforcement mechanism.

Comment: Many commenters stated that OCR's proposal to not import the title IX abortion neutrality provision is contrary to Congress's intent when it drafted section 1557 and explicitly adopted by reference the entire title IX scheme under 20 U.S.C. 1681 *et seq.* Commenters stated that enactment of title IX did not simply prohibit sex discrimination, because at least two categories of conduct are not, in Congress's view, what constitutes sex discrimination for purposes of title IX—religious decisions by an entity that conflict with the terms of title IX and the refusal to provide or pay for abortion. In their view, this means that OCR cannot prohibit discrimination based on termination of pregnancy or abortion as a form of sex discrimination.

Response: OCR appreciates commenters' concerns but disagrees that the manner in which Congress chose to cite title IX in section 1557 indicates an intent to limit what constitutes discrimination of the basis of sex for the reasons stated above. OCR specifically disagrees that the inclusion of ''*et seq.*'' indicates Congress's intent to incorporate the entire statute, thereby negating Congress's use of the terms ''ground prohibited'' and ''enforcement mechanisms'' when describing which portions of title IX shall be incorporated in section 1557. Moreover, as discussed in detail above (*see* Treatment of the Title IX Religious Exception), OCR's analysis considers the entire statute, including title IX's specific limitation to the context of educational programs and activities.

Comment: Commenters argued that title IX's adoption by reference supports Congress's longstanding position to legislate in a manner that remains neutral with respect to abortion. In support of this view, some commenters pointed to the Pregnancy Discrimination Act of 1978, where Congress prohibits discrimination on the basis of pregnancy, childbirth, or related medical conditions, but also explicitly included an exemption for health insurance benefits for abortion which, in their view, demonstrates Congress's intent to remain neutral on abortion.

Response: OCR will adhere to the specific terms Congress enacted in section 1557 as well as other applicable Federal laws, including section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, RFRA, and other applicable religious freedom and conscience laws.

Comment: Other commenters who objected to OCR's proposal not to import title IX's abortion neutrality provision in the rule expressed concern that OCR ignored section 1303 of the ACA, 42 U.S.C. 18023, which they opine requires abortion neutrality throughout the ACA. For example, commenters discuss that section 1303(a), which gives States the option to prohibit abortion coverage in health plans, would be rendered meaningless if the final rule requires such coverage by either prohibiting discrimination on the basis of pregnancy-related conditions or by failing to include a provision establishing section 1557's abortion neutrality. Commenters stated that section 1303 forecloses any construction of section 1557 that would require the provision or coverage of abortion.

Response: OCR appreciates commenters' concerns regarding section 1303's applicability to section 1557. Section 1303(a) provides that States and qualified health plans may, to the extent allowed by State law, opt to offer or prohibit abortion coverage; it does not require that section 1557 to import the language of title IX's abortion neutrality provision. Section 1303 primarily grants States flexibility to decide whether qualified health plans sold through their respective Exchanges can include coverage benefits for abortion services. *See* 42 U.S.C. 18023(a) (''State opt-out of abortion coverage''). And, unless otherwise prohibited by State law, participating issuers may elect to cover abortion services in qualified health plans. For qualified health plans that elect to offer as a coverage benefit abortion services for which Federal funding is prohibited, section 1303 establishes separate accounting requirements to ensure Federal funds are segregated and maintained separate from a policy holder's out-of-pocket funds, which may pay for abortion coverage. 42 U.S.C. 18023(b)(2)(B)–(C). OCR acknowledges that section 1303 allows qualified health plans the independence to choose whether to provide abortion coverage where consistent with State law, but it does not command that the final rule import title IX's abortion neutrality provision.

OCR reiterates, moreover, that a covered provider's decision not to provide abortions or abortion coverage does not itself constitute discrimination in violation of section 1557. A covered entity that generally offered abortion care could violate section 1557 if, for example, it refused to provide an abortion to a particular patient because of their race or disability. But a covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason. Further, OCR maintains that importing title IX's abortion neutrality provision is not required given the recognition of the ACA provisions on abortion and the inclusion of those provisions in regulatory text.

Comment: Several commenters pointed to the Weldon and Church Amendments to assert that OCR does not have the authority to prohibit discrimination on the basis of pregnancy termination and requested that OCR include title IX's abortion neutrality provision to avoid any uncertainty on the issue. Other commenters urged OCR to include affirmative language in the final rule that section 1557 does not require the provision of, referral for, or coverage of abortion to eliminate any uncertainty maintained by many religious providers.

Response: OCR remains committed to upholding the Federal laws, including the abortion and conscience provisions of the ACA itself, the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws that provide protection to covered entities. It is not necessary to include title IX's abortion neutrality provision in the final rule to provide certainty as to the safeguards in place to protect religious freedom and conscience. As discussed, a covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure. Also, we refer again to the process described at § 92.302, whereby

providers may rely on the protections in Federal law for religious freedom and conscience or seek assurance of such protections from OCR, if they wish.

Comment: Many commenters who objected to OCR's proposal not to import title IX's abortion neutrality provision in this rule expressed concern regarding the Proposed Rule's discussion of EMTALA and emergency medical conditions that may necessitate abortion. Some commenters opined that the Proposed Rule's preamble was a potential regulatory change by HHS to designate an ''abortion mandate'' in EMTALA. Some commenters also noted that such an ''abortion mandate'' meant that HHS could preempt State laws that prohibit abortion or alter State licensing and health and safety laws. Other commenters raised the ''major questions'' legal doctrine to conclude that Congress would not have granted HHS the authority to promulgate such rules that would rewrite the text of EMTALA on any grounds, including on the issue of abortion.

Response: These comments fall outside the scope of the final rule. To be clear, EMTALA does not alter any of section 1557's requirements, and this rule does not alter existing obligations under EMTALA, or any of the Department's previous guidance regarding EMTALA. Thus, nothing about the final rule imposes any change to EMTALA's statutory scheme, let alone a ''radical or fundamental change'' such that the major questions doctrine is implicated.[314] Further, commenters' view that the ''major questions'' legal doctrine applies is also misplaced. The ''major questions'' doctrine applies in certain ''extraordinary cases'' in which courts will refuse to defer to agency action it considers having ''vast economic and political significance'' absent express authorization from Congress.[315] As described, the final rule does not alter any existing obligations or guidance as to EMTALA. The ''major questions'' doctrine is not relevant here.

Additionally, there is no basis for commenters' concerns about a potential regulatory change or preemption of State laws, including those involving licensing and health and safety. Per the ACA itself, this rule does not override State laws regarding ''the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions'' or alter preexisting obligations under Federal law. *See* 42 U.S.C. 18023(c)(1), (d).

Comment: Other commenters stated that the *Franciscan Alliance* opinion vacating provisions similarly related to pregnancy-related conditions in the 2016 Rule precludes OCR from issuing this final rule with similar provisions that do not import title IX's abortion neutrality provision. Some commenters maintained that if OCR promulgates this rule with similar provisions, OCR risks being held in contempt of court. Other commenters stated that to adequately issue this final rule, OCR must explain why the holdings of the *Franciscan Alliance* court are incorrect or inapplicable to this rulemaking.

Response: OCR appreciates commenters' concerns, but notes that they mischaracterize the impact of the relief ordered in *Franciscan Alliance* on this rulemaking. The *Franciscan Alliance* court vacated a portion of the 2016 Rule—namely its interpretation of sex discrimination to include gender identity and termination of pregnancy.[316] The court also enjoined the Federal Government from interpreting or enforcing section 1557 or any related implementing regulations against the plaintiffs in that particular case in a manner that would require those plaintiffs to perform or provide insurance coverage for gender-transition procedures or abortions.[317] The court's orders have no effect on, and do not apply to, OCR's authority to promulgate new regulations, including this final rule, and to enforce those regulations against covered entities that were not plaintiffs in *Franciscan Alliance.* The instant rulemaking is new and includes significant changes that address concerns raised against the 2016 Rule in *Franciscan Alliance.* Also notable is the fact that § 92.302 outlines new procedures whereby persons may rely on the protections of Federal conscience or religious freedom laws or choose to seek assurance of such protections, if they wish. And OCR has issued a separate final rule codifying safeguards for Federal conscience protections. *See* 89 FR 2078 (Jan. 11, 2024). In addition, OCR has considered the legal and factual developments since the issuance of the 2016 Rule, which help to inform its decisions in this final rule. Therefore, OCR's promulgation of its new regulation in no way contravenes the *Franciscan Alliance* court's orders, and OCR will comply with that court's orders, and all other applicable orders, in enforcing this final rule. OCR thus disagrees that issuing this rule puts the agency at risk of being held in contempt, merely for acting within the authority that has been lawfully delegated to HHS under section 1557.

Comment: Some commenters requested that OCR provide clarification, either in a final rule or via sub-regulatory guidance, as to how the proposed pregnancy discrimination protections relate to and may be different from those guaranteed by the Pregnancy Discrimination Act of 1978.

Response: OCR appreciates these commenters' request and is intent on providing clear guidance on the scope of the final rule and its application through educational outreach efforts, trainings, and individualized assistance. OCR clarifies that it does not enforce the Pregnancy Discrimination Act of 1978, Public Law 95–555, which amended title VII, and applies to discrimination on the basis of pregnancy, childbirth, or related medical conditions in employment settings, while section 1557 applies to health programs or activities that receive Federal financial assistance. We also note that section 1557, title IX, and title VII are read consistently to apply similar protections in the different contexts in which they apply.

Comment: Other commenters expressed concern that *Dobbs* created tension between health care providers and patients, increasing distrust in providers. Commenters also stated that *Dobbs* has created chaos in the health care system, increasing the risk that patients will experience discriminatory care and suffer delays in lifesaving treatment as a direct result of legal and medical uncertainty. These commenters said that discrimination in care propagates more distrust, which is a significant barrier for individuals seeking care and is precisely what section 1557 was designed to protect against.

Response: OCR appreciates the commenters' concerns. OCR understands that the provider-patient relationship is critical to the provision of quality, competent health care and critical for achieving optimal health. For example, in proposing the policies and procedures required under § 92.8, OCR confirmed that patients value the ability to have their concerns directly heard by

[314] *West Virginia* v. *EPA,* 597 U.S. 697, 723 (2022).

[315] *West Virginia* v. *EPA,* 597 U.S. at 716 (Invalidating the Environmental Protection Agency's plan to require power plants to shift from coal to renewables, reducing gross domestic product by at least a trillion dollars within two decades); *Nat'l Fed. of Indep. Business* v. *OSHA,* 142 S. Ct. 661, 665 (2022) (per curiam) (Invalidating the Occupational Safety and Health Administration order requiring ''84 million Americans to either obtain a COVID–19 vaccine or undergo weekly medical testing'').

[316] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945–47 (N.D. Tex. 2019).

[317] *Franciscan All., Inc.* v. *Becerra,* 553 F. Supp. 3d 361, 378 (N.D. Tex. 2021).

their provider,[318] and understands that not all communities in the United States feel the same level of trust in their health care provider, particularly among racially and ethnically diverse communities.[319] OCR further recognizes that in light of *Dobbs,* in certain States, a patient may fear sharing critical information relevant to their health status. OCR is separately considering revisions to the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information related to reproductive health care, which will assist in generating more trusting patient-provider relationships. *See* HIPAA Privacy Rule To Support Reproductive Health Care Privacy, notice of proposed rulemaking, 88 FR 23506 (Apr. 17, 2023).

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.208, with modification. For clarity, we are finalizing by adding a cross-reference to § 92.101(a)(2)'s description of sex discrimination.

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209, we proposed prohibiting discrimination against an individual on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual is known to have a relationship or association.

The comments and our responses regarding proposed § 92.209 are set forth below.

Comment: Commenters on this provision overwhelmingly expressed support for the inclusion of an explicit prohibition on associational discrimination, which many stated will protect individuals, including children and elders, who associate with LGBTQI+ individuals. Other commenters said that a prohibition of associational discrimination will also protect individuals and families who associate with an individual who has a history of drug use or substance use disorder (SUD). Some commenters noted that the 2020 Rule repealed the 2016 Rule's associational discrimination protections at former 45 CFR 92.209, despite comments urging OCR to maintain the provision. Many commenters noted that courts have recognized an individual's right to be free from discrimination based on their association with another an individual protected on one or more bases under section 1557.[320]

Response: OCR agrees that it is important to include an explicit provision addressing associational discrimination, as both consistent with courts' interpretation of what constitutes discrimination as well as to protect those experiencing such forms of discrimination.[321] As commenters noted, this particularly impacts LGBTQI+ people because significant numbers of children and elders live with or are cared for by LGBTQI+ people,[322] and some providers have refused to provide health care to children, for example, because their parents are gay or lesbian.[323] This is

[318] Leslie Read et al., The Deloitte Ctr. for Health Solutions, *Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?,* p. 3 (2021) (''62% [of surveyed people of color] want their local hospitals to ensure patients have a voice to relay their experiences and take action to address their problems.''), *https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html.*

[319] Leslie Read et al., The Deloitte Ctr. for Health Solutions, *Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?* (2021); *https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html.*

[320] *Falls* v. *Prince George's Hosp. Ctr.,* No. Civ. A 97–1545, 1999 WL 33485550 at *11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under section 504 when hospital required hearing parent to act as interpreter for child who was deaf); *Holcomb* v. *Iona Coll.,* 521 F.3d 130 (2nd Cir. 2008) (an employee has a cognizable title VII claim against an employer who takes an adverse action against the employee because of the employee's association with a person of another race); *Larimer* v. *Int'l Bus. Machines Corp.,* 370 F.3d 698, 702 (7th Cir. 2004) (the court affirmed lower court's summary judgment in favor of defendant employer, in part, because plaintiff employee's employment claim did not fit into any one of three recognized categories of associational discrimination under the ADA); *Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 279 (2d. Cir. 2009) (court permitted associational discrimination claim brought by deaf father's children who were forced to interpret for him in the hospital); *Mx Grp., Inc.* v. *City of Covington,* 293 F.3d 326, 335 (6th Cir. 2002) (holding a drug and alcohol treatment center that was wrongfully denied a zoning permit because it provided services to individuals with disabilities was subjected to discrimination under title II of the ADA); *Barrett* v. *Whirlpool Corp.,* 556 F.3d 502, 512 (6th Cir. 2009) (title VII and sec. 1981 forbid employment discrimination on the basis of association with or advocacy for a protected party); *Tetro* v. *Elliot Popham Pontiac, Oldsmobile, Buick, & GMC Trucks, Inc.,* 173 F.3d 988, 994–95 (6th Cir. 1999) (court reversed lower court's dismissal of plaintiff's associational discrimination claim because title VII prohibits such discrimination); *Deffenbaugh-Williams* v. *Wal-Mart Stores, Inc.,* 156 F.3d 581, 589 (5th Cir. 1998) (court upheld jury's determination that employer wrongfully terminated employee based on employee's association with a Black person) vacated in part on other grounds by *Williams* v. *Wal-Mart Stores, Inc.,* 182 F.3d 333 (5th Cir. 1999) (en banc); *Parr* v. *Woodmen of the World Life Ins. Co.,* 791 F.2d 888, 892 (11th Cir. 1986) (trial court erred in dismissing plaintiff's associational discrimination claim because § 1981 prohibits associational discrimination); *Hively* v. *Ivy Tech Cmty. Coll. of Ind.,* 853 F.3d 339, 345 (7th Cir. 2017) (finding plaintiff had a case for sex discrimination in part based on the gender and orientation of her partner); *Zarda* v. *Altitude Express,* 883 F.3d 100, 124 (2d Cir. 2018), (court held that prohibition of associational discrimination applies with equal force to all the classes protected by title VII); *Videckis* v. *Pepperdine Univ.,* 150 F. Supp. 3d 1151, 1161 (C.D. Cal. 2015) (sexual orientation discrimination is sex discrimination in part because it involves treatment that was based on the sex of the person(s) with whom the individual associates); *Baldwin* v. *Foxx,* 2015 WL 4397641 (EEOC July 15, 2015) (''Sexual orientation discrimination is also sex discrimination because it is associational discrimination on the basis of sex.''); *Kauffman* v. *Maxim Healthcare Servs., Inc.,* No. 04–CV–2869, 2006 WL 1983196, at *3 (E.D.N.Y. July 13, 2006) (''Although Defendant correctly points out that the Second Circuit has not recognized as valid causes of action third-party claims of association discrimination or retaliation like those presented in the instant case, there is nevertheless a wealth of support in the prior decisions of the courts in this Circuit and our highest Court for recognizing these types of claims.'').

[321] *See Kengerski* v. *Harper,* 6 F.4th 531, 537–539 (3d Cir. 2021) (a white plaintiff employee's claim is justiciable under an associational discrimination legal theory under title VII of the Civil Rights Act of 1964, where his employer retaliated against him for complaining about a supervisor's racist remarks directed at the employee's biracial family member and other minority coworkers); *Kelleher* v. *Fred A. Cook, Inc.,* 939 F.3d 465, 469–470 (2d Cir. 2019) (an employer's reaction to a non-disabled employee's reasonable accommodation request to care for disabled dependent can support an inference of associational discrimination); *McGinest* v. *GTE Serv. Corp.,* 360 F.3d 1103, 1118 (9th Cir. 2004) (case involving indirect comments in the workplace that crossed racial lines, noting that ''Title VII has . . . been held to protect against adverse employment actions taken because of the employee's close association with black friends or coworkers'') (internal citations omitted); *Johnson* v. *Univ. of Cincinnati,* 215 F.3d 561, 574 (6th Cir. 2001) (a plaintiff who is not a member of a recognized protected class nevertheless alleges a cognizable discrimination claim under title VII and 42 U.S.C. 1981 if he alleges that he was discriminated against based on his association with a member of a recognized protected class); *Tetro* v. *Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 994–95 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under title VII based on his own race ''even though the root animus for the discrimination is a prejudice against the biracial child''); *Parr* v. *Woodmen of the World Life Ins.,* 791 F.2d 888, 892 (11th Cir. 1986) (''Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.''). *Cf. Loving* v. *Va.,* 388 U.S. 1 (1967).

[322] Family Equality Council, *LGBTQ Family Fact Sheet, https://www2.census.gov/cac/nac/meetings/2017-11/LGBTQ-families-factsheet.pdf,* (as of 2017, between 2 and 3.7 million children in the US have LGBTQ+ parents); Family Equality Council, *LGBTQ Family Building Survey* (2019), *https://www.familyequality.org/wp-content/uploads/2019/02/LGBTQ-Family-Building-Study_Jan2019-1.pdf* (77 percent of LGBTQ+ millennials either are already parents or are considering expanding their families in the years ahead); SAGE, *Caregiving in the LGBT Community* (2017), *https://www.lgbtagingcenter.org/resources/pdfs/SAGE%20Caregiver%20Guide%20Final%20Interactive.pdf* (approximately 3 million LGBTQ+ people are the primary caregiver for someone over the age of 50).

[323] Tresa Baldas, *Pediatrician Won't Treat Baby With 2 Moms,* USA Today (Feb. 18, 2015), *https://www.usatoday.com/story/news/nation/2015/02/18/doctor-discrimination-baby/23642091/.*

likely also to be particularly important for people, especially children, who cannot access health care without the support of a caregiver. Such conduct by a covered entity may violate this provision and other provisions of this part, including §§ 92.101 (Discrimination prohibited), 92.206 (Equal program access on the basis of sex), 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage), and 92.208 (Prohibition on sex discrimination related to marital, parental, or family status). Additionally, associational or caregiver discrimination also frequently arises in the context of disability discrimination, as addressed above in the preamble discussion of § 92.202 (Effective communication for individuals with disabilities). Another potential example of discrimination based on association relates to individuals with a substance use disorder (SUD) [324] and related stigma.[325] The ADA, section 504, and section 1557 prohibit discrimination on the basis of disability, and individuals with an SUD or a history of having an SUD typically are protected under these authorities, unless they are engaged in the current illegal use of drugs.[326] Section 92.209 makes clear that discrimination against individuals (including friends, nonfamilial caregivers, and family members) based on their association with individuals in recovery from SUD or with a history of drug use is prohibited under section 1557.

Comment: One commenter accurately observed that, unlike the Proposed Rule, the 2016 Rule's associational nondiscrimination provision referenced protections for both individuals and *entities* that associate with others. Emphasizing that an entity can also be discriminated against by other covered entities based on the original entity's association with an individual due to the individual's race, color, national origin, sex, disability or age, this commenter described a scenario where a health plan might discriminate against an entity that largely serves patients with LEP, LGBTQI+ populations, or an entity that provides Medications for Opioid Use Disorder (MOUD) to individuals with opioid use disorder.

Response: OCR recognizes that there may be instances where covered entities may discriminate against other entities based on these other entities' associations with populations they serve (including LGBTQI+ individuals, individuals with disabilities, etc.). For example, § 92.209 prohibits a covered entity from discriminating against another entity because that entity serves individuals protected under this rule, *e.g.,* individuals with SUD,[327] people with intellectual and developmental disabilities, people of a particular race or national origin, or people of a particular age. In this case, § 92.209 is violated based on the discriminated-against entity's association with an individual or individuals based on their race, color, national origin, sex, age, or disability. OCR did not intend to suggest in the Proposed Rule that this was no longer considered a prohibited form of discrimination and therefore is including ''entity'' in the final rule text.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.209, with modification. We have revised the provision to clarify that covered entities are prohibited from discriminating against individuals and entities under this provision by adding ''or entity'' in the following locations: ''. . . against an individual *or entity . . .,*'' and ''. . . with whom the individual *or entity . . . .*''

Nondiscrimination in the Use of Patient Care Decision Support Tools (§ 92.210)

Proposed § 92.210, entitled ''Use of clinical algorithms in decision-making,'' provided that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. We invited extensive public comment on this proposed provision, including on whether to limit the provision to clinical algorithms or to include additional forms of automated or augmented decision-making tools or models, such as artificial intelligence (AI) and machine learning, and whether the provision should include more specificity, such as explaining actions covered entities must take to identify and mitigate potential discrimination from these tools. 87 FR 47884. The Proposed Rule preamble described clinical algorithms as ''tools used to guide health care decision-making that could range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models.'' 87 FR 47880. The preamble also described clinical algorithms as tools used by ''hospitals, providers, and payers (*e.g.,* health insurance issuers) . . . to assist with health care decision-making for various purposes,'' including ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources, all of which affect the care that individuals receive.'' 87 FR 47880. The comments and our responses regarding § 92.210 are set forth below.

Comment: Many commenters requested that OCR codify a definition for the term ''clinical algorithm.'' Some commenters requested a definition for ''clinical algorithm'' to include any form of automated decision systems and AI used in health programs or activities. Many commenters also recommended that § 92.210 apply to tools used in a covered entity's health programs and activities in addition to those used in a clinical setting. These commenters suggested that § 92.210 should apply to a covered entity's administrative health care operations because the use of these tools can impact individuals' access to a covered entity's health programs and activities and the quality of services provided.

Arguing that the term ''clinical algorithm'' is insufficient, some commenters cited examples of tools that covered entities use in their health programs and activities, such as those used for budgeting and billing processes, utilization management, benefit design, program eligibility and enrollment, provider contracting, and pricing by providers and insurers which are susceptible to discriminatory bias. Commenters also identified tools used in skilled nursing facilities, tools used to allocate home and community-based services, and Medicaid eligibility systems.

Response: In the Proposed Rule's preamble, we indicated that ''clinical algorithms'' include tools beyond actual algorithms, 87 FR 47880, and we solicited comment about whether ''clinical algorithms'' should ''include additional forms of automated or augmented decision-making tools or models such as artificial intelligence or

[324] *Substance Use Disorder Demographics,* American Addiction Centers, (Dec. 9, 2022), *https://sunrisehouse.com/addiction-demographics* (more than 40 million Americans aged 12 or older suffered from a substance use disorder in 2020).

[325] Janet Zwick et al., *Stigma: How It Effects the Substance Use Disorder Patient,* 15 Substance Abuse Treatment, Prevention, & Pol., (2020), *https://link.springer.com/article/10.1186/s13011-020-00288-0* (Stigma serves as a barrier to individuals with SUD seeking help, entering treatment, and accepting medications.).

[326] *See, e.g.,* U.S. Dep't of Justice, *The ADA and Opioid Use Disorder: Combatting Discrimination Against People in Treatment and Recovery* (Apr. 5, 2022), *https://www.ada.gov/resources/opioid-use-disorder/.*

[327] *See MX Grp., Inc.* v. *City of Covington,* 293 F.3d 326, 335 (6th Cir. 2002) (a public entity violated title II of the ADA when it discriminated against a drug and alcohol treatment center by denying it a zoning permit because the center provided services to individuals with disabilities).

machine learning,'' 87 FR 47884. The Proposed Rule described ''clinical algorithms'' as ''*tools* used to guide health care decision-making that can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models,'' which hospitals, providers and health insurance issuers use to ''assist with decision-making for various purposes,'' including ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, *health care operations,* and *allocation of resources,* all of which affect the care that individuals receive.'' 87 FR 47880 (emphases added). Thus, the Proposed Rule described clinical algorithms broadly to include a variety of health care decision-making tools in a covered entity's health programs and activities related to patient care. We further solicited comment about ''what types of clinical algorithms are being used in covered health programs and activities; how such algorithms are being used by covered entities; [and] whether they are more prevalent in certain health settings . . . .'' 87 FR 47884.

As discussed in the preamble under § 92.4, we are adopting the more precise term ''patient care decision support tool'' to replace the term ''clinical algorithm.'' This new term more closely aligns with what we described as ''clinical algorithms'' in the preamble to the Proposed Rule, such as various tools used to guide health care decision-making that affect the care that patients receive. *See* 87 FR 47880. In § 92.4, we define ''patient care decision support tool'' to mean ''any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.'' The definition applies to tools that are used by a covered entity in its clinical decision-making that affect the patient care that individuals receive. Given covered entities' widespread use of automated decision systems and AI, and the scale by which AI can influence covered entities' clinical decision-making,[328] we are confirming that the types of patient care decision support tools subject to § 92.210 include automated decision systems and AI used to support clinical decision-making.

Covered entities may use patient care decision support tools in their health care decision-making in a variety of ways. Covered entities typically use patient care decision support tools at the individual patient level, such as a provider using clinical guidance from an algorithm to assess a patient's risk of a severe cardiac event.[329] Other patient care decision support tools pertain to health care administration decisions, typically used with regard to a group of patients (or a population) based on shared characteristics. For example, there is evidence that hospital system treatment protocol varies by geographic area due to variations produced by risk adjustment modeling.[330] In addition to these examples, patient care decision support tools would also include tools used for prior authorization and medical necessity analysis,[331] which directly impacts clinical decision-making and affects the care received by patients as directed by their providers. For example, a medical necessity review tool used by Medicare Advantage plans has been shown to deny enrollees' medical claims for rehabilitative care without considering enrollees' individual circumstances.[332]

One subset of patient care decision support tools to which § 92.210 applies includes ''predictive decision support interventions'' as defined in the Office of the National Coordinator for Health Information Technology's (ONC) recently published final rule for ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.'' [333] In its rule, ONC defines the term ''predictive decision support intervention'' (Predictive DSI) to mean ''technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis.'' 89 FR 1192 (codified at 45 CFR 170.102). As ONC discussed in the Proposed Rule, Predictive DSI are used to predict unknown values based on relationships learned in training data, and they pertain to automated tools used for clinical, financial, or administrative purposes. ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.'' 88 FR 23746, 23785 (April 18, 2023).

It is important to note that § 92.210 is not duplicative of ONC's rule regarding Predictive DSIs because ONC's rule applies to and includes requirements for health information technology (IT) *developers,* whereas § 92.210 applies to and includes requirements for section 1557 covered entity *users* of patient care decision support tools (including Predictive DSIs). A section 1557 covered entity may, of course, develop its own Predictive DSI, in which case that entity may be subject to ONC's Predictive DSI requirements as well as section 1557's nondiscrimination requirements under § 92.210. Refer to section V of ONC's January 2024 Final Rule, 89 FR 1242–54, for more detailed information regarding Predictive DSIs. OCR worked closely with ONC during the development of this final rule and ONC's rule to advance a coordinated Departmental response in regulating

[328] Nat'l Acad. of Med., *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril,* pp. 2, 3 (2019), *https://doi.org/10.17226/27111*; Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, pp. 1, 17, 40 (2023), *https://doi.org/10.6028/NIST.AI.100-1*.

[329] *See, e.g.,* Darshali A. Vyas et al., *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms,* 383 N. Engl. J. Med. 874, 876–78 (Aug. 27, 2020).

[330] Elliott Fisher et al., *Health Care Spending, Quality, and Outcomes—More Isn't Always Better,* The Dartmouth Inst. for Health Pol. & Clinical Practice (2009), *https://www.ncbi.nlm.nih.gov/books/n/darthhcspending/pdf/*; Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations,* 366 Science 447 (2019), *https://www.science.org/doi/10.1126/science.aax2342*.

[331] *See, e.g.,* Casey Ross & Bob Herman, *UnitedHealth Pushed Employees to Follow an Algorithm to Cut Off Medicare Patients' Rehab Care,* STAT News (Nov. 14, 2023), *https://www.statnews.com/2023/11/14/unitedhealth-algorithm-medicare-advantage-investigation/*; Patrick Rucker et al., *How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them,* ProPublica (March 25, 2023), *https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims*; Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News, (Mar. 13, 2023) *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/*; Shahed Al-Haque et al., *AI Ushers in Next-Gen Prior Authorization in Healthcare,* McKinsey & Co. (Apr. 19, 2022), *https://www.mckinsey.com/industries/healthcare/our-insights/ai-ushers-in-next-gen-prior-authorization-in-healthcare#/*.

[332] *See, e.g.,* Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News, *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/* (Mar. 13, 2023).

[333] 45 CFR 170.102; U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., Health Data, *Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024). Regarding the term ''intervention,'' ONC notes that the term ''intervention'' in ''prediction decision support intervention'' was not intended to mean an intervention (medicine, medical procedure, or medical treatment) as the term is used in the practice of medicine, but rather, an intervention occurring within a workstream, including but not limited to alerts, order sets, flowsheets, dashboards, patient lists, documentation forms, relevant data presentations, protocol or pathway support, reference information or guidance, and reminder messages. Their use of the term intervention was consistent with how the Program used the term in § 170.315(a)(9).

tools used to support health care decision-making.

Section 92.210's definition for ''patient care decision support tool'' also includes non-automated and evidence-based tools that rely on rules, assumptions, constraints, or thresholds, as these also have the potential to result in discrimination. This includes ''evidence-based decision support interventions'' identified in ONC regulations at 45 CFR 170.315(b)(11)(iii). An example of a non-automated patient care decision support tool is a Crisis Standards of Care [334] flowchart for triage guidance. Such a flowchart may result in discrimination if, for example, it screens out individuals with disabilities, prohibiting them from equally accessing a health care service, program, or activity that a covered entity offers by assessing an individual's potential response to life-saving care without making an individualized assessment of the individual's health and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment. Another example is the race-adjusted estimated glomerular filtration rate (eGFR) equation that relies not only on training data, but also discriminatory assumptions and thresholds such as by applying a race-adjusted coefficient to the eGFR equation to reflect that Black people have been associated with higher levels of blood creatinine as compared with that of non-Black people, which results in a higher significance threshold for Black patients, thereby requiring more advanced kidney failure for Black patients than non-Black patients before they can receive the same level of care. Other examples of patient care decision support tools include, but are not limited to: flowcharts; formulas; equations; calculators; algorithms; utilization management applications; software as medical devices (SaMDs); software in medical devices (SiMDs); screening, risk assessment, and eligibility tools; and diagnostic and treatment guidance tools.

Comment: Some commenters urged OCR to narrow the definition for ''clinical algorithm'' and to clarify that the scope of § 92.210 does not extend beyond flowcharts and clinical algorithms to any forms of automated decision systems or AI. These commenters contended that a narrow definition is necessary to limit covered entities' liability and burden, disruption to covered entities' decision-making, and patients' exposure to greater health risks.

Response: Section 92.210 does not apply to tools used to support decision-making unrelated to clinical decision-making affecting patient care or that are outside of a covered entity's health programs or activities. For example, § 92.210 does not apply to the following activities when such activities are unrelated to clinical decision-making affecting patient care: automated or non-automated tools that covered entities use for administrative and billing-related activities; automated medical coding; fraud, waste and abuse; patient scheduling; facilities management; inventory and materials management; supply chain management; financial market investment management; or employment and staffing-related activities.

The purpose of § 92.210 is to prohibit discrimination that occurs through covered entities' use of patient care decision support tools in their health programs or activities. The rule does not seek to disrupt covered entities' clinical decision-making, expose patients to greater health risks, or to prevent the use of these tools entirely. We encourage covered entities to continue procuring, developing, and using patient care decision support tools that will improve patient care and access to quality care. Section 92.210 will help covered entities use these tools in a nondiscriminatory manner. Under § 92.210, evidence-based researchers, whose findings inform many inputs to patient care decision support tools, will be incentivized to recalibrate data, assumptions, and methods used in earlier studies.

Comment: Many commenters expressed support for proposed § 92.210 and discussed the extent of discrimination in health care resulting from the use of algorithms. Commenters were particularly concerned about the prevalence of ethnic and racial bias in clinical algorithms that results in fewer health care services provided to Black, Hispanic/Latino, Asian, and American Indian/Alaska Native patients. Others discussed Crisis Standards of Care, stating they are too often biased against people with disabilities, people of color (who disproportionately have at least one disability), and older individuals because these tools assess an individual's potential response to life-saving care without making an individualized assessment of the individual's health and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment.

Response: OCR appreciates commenters' feedback regarding proposed § 92.210. We share commenters' concerns about the potential for discrimination caused by the use of algorithms in health care, which are receiving considerable attention from the Department and Administration,[335] other executive agencies, Congress, stakeholders, professional associations, medical journals, and the media. As OCR implements section 1557 and other civil rights laws, it will continue to consider additional actions to support covered entities in implementation and compliance consistent with Federal law, including guidance or provision of technical assistance.

We particularly note that, since publication of proposed § 92.210, the Administration has issued: (1) a *Blueprint for an AI Bill of Rights,* which includes a principle for protecting the public from algorithmic discrimination; [336] (2) E.O. 14091, *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* which includes a section requiring agencies to consider opportunities to ''prevent and remedy discrimination, including by protecting the public from algorithmic discrimination;'' [337] and (3) E.O. 14110, *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,* which sets forth

[334] Crisis Standards of Care inform decision-making designed to accomplish the best outcome for a group of patients rather than focusing on an individual patient.

[335] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., *HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency* (2023), *https://www.hhs.gov/about/news/2023/12/13/hhs-finalizes-rule-to-advance-health-it-interoperability-and-algorithm-transparency.html*; U.S. Dep't of Health & Hum. Servs., *Guiding Principles Help Healthcare Community Address Potential Bias Resulting from Algorithms* (2023), *https://www.hhs.gov/about/news/2023/12/15/guiding-principles-help-healthcare-community-address-potential-bias-resulting-from-algorithms.html*; U.S. Dep't of Health & Hum. Servs., *Delivering on the Promise of AI to Improve Health Outcomes* (2023), *https://www.whitehouse.gov/briefing-room/blog/2023/12/14/delivering-on-the-promise-of-ai-to-improve-health-outcomes/*; U.S. Dep't of Health & Hum. Servs., *FACT SHEET: Biden-Harris Administration Announces Voluntary Commitments from Leading Healthcare Companies to Harness the Potential and Manage the Risks Posed by AI* (2023), *https://www.hhs.gov/about/news/2023/12/14/fact-sheet-biden-harris-administration-announces-voluntary-commitments-leading-healthcare-companies-harness-potential-manage-risks-posed-ai.html.*

[336] The White House, *Blueprint for an AI Bill of Rights* (Oct. 4, 2022), *https://www.whitehouse.gov/ostp/ai-bill-of-rights/.*

[337] E.O. 14091, sec. 8(f), 88 FR 10825, 10831 (Feb. 22, 2023), *https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal.*

numerous executive actions designed to ensure the equitable, safe, and secure use of AI.[338] E.O. 14110 addresses civil rights violations and discrimination related to AI and seeks to protect individuals' civil rights by preventing discrimination, including algorithmic discrimination, through the use of automated systems and AI.[339]

Executive Order 14110 directs the Department to take actions, ''possibly including regulatory action,'' to ''ensure the safe, responsible deployment and use of AI in the healthcare, public-health, and human-services sectors.'' [340] It also directs the Department to ''consider appropriate actions to advance the prompt understanding of, and compliance with, Federal nondiscrimination laws by health and human services providers that receive Federal financial assistance, as well as how those laws relate to AI.'' [341]

We also acknowledge the recent surge in academic research highlighting potential harms caused by use of patient care decision support tools that may create or contribute to discrimination prohibited by section 1557, as discussed in the Proposed Rule at 87 FR 47880–82.

We appreciate the comments addressing the potential bias in Crisis Standards of Care, which, as discussed at length in the Proposed Rule, 87 FR 47881–82, were the focus of OCR's enforcement efforts during the COVID–19 Public Health Emergency and resulted in six States revising their Crisis Standards of Care to prevent discriminatory prioritization of hospital resources.[342]

Comment: Some commenters opposed proposed § 92.210, in part, because existing laws and regulations already prohibit discrimination in algorithmic tools. Other commenters opposed to finalizing § 92.210 urged OCR to use the feedback we received during the public comment period to inform engagement with stakeholders, including the Food and Drug Administration (FDA), device manufacturers, algorithm developers, clinicians, patients, and others, through which OCR could develop a regulatory framework involving risk-based approaches.

Response: While several Federal departments and agencies are taking action to regulate AI and other decision-making tools,[343] OCR, consistent with its underlying authority, is in a unique position to provide additional specificity regarding the application of long-standing nondiscrimination requirements to the use of such tools to ensure that discrimination does not result from covered entities' use of patient care decision support tools in their health programs or activities. The Department has authority to enforce section 1557, which prohibits covered entities from discriminating in their health programs and activities, including through the use of AI and other tools. Section 92.210 provides additional clarity to covered entities regarding their obligations. We are finalizing § 92.210 with a delayed applicability date of no later than 300 days after the final rule's effective date to give covered entities a reasonable period of time to come into compliance with § 92.210(b) and (c).

We received significant input on this issue from stakeholders during the public comment period, and the breadth of stakeholders' input and available research has informed the revisions in the final version of § 92.210. As OCR implements section 1557 and other civil rights laws, it will continue to consider additional actions to support covered entities in implementation and compliance consistent with Federal law, including guidance or engaging in future rulemaking. As AI, clinical algorithms, and predictive analytics are more widely used, OCR will continue to engage with the FDA, ONC, and other Federal partners to ensure consistency and a coordinated governmental effort to regulate such tools in health care. We will also continue to solicit stakeholders' input and to assist covered entities with compliance.

Comment: Some commenters expressed concern that proposed § 92.210 would not apply to health care-related AI products that are autonomous or that augment a covered entity's decision-making in its health programs and activities.

Response: This final rule clarifies that § 92.210 applies to all patient care decision support tools used in a covered entity's health programs or activities to support clinical decision-making, including patient care decision support tools that are autonomous and those that assist or augment a covered entity's clinical decision-making.

Comment: Some commenters recommended that § 92.210 exclude tools designed to improve health equity because these tools serve to protect members of historically marginalized communities. Relatedly, one commenter asked how proposed § 92.210 would affect algorithms that are currently in use and specifically designed to identify certain groups of patients susceptible to a particular condition or that may benefit from a particular therapy.

Response: Section 92.210 does not prohibit covered entities from using patient care decision support tools that identify, evaluate, and address health disparities so long as their use does not constitute prohibited discrimination on

[338] E.O. 14110, 88 FR 75191 (Nov. 1, 2023).

[339] E.O. 14110, sec. 7, 88 FR 75191, 75211 (Nov. 1, 2023).

[340] E.O. 14110, sec. 8(b)(i), 88 FR 75191, 75214 (Nov. 1, 2023).

[341] E.O. 14110, sec. 8(b)(iii), 88 FR 75191, 75214 (Nov. 1, 2023).

[342] For more information on OCR's work related to discrimination in Crisis Standards of Care, *see Civil Rights and COVID–19, Non-Discrimination in Crisis Standards of Care,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html.*

[343] *See, e.g.,* Proposed Rule at 87 FR 47882–84, n.569, 571, 578; U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,* Final Rule, 88 FR 22120, 22195 (Apr. 12, 2023), *https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf* (''MA organizations must ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as outlined at § 422.101(c), as opposed to using an algorithm or software that doesn't account for an individual's circumstances.''); U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19,* Final Rule, 87 FR 71748, 72036 (Nov. 23, 2022), *https://www.federalregister.gov/documents/2022/11/23/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment* (responding to comment solicitation on how to prevent and mitigate bias in algorithms and predictive modeling); U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* (2021), *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device*; U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024); Consumer Fin. Protection Bureau, U.S. Dep't of Justice, U.S. Equal Employment Opportunity Comm'n, & Fed. Trade Comm'n, *Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems* (Apr. 2023), *https://files.consumerfinance.gov/f/documents/cfpb_joint-statement-enforcement-against-discrimination-bias-automated-systems_2023-04.pdf;* Fed. Deposit Ins. Corp., *Request for Information and Comment on Financial Institutions' Use of Artificial Intelligence, Including Machine Learning,* 86 FR 16837–38 (May 24, 2021), *https://www.govinfo.gov/content/pkg/FR-2021-05-24/pdf/2021-10861.pdf;* Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1 (2023), *https://doi.org/10.6028/NIST.AI.100-1.*

the basis of race, color, national origin, sex, age, or disability.

Comment: Many commenters requested that OCR revise § 92.210 to include transparency requirements for covered entities regarding their use of clinical algorithms in their health programs and activities, including a requirement that covered entities notify individuals about the training data, assumptions, constraints, thresholds, and other inputs used to design each clinical algorithm in use. Commenters noted that otherwise, individuals would not know whether there has been a violation of § 92.210.

Response: A covered entity may routinely change the patient care decision support tools it uses. While there may be benefits to providing such information to patients, we decline to revise § 92.210 to require covered entities to notify patients about the patient care decision support tools used in their health programs and activities given the possible frequent changes and the costs associated with notifying patients.

We similarly decline to revise § 92.210 to require covered entities to notify patients about the training data and other inputs used to design and develop the patient care decision support tools used by a covered entity because, in addition to the costs discussed above, currently, patient care decision support tool developers may not ordinarily share this information with covered entities. We note, however, that ONC's final rule requires decision support interventions, supplied by a developer of certified health IT as part of its Health IT Module certified to 45 CFR 170.315(b)(11) criterion, to support making this information (source attributes) available to users of the Health IT Module. In addition, developers of certified health IT certified to 45 CFR 170.315(b)(11)(iii)(B) are required to make summary information of intervention risk management practices publicly available for Predictive DSIs the developer supplies as part of its Health IT Module provided through 45 CFR 170.523(f)(1)(xxi). 89 FR 1192 (January 9, 2024). Covered entities using decision support interventions supplied by a developer of certified health IT should have this type of information available to them.

In addition, to the extent that covered entities subject to HIPAA document their use of a patient care decision support tool in an individual's medical record, individuals may obtain that information when they exercise their HIPAA right of access to their protected health information contained in their respective designated record sets. *See* 45 CFR 164.524. Other Departmental agencies may also issue transparency-related guidance and requirements for AI developers. OCR seeks to partner with other agencies and covered entities to address best practices and may release guidance in the future.

While we decline to impose transparency requirements under § 92.210 for the reasons stated above, we note that it would be a best practice for covered entities to disclose information to patients about the patient care decision support tools used in their health programs and activities.[344] We further note, however, that such voluntary disclosure does not ensure compliance with § 92.210.

Comment: Many commenters recommended that OCR revise § 92.210 to clarify the steps that a covered entity must take to comply with § 92.210 and to ensure nondiscriminatory use of clinical algorithms. Commenters explained that when providers use a patient care support tool, they often rely on a developer's intended uses for the tool. Commenters discussed that covered entities do not design or develop many of the clinical algorithms that they use and are therefore unlikely to be aware of how the tool operates. They also stated that it is infeasible to require a covered entity to audit all algorithms in its health programs or activities and that proposed § 92.210 would force covered entities to police their own supply chains for clinical algorithms, which they state is also impracticable. Commenters expressed concern that covered entities may incur liability when they are unaware that an algorithmic output may result in discrimination and opined that covered entities should not be liable in such cases. Another commenter specified that physician liability should be limited to when a reasonable physician knows or should have known that the algorithm in question utilizes inputs and logic that are likely to result in discrimination. Further, commenters asserted that the additional steps that covered entities would need to take to comply with proposed § 92.210 are very likely to contribute to providers' already strained workload and further contribute to burnout.

Response: We appreciate commenters' concerns and have revised § 92.210 to provide additional clarity. We have added additional clarification on covered entities' obligations under § 92.210. Section 92.210 sets forth the general prohibition on discrimination on the basis of race, color, national origin, sex, age, or disability by a covered entity in its health programs or activities through the use of patient care decision support tools. Section 92.210(b) requires a covered entity to make reasonable efforts to identify patient care decision support tools used in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability. Section 92.210(c) requires that for each patient care decision support tool identified in paragraph (b), a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

We appreciate comments regarding how a covered entity may learn that a patient care decision support tool used in its health programs or activities creates a risk of discrimination on a protected basis. In the Proposed Rule, we noted that use of clinical algorithms may result in discriminatory outcomes when variables are used as a proxy for a protected basis, and that discrimination may result from correlations between a variable and a protected basis. 87 FR 47881. As a threshold matter, we note that section 1557 prohibits proxy discrimination as a general civil rights principle that applies to the entire final rule.[345] However, given the many possible indirect measures of race, color, national origin, sex, age, and disability, covered entities are not required to identify all patient care decision support tools with input variables or factors that indirectly measure these protected bases. However, covered entities should exercise caution when using patient care decision support tools that are known to use indirect measures for race, color, national origin, sex, age, or disability, which could result in prohibited discrimination.

We understand that covered entities in some circumstances may be largely unaware of the datasets developers use to train the patient care decision support tools that covered entities use. Section 92.210 does not require covered entities to obtain datasets or other attribute information from developers when purchasing or using patient care decision support tools. However, if a covered entity does not know whether a developer's patient care decision support tool uses variables or factors that measure race, color, national origin,

[344] *See, e.g.,* Am. Med. Ass'n, *American Medical Association Principles for Augmented Intelligence Development, Deployment, and Use,* pp. 2–4 (2023), *https://www.ama-assn.org/system/files/ama-ai-principles.pdf.*

[345] *See* discussion of proxy discrimination at § 92.207.

sex, age, or disability but has reason to believe such variables or factors are being used, or the covered entity otherwise knows or should know that the tool could result in discrimination, the covered entity should consult publicly available sources or request this information from the developer.

Further, ONC's recently published final rule discussed above revises existing certification criteria for developers of certified health IT by requiring developers with Health IT Modules certified to § 170.315(b)(11) to disclose information about a decision support intervention's source attributes relevant to health equity with the decision support intervention users. 89 FR 1192. This disclosure requirement will work in tandem with § 92.210 by enabling a covered entity that uses Health IT Modules certified to § 170.315(b)(11) to learn from a developer whether a specific decision support intervention relies on attributes that measure race, color, national origin, sex, age, or disability.

We are aware that covered entities use patient care decision support tools based on their respective needs and in accordance with developers' intended uses. But covered entities must exercise due diligence when acquiring and using such tools to ensure compliance with § 92.210.

Covered entities may learn that use of patient care decision support tools risk resulting in discrimination when OCR included that information in the Proposed Rule. In the Proposed Rule, in addition to the use of the race-adjusted eGFR equation discussed above, we identified uses of other categories of tools that may result in discrimination based on race, including tools used in ''cardiology (to assess the risk of heart failure), cardiac surgery (to assess the risk of complications and death), obstetrics (to determine risks associated with vaginal birth after cesarean), urology (to assess the risk of kidney stones and urinary tract infections), oncology (to predict rectal cancer survival and breast cancer risk), endocrinology (to assess osteoporosis and fracture risks), and pulmonology (to measure lung function).'' 87 FR 47881. The Proposed Rule also identified that use of Crisis Standards of Care to allocate health care resources may also discriminate on the basis of disability and/or age. 87 FR 47880–82. OCR aims to continue providing additional guidance to the public and covered entities as such information on potential discrimination in the use of such tools becomes available.

The Department itself regularly publishes information and advisories to the public. For example, the Agency for Healthcare Research and Quality (AHRQ) recently issued a report on the ''Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare.'' [346] Additionally, addressing published medical journals' research studies and the subsequent media attention about racial bias resulting from the use of pulse oximeters, the FDA published a safety communication to announce that the FDA was reassessing the content of its pulse oximetry guidance document and would share additional updates with the public.[347]

Published articles of research studies in peer-reviewed medical journals are also a reliable source of information about evidence-based adverse outcomes based on patient care decision support tools that may result in discrimination. Such articles are increasing in prevalence given the growing use of AI and other patient care decision support tools in health care decision-making.[348] For example, peer-reviewed medical journals have recently published several articles related to racial discrepancies resulting from the use of pulse oximeters.[349] One such study found that pulse oximeters more commonly overestimated arterial oxygen saturation levels in patients from minority racial and ethnic groups and led to delayed recognition of need for COVID–19 therapy among Black patients compared with white patients.[350]

Covered entities also may gain knowledge that use of a patient care decision support tool creates a risk of discrimination based on a prohibited basis through media outlets that may report on reliable studies.[351]

Health care professional and hospital associations are also often dependable sources of information that notify health care providers about developments in the practice of various specialties and in the administration of medical care, which can include potential discrimination that may result from the use of certain patient care decision support tools.[352] Health insurance-related associations also provide information to their members and the public.[353] Relevant information is also

[346] Kelley Tipton et al., U.S. Dep't of Health & Hum. Servs., Agency for Healthcare Rsch. & Quality, *Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare,* Comparative Effectiveness Review No. 268, AHRQ Publication No. 24–EHC004 (2023), *https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/cer-268-racial-disparities-health-healthcare.pdf.*

[347] U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Pulse Oximeter Accuracy and Limitations: FDA Safety Communication, https://public4.pagefreezer.com/content/FDA/20-02-2024T15:13/https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication.*

[348] *See, e.g.,* Armando D. Bedoya et al., *A Framework for the Oversight and Local Deployment of Safe and High-Quality Prediction Models,* 29 J. of Am. Med. Informatics Ass'n. 9, 1631–1636 (2022), *https://doi.org/10.1093/jamia/ocac078* (describing a governance framework that combines current regulatory best practices and lifecycle management of predictive models being used for clinical care and maintaining a governance portfolio where models are actively added); Shyam Visweswaran et al., *Clinical Algorithms with Race: An Online Database,* medRxiv [Preprint], doi: 10.1101/2023.07.04.23292231 (2023), *https://pubmed.ncbi.nlm.nih.gov/37461462/#:~:text=These%20clinical%20algorithms%20based%20on,the%20inappropriate%20use%20of%20race* (conducting a comprehensive search of online resources, the scientific literature, and the FDA Drug Label Information to identify clinical algorithms that incorporate race or ethnicity as an input variable or predictor in determining diagnoses, prognoses, treatment plans, or risk assessments; finding 39 race-based risk calculators, 6 laboratory test results with race-based reference ranges, 1 race-based therapy recommendation, and 15 medications with race-based recommendations; and creating a current and open-access database to track race-based clinical algorithms).

[349] *See, e.g.,* Ashraf Fawzy et al., *Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients with COVID–19,* 182 JAMA Internal Med. 730 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653*; Valeria S.Valbuena et al., *Racial and Ethnic Bias in Pulse Oximetry and Clinical Outcomes,* 182 JAMA Internal Med. 699 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792654*; Michael W. Sjoding et al., *Racial Bias in Pulse Oximetry Measurement,* 383 New Eng. J. Med. 2477 (2020) *https://www.nejm.org/doi/full/10.1056/nejmc2029240.*

[350] Ashraf Fawzy et al., *Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients with COVID–19,* 182 JAMA Internal Med. 730 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653.*

[351] Following medical journals' publication of research articles related to racial bias through the use of pulse oximeters, several media outlets amplified those findings further to the public. *See, e.g.,* Anil Onza et al., *COVID–19 Made Pulse Oximeters Ubiquitous. Engineers are Fixing Their Racial Bias,* (Feb. 13, 2023), *https://www.npr.org/2023/02/10/1156166554/covid-19-pulse-oximeters-racial-bias*; *Pulse Oximeters Should Not Be Used to Diagnose COVID–19, U.S. FDA Says,* Reuters (Feb. 19, 2021), *https://www.reuters.com/article/us-health-coronavirus-pulse-oximeter/pulse-oximeters-should-not-be-used-to-diagnose-covid-19-u-s-fda-says-idUSKBN2AJ2G7.*

[352] *See, e.g., Augmented Intelligence in Medicine,* Am. Med. Ass'n, *https://www.ama-assn.org/practice-management/digital/augmented-intelligence-medicine* (updated Mar. 1, 2024); *Clinical Applications of Artificial Intelligence* (webinar), Am. Coll. of Physicians, *https://www.acponline.org/meetings-courses/webinars/clinical-applications-of-artificial-intelligence* (June 8, 2023). *See generally, Medical & Professional Associations,* Meditech, *https://www.meditec.com/resourcestools/professional-associations-list.*

[353] *See, e.g., Artificial Intelligence,* Nat'l Ass'n of Ins. Comm'rs, *https://content.naic.org/cipr-topics/artificial-intelligence*; *Creating Better Health Outcomes with Digital Tools and Artificial*

Continued

provided through various nonprofit organizations in the field of AI.

ONC's rule also provides an opportunity for covered entities to learn about the data used in decision support interventions. Developers of decision support interventions that develop certified health IT as part of its Health IT Module are required to support making specific information disclosures under ONC's rule regarding discriminatory bias in their tools, including disclosure of source attributes, and risk management and governance practices.[354]

OCR will assess each allegation that a covered entity is violating § 92.210 on a case-by-case basis. For example, when OCR investigated complaints related to State Crisis Standards of Care guidelines during the COVID–19 pandemic, the investigations involved a fact-specific analysis of each of the guidelines in question. They also included extensive technical assistance with States to revise their Crisis Standards of Care guidelines to remove the alleged discriminatory.[355]

In our analysis of whether a covered entity is in compliance with § 92.210(b)'s ''reasonable efforts to identify'' requirement, OCR may consider, among other factors: (1) the covered entity's size and resources (*e.g.,* a large hospital with an IT department and a health equity officer would likely be expected to make greater efforts to identify tools than a smaller provider without such resources); (2) whether the covered entity used the tool in the manner or under the conditions intended by the developer and approved by regulators, if applicable, or whether the covered entity has adapted or customized the tool; (3) whether the covered entity received product information from the developer of the tool regarding the potential for discrimination or identified that the tool's input variables include race, color, national origin, sex, age, or disability; and (4) whether the covered entity has a methodology or process in place for evaluating the patient care decision support tools it adopts or uses, which may include seeking information from the developer, reviewing relevant medical journals and literature, obtaining information from membership in relevant medical associations, or analyzing comments or complaints received about patient care decision support tools.

In summary, OCR recognizes the challenges in identifying the discriminatory potential of every use of each patient care decision support tool, and therefore § 92.210(b) requires covered entities to make reasonable efforts to identify tools that employ input variables based on a protected basis.

Comment: Many commenters referred to potential devastating consequences from the use of specific clinical algorithms [356] and recommended that § 92.210 be revised to include a requirement for covered entities to mitigate the risk of discrimination that results from the use of clinical algorithms. Some commenters suggested that OCR require specific mitigation efforts, such as requiring covered entities to: develop and implement policies specific to covered entities' use of clinical algorithms; require staff training; use clinical algorithms in accordance with FDA clearance and developer's intended uses; use peer-reviewed research to inform adjustments to clinical algorithms; notify patients of suspect clinical algorithms; request an assessment of discriminatory inputs from developers; neutralize any discriminatory inputs by using the predominant cohort in the tool's training data; and submit annual reports to OCR regarding their use of clinical algorithms and mitigation efforts.

Response: OCR agrees with commenters' concerns about the potential for harm resulting from discriminatory algorithms and the need to mitigate the risks of discrimination when possible. However, we acknowledge that it is not always possible to completely eliminate the risk of discriminatory bias in patient care decision support tools,[357] and these tools also serve important health care functions. Section 92.210(c) requires covered entities to make reasonable efforts to mitigate the risk of discrimination resulting from the covered entity's use of a patient care decision support tool identified in § 92.210(b). This standard allows a covered entity to adopt more robust safeguards to prevent discrimination, should it choose to do so.

For example, in order to comply with § 92.210(c)'s mitigation requirement, a covered entity that uses the race-adjusted eGFR equation could discontinue using that equation and instead use the revised eGFR equation that does not adjust for race.[358] The covered entity may also implement measures to ensure that staff members follow proper protocols when using the race-adjusted eGFR equation.[359] OCR will evaluate mitigation measures covered entities take on a case-by-case basis to determine compliance with § 92.210(c).

A covered entity's obligation to mitigate risk of discrimination under § 92.210(c) is consistent with the National Institutes of Standards and Technology's (NIST) Artificial Intelligence Risk Management Framework, which explains that AI bias mitigation helps minimize potential negative impacts of AI systems while providing opportunities to maximize positive impacts, without articulating express mitigation measures.[360] The same is true for patient care decision support tools that a covered entity uses

Intelligence (webinar), Am.'s Health Ins. Plans, *https://www.ahip.org/webinars/creating-better-health-outcomes-with-digital-tools-and-artificial-intelligence* (Dec. 8, 2023).

[354] U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024).

[355] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Civil Rights and COVID–19, Non-Discrimination in Crisis Standards of Care, https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html*; Press release, U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Complaint with Utah After It Revised Crisis Standards of Care to Protect Against Age and Disability Discrimination* (Aug. 20, 2020), *https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/08/20/ocr-resolves-complaint-with-utah-after-revised-crisis-standards-of-care-to-protect-against-age-disability-discrimination.html*.

[356] Examples included race-adjusted correction factors used in spirometry, nephrology, and cardiology; State Medicaid eligibility systems that reduce benefits impacting historically marginalized individuals disproportionately to the overall population; health care utilization algorithms that use prior health care spending data to predict future health care needs that results in under-representing Black patients as compared to white patients; and other examples discussed throughout this preamble.

[357] *See, e.g.,* Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, (2023), *https://doi.org/10.6028/NIST.AI.100-1*.

[358] *See, e.g.,* Cynthia Delgado et al., *Special Report: A Unifying Approach for GFR Estimation: Recommendations of the NKF–ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease,* 79 a.m. J. of Kidney Diseases, 268–288 (Sept. 23, 2021), *https://www.ajkd.org/article/S0272-63862100828-3/fulltext*.

[359] *See, e.g.,* Press Release, U.S. Dep't of Health & Hum. Servs., Health Servs. & Rsch. Admin., Organ Procurement & Transplantation Network, *OPTN Board Approves Waiting Time Adjustment for Kidney Transplant Candidates Affected by Race-Based Calculation* (Jan. 5, 2023), *https://optn.transplant.hrsa.gov/news/optn-board-approves-waiting-time-adjustment-for-kidney-transplant-candidates-affected-by-race-based-calculation/*.

[360] Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, p. 4 (2023), *https://doi.org/10.6028/NIST.AI.100-1*, (The NIST AI Framework provides: ''Where tradeoffs among the trustworthy characteristics arise, measurement provides a traceable basis to inform management decisions. Options may include recalibration, impact mitigation, or removal of the system from design, development, production, or use, as well as a range of compensating, detective, deterrent, directive, and recovery controls.'').

in its health programs and activities for clinical decision-making.

While we appreciate the breadth of mitigation techniques suggested by commenters—and agree that many of those efforts would be best practices to prevent algorithmic discrimination—we decline to require covered entities to take any specific mitigation efforts under § 92.210(c). We have determined that a reasonable efforts mitigation requirement strikes the right balance between the need for covered entities to mitigate the risk of discrimination resulting from their use of patient care decision support tools and the burden placed on covered entities. In the Proposed Rule, 87 FR 47883, we noted that covered entities may choose to mitigate discrimination by establishing written policies and procedures governing how clinical algorithms will be used in decision-making, including adopting governance measures; monitoring any potential impacts and developing ways to address complaints; and training staff on the proper use of such systems in decision-making. We encourage covered entities to take these and other additional mitigating efforts to comply with § 92.210.[361] We further note that this rule does not excuse a covered entity from complying with any other applicable Federal or State law that may apply, including but not limited to requirements for FDA approval where appropriate, such as the Food Drug and Cosmetic Act [362] and the Medical Device Amendments.[363]

In addition, once a covered entity identifies a particular use of patient care decision support tool under § 92.210(b), a covered entity's mitigation efforts under § 92.210(c) may vary based on the input variable or factor, as well as the purpose of the tool in question. OCR acknowledges that some input variables may generate greater scrutiny, such as race, which is highly suspect,[364] as compared to other variables, such as age, which is more likely to have a clinically and evidence-based purpose. Some bases protected by section 1557, such as age, are likely prevalent in patient care decision support tools and may not require extensive mitigation efforts under § 92.210(c) if use of the variable in the tool does not result in discrimination. For instance, where a tool employs an input variable for age, the covered entity's mitigation efforts under § 92.210(c) regarding that tool may include justifying the tool's use of age as an input variable by showing that age is clinically indicated as a measure in the particular tool and/or aligns with evidence-based clinical best practices that do not result in discrimination. We further note that the Age Act itself allows age distinctions under certain circumstances, including when related to age distinctions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. 42 U.S.C. 6103(b)(1); 45 CFR 91.13 (adopting statutorily permissive age distinctions found at 42 U.S.C. 6103(b)(1)).

Comment: Some commenters indicated that clinicians trust the FDA's process for reviewing and approving clinical use of patient care decision support tools as well as published data illustrating a tool's efficacy in their use of these tools.

Response: The FDA regulates the sale of medical devices (including diagnostic tests) and monitors the ongoing safety and effectiveness of regulated marketed devices.[365] The FDA has released draft guidance on Predetermined Change Control Protocol (PCCP AI/ML) [366] and will be publishing draft guidance for Artificial Intelligence/Machine Learning (AI/ML)-enabled Device Software Functions: Lifecycle Management Considerations and Premarket Submission Recommendations. In addition, FDA is actively working through public-private partnerships to set uniform guidelines on addressing bias in AI across its lifecycle.

Section 92.210 is concerned with ensuring that covered entities' use of a patient care decision support tool does not result in prohibited discrimination, which includes medical devices as ''automated or non-automated tool[s] . . . used by a covered entity to support clinical decision-making.'' While FDA's premarket review processes strive to minimize discriminatory biases in patient care decision support tools before they are authorized to market, real world post-market deployment of FDA-approved devices can introduce discriminatory bias. Therefore, it is important to identify different points of bias and provide an action plan for remediation.[367]

Comment: Many commenters suggested that covered entities should share liability with algorithm creators for the consequences related to covered entities' use of these tools because clinicians may lack sufficient information to detect that an algorithm can result in discrimination. Another commenter suggested that § 92.210 should impose strict liability on manufacturers of algorithms, not the end users. Yet another commenter suggested that OCR create a safe harbor for covered entities that use clinical algorithms consistent with and within the scope of their intended purpose.

Response: Each covered entity is independently required to comply with all provisions in section 1557, including § 92.210. A covered provider's liability under section 1557 is not contingent on or related to a developer's potential liability under this rule or this provision. As discussed above, § 92.210(b) requires a covered entity to identify use of patient care decision support tools in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability, and § 92.210(c) requires covered entities to make reasonable efforts to mitigate the risk of discrimination that results from the covered entity's use of a tool identified in § 92.210(b) in clinical decision-making.

If a developer is subject to section 1557, § 92.210 applies to it in the same manner it applies to all covered entities. Under § 92.210, covered entities must take requisite actions to ensure their use of a patient care decision support tool does not result in discrimination. We decline to impose strict liability on covered entities in their use of these tools, including covered developers.

---

[361] *See, e.g.,* Marshall H. Chin et al., *Guiding Principles to Address the Impact of Algorithm Bias on Racial and Ethnic Disparities in Health and Health Care,* 6 JAMA Network Open 12 (2023), *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2812958*; Coalition for Health AI, *Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare* (2023), *https://www.coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai_V1.0.pdf.*

[362] 21 U.S.C. 301 *et seq.*

[363] Pub. L. 94–925.

[364] *See, e.g.,* Michelle Tong & Samantha Artiga, *Use of Race in Clinical Diagnosis and Decision Making: Overview and Implications,* KFF (2021), *https://www.kff.org/report-section/use-of-race-in-clinical-diagnosis-and-decision-making-overview-and-implications-issue-brief/.*

[365] *See* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *FDA's Role in Regulating Medical Devices, https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices#:~:text=FDA%20regulates%20the%20sale%20of,of%20all%20regulated%20medical%20products.*

[366] 88 FR 19648 (Apr. 3, 2023); *see also* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *CDRH Issues Draft Guidance on Predetermined Change Control Plans for Artificial Intelligence/Machine Learning-Enabled Medical Devices, https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-draft-guidance-predetermined-change-control-plans-artificial-intelligencemachine.*

[367] *See* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *About FDA: Patient Q&A, https://www.fda.gov/media/151975/download#:~:text=The%20FDA%20does%20not%20regulate,by%20health%20insurance%20or%20Medicare*; Alessandro Hammond et al., *An Extension to the FDA Approval Process Is Needed to Achieve AI Equity,* 5 Nature Machine Intelligence 96 (2023), *https://www.nature.com/articles/s42256-023-00614-8.*

Comment: Some commenters opined that proposed § 92.210 lacked sufficient specificity and that our reference in the Proposed Rule to covered entities' overreliance on clinical algorithms was confusing because there is no definition or criteria about what it means to ''rely'' on a clinical algorithm.

Response: We appreciate commenters' concerns. We note that § 92.210 relates to covered entities' *use* of patient care decision support tools rather than their reliance on them. In the Proposed Rule, we cautioned that a covered entity's overreliance on clinical algorithms in its decision-making can result in discrimination, and that covered entities should refrain from *over-relying* on patient care decision support tools by using them beyond their reasonably expected scope as a replacement or substitute for providers' clinical judgment. 87 FR 47880–82.

Comment: Some commenters characterized § 92.210 as a novel provision and argued that, in consequence, OCR investigative staff need to conduct fact-specific analyses of allegations of discrimination. Other commenters supported OCR's proposed approach to conduct a case-by-case factual inquiry into compliance with § 92.210. Many commenters pointed out that proactive oversight by OCR is also needed due to the non-transparent, systemic nature of this form of discrimination, which may limit complaints.

Response: OCR will investigate each complaint under § 92.210 on a case-by-case basis. OCR will review all applicable evidence to determine whether the covered entity took reasonable steps to identify whether the patient care decision support tool it is using is a tool that employs input variables that measure race, color, national origin, sex, age, or disability under § 92.210(b). When an investigation reveals that a covered entity has appropriately identified its use of a patient care decision support tool under § 92.210(b), OCR will determine whether the covered entity took reasonable efforts to mitigate the risk of discrimination resulting from the use of the patient care decision support tool at issue in accordance with § 92.210(c), as described above. As we have affirmed elsewhere with respect to other provisions of this final rule, OCR will employ all available means to investigate alleged violations of § 92.210, including through complaint investigations and compliance reviews based upon potential complaints in order to provide proactive oversight over the use of these tools.

Comment: A professional association commenter recommended that OCR's enforcement actions should consider whether covered entities have set up incentives to pressure health care professionals to follow the recommendations of clinical algorithms even if they conflict with the professional's clinical judgment.

Response: We appreciate this comment, and OCR will take such situations into account on a case-by-case basis when determining whether a covered entity violates this provision as OCR evaluates the facts in complaints brought under § 92.210.

Comment: Commenters recommended that OCR work with covered entities to achieve compliance by providing covered entities, specifically physician practices, with technical assistance and guidance, to help them integrate both clinical algorithms and improvements for these algorithms into existing clinical workflows to increase efficiency and minimize administrative burden.

Response: OCR seeks to provide covered entities with technical assistance regarding compliance with all civil rights requirements, including compliance with § 92.210. OCR is committed to partnering with covered entities to eliminate discrimination resulting from the use of patient care decision support tools in covered entities' health programs and activities.

Comment: Some commenters were concerned that complying with § 92.210 would be difficult for smaller covered entities with fewer resources.

Response: Section 92.210 applies to all covered entities regardless of size, including smaller entities. All covered entities must make reasonable efforts to mitigate the risk of discrimination resulting from their use of a patient care decision support tool identified in § 92.210(b), but the size and resources of the covered entity will factor into the reasonableness of their mitigation efforts and their compliance with § 92.210.

Comment: Some commenters encouraged OCR to require covered entities to comply with § 92.210 as quickly as possible, while one commenter suggested that covered entities should be required to evaluate their algorithms and mitigate bias within 12 months.

Response: We acknowledge that covered entities may need additional time to comply with the new requirements in § 92.210(b) and (c). Therefore, OCR is revising § 92.1 to reflect a delayed applicability date that specifies covered entities must comply with § 92.210(b) and (c) within 300 days following the effective date of the rule.

Request for Additional Comment

OCR seeks comment on whether we should engage in additional rulemaking to expand the scope of § 92.210, and if so, in what ways. Specifically, OCR seeks comment on other decision support tools that are being used in covered entities' health programs and activities that do not directly impact patient care and clinical decision-making, but may nevertheless result in unlawful discrimination in violation of section 1557, and whether § 92.210 should apply to such decision support tools. For example, we are aware of decision support tools that are used by health insurance issuers to determine amounts owed to them or by providers for services rendered. Other examples include tools used for automated coding for billing,[368] and fraud, waste, and abuse.[369] Additionally, covered entities may use decision support tools for administrative and operational activities, such as patient scheduling, and we are aware that there is research suggesting that these tools can result in rushed and inadequate care for lower socioeconomic patients.[370] Decision support tools may also be used to allocate resources, such as allocating spending geographically on diagnostic imaging that favors regions with historically more expensive, high-tech equipment and a lower presence of historically marginalized and underserved persons.[371] OCR seeks comment on these uses and others that may result in unlawful discrimination in violation of section 1557, and whether § 92.210 should be expanded to cover these tools as well.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 92.210 with modifications. First, we are adding a § 92.210(a), which reads

[368] *See, e.g.,* Jessica Miller, *How Is AI Quickly Taking Medical Coding to the Next Level?,* Medicodio (June 6, 2023) *https://medicodio.com/how-is-ai-quickly-taking-medical-coding-to-the-next-level/#:~:text=AI%20has%20transformed%20medical%20coding,codes%2C%20and%20assign%20them%20automatically.*

[369] *See, e.g.,* Bill Siwicki, *At UMich, AI-Based Fraud, Waste, and Abuse System Aims to Cut Costs and Protect Patients,* HealthcareITNews (Aug. 1, 2023), *https://www.healthcareitnews.com/news/umich-ai-based-fraud-waste-and-abuse-system-aims-cut-costs-and-protect-patients.*

[370] *See, e.g.,* Howard Fine et al., *Health Care Embraces AI,* Los Angeles Business Journal (June 12, 2023), *https://labusinessjournal.com/special-reports/health-care-embraces-ai/.*

[371] *See, e.g.,* Brent Nelson et al., *Computerized Decision Support for Concurrent Utilization Review Using the HELP System,* 1 J. Am. Med. Informatics Ass'n. 339 (1994), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC116216/pdf/0010339.pdf.*

the same as proposed § 92.210 except that we added ''General prohibition'' to the beginning of the provision and replaced the term ''clinical algorithm'' with the term ''patient care decision support tool.'' Second, we added § 92.210(b), which states, ''A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.'' Third, we have added § 92.210(c), which states, ''For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in the covered entity's health programs or activities.''

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

In § 92.211, we proposed that a covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability.

OCR sought comment on this approach and whether covered entities and others would benefit from a specific provision addressing accessibility in telehealth services for individuals with disabilities and individuals with LEP. We invited comment on what such a provision should include, and why the provisions at proposed §§ 92.201 (Meaningful access for individuals with LEP), 92.202 Effective communication for individuals with disabilities), and 92.204 (Accessibility of ICT for individuals with disabilities), would be insufficient. Further, we requested comment on challenges with accessibility specific to telehealth and recommendations for telehealth accessibility standards that would supplement the effective communication and ICT provisions of this part. We encouraged commenters to consider the range of technology available for accessing telehealth, including user-friendly design, as well as security and privacy requirements (for example, when using public Wi-Fi access).

The comments and our responses regarding § 92.211 are set forth below.

Comment: Most commenters on this issue were supportive, stating that a specific provision requiring nondiscrimination in delivery of health programs and activities through telehealth services is important for addressing health equity for underserved groups and areas, social determinants of health, and improving access to a wide range of health care. Some commenters added that the expansion of telehealth has been particularly important for access to care for those who are immunocompromised or otherwise at risk for COVID–19 and potential future pandemics, those who live in rural communities, and those in need of gender-affirming care. Many commenters called for increased investment and training to promote technological literacy as a vital complement to this effort.

Response: We agree that a standalone provision requiring nondiscrimination in delivery of health programs and activities through telehealth services is warranted and we appreciate the thoughtful comments. We welcome the opportunity to promote health literacy and provide technical assistance within our scope of authority.

Comment: A few commenters indicated that covered entities will require additional time, technical assistance, and/or safe harbors to come into compliance with this provision, particularly if specific language access and accessibility requirements regarding telehealth platforms are incorporated. Furthermore, one commenter contended that regulation is premature since telehealth technology and platforms are too new.

Response: While we appreciate the concerns expressed by covered entities, we respectfully disagree with the proposition that it is premature to regulate nondiscrimination in health programs and activities delivered via telehealth. As stated in the Proposed Rule and the Department's joint guidance with DOJ on nondiscrimination in telehealth (Telehealth Guidance),[372] covered entities that use telehealth are already prohibited from doing so in a discriminatory manner. The Telehealth Guidance explains covered entities' responsibilities to ensure effective communication and the provision of auxiliary aids and services (section 504 and § 92.202) and the provision of language assistance services for individuals with LEP (title VI and § 92.201). Telehealth platforms, in particular, are also covered by the ICT provision (§ 92.204). Given the dramatic expansion in the use of telehealth and continuing barriers in access to care experienced by individuals due to inaccessibility of telehealth services, we believe it is necessary and appropriate to regulate this medium of health care provision. OCR will provide further technical assistance and clarifying guidance as appropriate to help covered entities further understand their responsibilities.

Comment: Some commenters requested that OCR apply a broad definition of ''telehealth'' requesting inclusion of medical devices, tests, and equipment used as part of telehealth services. Other commenters requested OCR define telehealth as ''the use of digital technology to deliver health care, health information, and other health services, including diagnosis, treatment, assessment, monitoring, communications, and education.''

Some commenters also requested that audio-only and remote patient monitoring be required to comply with §§ 92.201 (Meaningful access for individuals with LEP), 92.202 (Effective communication for individuals with disabilities), and 92.204 (accessibility of ICT for individuals with disabilities).

Response: OCR has determined it is appropriate to codify the definition of the term ''telehealth'' as provided by the Health Resources and Services Administration [373] and the Office of the National Coordinator for Health Information Technology [374] referenced in the Proposed Rule at 87 FR 47884. As such, we are adding a definition for telehealth to the final rule under § 92.4. which will read ''use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.'' Audio-only and remote patient monitoring services are included in this definition. Additionally, medical devices, tests, and equipment that are used as part of a health program or activity delivered through telehealth services must also be accessible.

Comment: Some commenters requested OCR amplify and make clear

[372] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons* (July 29, 2022), *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

[373] U.S. Dep't of Health Hum. Servs., Health Rsch. Servs. Admin., *What Is Telehealth?, https://www.hrsa.gov/rural-health/telehealth/what-is-telehealth.*

[374] HealthIT.gov, *What Is Telehealth? How Is It Different from Telemedicine?, https://www.healthit.gov/faq/*what-telehealth-how-telehealth-different-telemedicine.

that the privacy provisions under HIPAA are a part of this section. Many commenters detailed privacy concerns specific to individuals with disabilities and individuals with LEP. For individuals with disabilities, concerns were expressed for those who lack privacy in the home and might need additional functionality to be able to use telehealth privately.[375] Other commenters described concerns individuals with LEP may have about their data being shared with immigration or law enforcement.[376]

Response: Comments related to HIPAA are outside of the scope of this rulemaking. However, we direct commenters to HIPAA guidance we have released related to HIPAA and reproductive health care,[377] protecting the security of health information,[378] and audio-only telehealth.[379] Given our responsibility for HIPAA, OCR is very sensitive to privacy concerns among both people with disabilities and individuals with LEP and we remain committed to protecting their privacy and confidentiality.[380]

Comment: One commenter requested that OCR clarify that proposed § 92.211 on nondiscrimination through telehealth services does not apply to prescribing medication abortion or referring for abortion.

Response: The specific content of the health services provided via telehealth is beyond the scope of this rulemaking. In the same way in which we have generally declined to revise the final rule to address how a particular provision applies in the context of the provision of a particular type of care, we decline to do so here as well.

Comment: Many commenters wrote that ensuring equitable payment for and access to telehealth across a range of modalities (including audio-only telehealth, audio-video telehealth, real-time text, and in-person services), as well as making payment rules for telehealth implemented during the COVID–19 Public Health Emergency permanent, is needed to ensure nondiscrimination in the administration of telehealth. Other commenters said that audio-only telehealth should be reimbursed for individuals without smartphones or reliable broadband service. One State commenter requested CMS provide additional guidance on how this rule would impact service delivery in rural areas in light of CMS' audio-only service delivery in Medicare.

Response: Although OCR is cognizant of and sensitive to health equity concerns involving coverage and payment policies for health care services delivered via telehealth, such policies are outside the scope of OCR authorities and the section 1557 rulemaking. However, in general, OCR does not expect the rule to affect audio-only delivery of Medicare services in rural areas.

Comment: Several commenters wrote that inadequate reimbursement of telehealth and disparate medical management requirements limiting access to telehealth are discriminatory and that such practices ought to be prohibited.

Response: OCR will consider complaints raising the issues of whether inadequate reimbursement of telehealth or disparate medical management requirements limiting access to telehealth is discriminatory under section 1557 on a case-by-case basis. To the extent a covered entity's telehealth policies or practices delay or deny an individual's access to a health program or activity delivered via telehealth, OCR will consider whether the delay or denial is based on prohibited grounds under section 1557 as set forth in this rule, including as a discriminatory benefit design prohibited under § 92.207(b)(2). Covered entities have flexibility in determining the reimbursement rates and medical management requirements in their plans, and this rule does not establish specific reimbursement requirements or medical management requirements. However, as noted elsewhere in this preamble, such practices must be implemented in a nondiscriminatory manner.

Comment: Some commenters requested the rule prohibit covered entities from requiring individuals to use telehealth for programs, services, and assessments for which telehealth is inappropriate or risks substandard services or findings. Some commenters also asked OCR to require covered entities to offer in-person alternatives to telehealth services.

Response: OCR recognizes that not all health programs and activities are appropriately delivered via telehealth, and OCR will review complaints related to payers or providers that require individuals to receive programs, services, or assessments via telehealth for potential discrimination concerns. However, we decline to issue a blanket prohibition on the use of telehealth in specific circumstances as requested by commenters, as the use in those situations may not be per se discriminatory or there may be a legitimate, non-discriminatory reason for the practice.

A covered entity may need to offer in-person alternatives to telehealth, as a reasonable modification for individuals with disabilities who cannot be properly provided with effective communication or as a reasonable step to provide meaningful access for individuals with LEP through telehealth services. However, we decline to implement a general requirement that covered entities providing telehealth offer an in-person alternative.

Comment: Many commenters urged that individuals with a disability be afforded the opportunity to choose between telehealth and in-person care based on the service delivery model that works better for their health and communications needs and urged the inclusion of an opt-out provision.

Response: Any individual with a disability who needs to opt-out from receiving care via telehealth should request a reasonable modification of policies and procedures from the covered entity. Unless the reasonable modification fundamentally alters the health program or activity, the covered entity should approve an in-person visit.

Comment: A number of commenters called on OCR to codify WCAG 2.0 (AA), WCAG 2.1 (AA),[381] section 508, or related standards for telehealth platforms. Some recommended requiring certifications of compliance

[375] Rupa S. Valdez et al., *Ensuring Full Participation of People with Disabilities in an Era of Telehealth,* 28 J. Am. Med. Inform. Ass'n 389 (Feb. 2021), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717308/.*

[376] Aswita Tan-McGrory et al., *Addressing Virtual Care Disparities for Patients With Limited English Proficiency,* The Am. J. of Managed Care (2022) *https://www.ajmc.com/view/addressing-virtual-care-disparities-for-patients-with-limited-english-proficiency.*

[377] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care* (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.*

[378] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet* (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[379] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth* (Jun. 13, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html.*

[380] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *A Health Care Provider's Guide to the HIPAA Privacy Rule: Communicating with a Patient's Family, Friends, or Others Involved in the Patient's Care* (Sept. 16, 2008), *https://www.hhs.gov/sites/default/files/provider_ffg.pdf.*

[381] Web Content Accessibility Guidelines 2.1 (AA), W3C World Wide Web Consortium Recommendation, *https://www.w3.org/TR/WCAG21/.*

from covered entities. One commenter recommended that covered entities be required to attest to making their best effort to accommodate patient needs. Another commenter suggested an elaborate alternative regulatory scheme that would treat telehealth platforms like public accommodations. Other commenters suggested that standards should be adopted in such a manner as to grant covered entities time to come into compliance, and others suggested safe harbors for compliance if a covered entity meets WCAG standards.

Response: OCR recognizes that this is a complex and evolving area, and given the rapid evolution of platforms and technologies, we have decided not to adopt specific accessibility standards at this time for telehealth platforms, particularly given other ongoing rulemakings in this field. Both OCR and DOJ recently issued NPRMs addressing the accessibility of web content and mobile apps used by recipients of Federal financial assistance and public entities, respectively.[382] Those rulemakings provide greater clarity on obligations to ensure that web content and mobile applications are accessible. This rulemaking requires covered entities to ensure telehealth platforms are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of a covered entity's health programs or activities. Specifically, OCR notes that communications before, during, and after telehealth appointments must be accessible to individuals with disabilities and individuals with LEP, consistent with pre-existing section 504, title VI, and section 1557 requirements.

Comment: A number of commenters recommended expanding the nondiscrimination requirement of § 92.211 to designated companions or caregivers of people with disabilities, since shared involvement is often necessary to set and facilitate telehealth appointments.

Response: Yes, companions with disabilities are covered under the effective communications requirements of this rule at § 92.202, and therefore we do not believe this language needs to be added. Companions with LEP are similarly covered under the meaningful access requirements of this rule at § 92.201.

Comment: Many commenters stated that providers should assess individuals with disabilities seeking to use telehealth platforms for visual, cognitive, intellectual, mobility, and functional needs, and that platforms should be adapted to address the needs of a wide variety of people with diverse functional limitations who have difficulties communicating through traditional telehealth, including, but not limited to, people with visual, hearing, and speech disabilities.

Response: OCR agrees that such an assessment would be informative and is recommended as a best practice and as a means of connecting individuals with the most appropriate auxiliary aids and services to meet their needs. However, OCR has concluded it is important to allow covered entities flexibility in determining whether to assess individuals with disabilities seeking to use telehealth platforms. We therefore decline to adopt an assessment requirement at this time. However, OCR will continue to monitor developments in methodology for assessing individuals with disabilities.

Comment: Many commenters recommended that covered entities be required to provide individuals with a Notice of Availability (§ 92.11) when covered entities electronically communicate to individuals that they may make telehealth appointments with the covered entity.

Response: Such a scheduling communication is already covered by § 92.11(c)(5)(v), because it relates to services that ''require or request a response from a participant, beneficiary, enrollee, or applicant.''

Comment: A significant number of commenters recommended adopting detailed specifications and performance standards for accessibility features on telehealth platforms for individuals with specific disabilities. Several commenters also said OCR needed to provide specific requirements related to qualified interpreters on telehealth platforms with ''specific provisions addressing accessibility in telehealth services and particularly related to access for individuals with disabilities and LEP individuals.''

Response: While OCR appreciates commenters' request for detailed performance standards, we decline to adopt such provisions at this time given the rapid evolution of platforms and technologies. Requirements addressed elsewhere in the rule, including at §§ 92.201 (Meaningful access for individuals with LEP) and 92.202 (Effective communication for individuals with disabilities), provide a baseline from which covered entities can tailor their compliance. OCR will continue to consider issuing additional guidance on this topic.

Comment: One commenter wrote that audio-only visits are inherently inferior to audio-visual telehealth visits as they exclude information and meaning conveyed through visual cues, increasing chances for poor communications, misdiagnoses, flawed evaluations, and other subpar outcomes. This commenter advised requiring in-person care be available on the same terms as telehealth.

Response: Although OCR appreciates the comment and recognizes that audio-only telehealth communication may not be appropriate for all circumstances, we decline to disallow audio-only as an option for telehealth delivery. We believe this would erect an unnecessary and unjustified barrier to telehealth for individuals who lack the quality or consistent internet access necessary for audio-visual telehealth. As stated previously, a covered entity may need to offer in-person alternatives to telehealth to ensure effective communication for individuals with disabilities (section 504, the ADA, and section 1557), or meaningful access for individuals with LEP (title VI and section 1557), but we decline to implement a general requirement that in-person care be available on the same terms as telehealth. For further information, we once again direct commenters to the Telehealth Guidance.[383]

Comment: One commenter wrote that, given that telehealth is incorporated in ''information and communication technology for individuals with disabilities'' (§ 92.204), it would be helpful to explain the interaction between these two sections.

Response: This commenter is correct that telehealth is closely related to the ICT section. ICT is generally a means by which to facilitate access to information in a health program or activity, whereas telehealth is a medium through which a health program or activity is delivered and for which access is needed. Health programs and activities provided through ICT include telehealth, which we define as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. In contrast, ICT relates to the technology and other equipment,

[382] *See* 88 FR 63392 (Sept. 14, 2023) (HHS) and 88 FR 51948 (Aug. 4, 2023) (DOJ).

[383] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons* (July 29, 2022), *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

such as computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents. Thus, while telehealth interfaces and applications are a form of ICT, the rapid expansion of its use by providers and broad impact on the health care landscape necessitate careful consideration independent of a broader ICT section. The telehealth section is designed to ensure that health programs and activities delivered via telehealth technologies are done so in a manner that does not discriminate.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.211 without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

Proposed § 92.301 provides that the enforcement mechanisms available for and provided under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of section 1557 as implemented by the part.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters strongly supported OCR's clarification that section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities. Supporters indicated that the rule as proposed would provide for robust enforcement of section 1557, consistent with existing law and the clear intent of Congress. One commenter expressed support for the different mechanisms of enforcement and emphasized the importance of enforcement that is level, targeted, and constant to ensure long-term adherence to section 1557's nondiscrimination provisions.

Response: OCR appreciates and acknowledges the need for strong enforcement mechanisms in order to adequately address discrimination in health programs and activities.

Comment: One commenter noted that making a clear procedure for claims of discrimination on multiple bases is important, not only for the complainant to fully understand their rights and remedies, but also for the covered entity to know how best to respond to a grievance. Commenters also suggested that OCR provide guidance on how covered entities should proceed with complaints that involve multiple bases of discrimination.

Response: OCR agrees that it is important to provide clarity to both complainants and covered entities regarding the procedures for raising a claim under section 1557. We currently offer resources on our website to provide the public and covered entities with information about the complaint process and how covered entities implement and maintain compliance. As discussed in § 92.303, in an effort to simplify the complaint process, OCR is revising the regulatory text to apply a single administrative enforcement procedure for discrimination complaints filed under section 1557, regardless of the alleged basis of discrimination. This will eliminate confusion for both covered entities and the public with regard to how OCR will evaluate and investigate allegations of discrimination brought under this part, including allegations involving multiple bases of discrimination. Covered entities should handle section 1557 grievances involving multiple bases of discrimination under one process. OCR will continue to provide guidance to covered entities on an ongoing basis to ensure compliance with the rule.

Comment: Several commenters stated that section 1557 creates a health-specific, nondiscrimination private cause of action. They opine that, because Congress expressly adopted one provision to prohibit discrimination on multiple grounds, the enforcement mechanisms available under each of the referenced statutes are not intended to be limited to the particular ground of alleged discrimination but rather would be available regardless of the ground of discrimination at issue.

Many commenters strongly recommended that OCR expressly state, as it did in the 2016 Rule preamble, that it will interpret section 1557 as authorizing a private right of action for claims of disparate impact for all grounds of prohibited discrimination. They stated that making the private right of action language explicit in the rule will provide for transparency and patient protection and enable more consistent enforcement of section 1557. Commenters stated that without a disparate-impact theory of liability, a private right of action will ring hollow for people of color and other systemically marginalized groups. Additionally, commenters noted that in an era where artificial intelligence and automated decision-making are increasingly responsible for resource allocation, recognition of disparate-impact liability is critical. Other commenters noted that a private right of action is essential to ensuring that individuals who experience discrimination on the basis of sex in health care are not solely reliant on OCR to enforce the law and may be entitled to seek compensation through a private right of action for the harm they experience.

Commenters further stated that the Supreme Court has affirmed the right of all private individuals to sue in Federal court to challenge violations of the protections of section 1557. Other commenters noted that a private right of action is essential to ensuring that individuals who experience discrimination on the basis of sex in health care are not solely reliant on OCR to enforce the law. Commenters also stated that by expressly including enforcement mechanisms ''available under'' the statutes, Congress authorized disparate-impact claims to be brought under section 1557.

Finally, commenters raised specific concerns regarding the Age Act's administrative exhaustion requirement, 42 U.S.C. 6104(f), and many commenters recommended that OCR include regulatory language in the final rule clarifying that administrative exhaustion is not required before a court action involving multiple bases of discrimination that includes age can be filed by the complainant. These commenters stated that because section 1557 is its own statute—enforceable by private right of action in the courts—an older adult who is discriminated against based on age and another basis should not be disadvantaged due to the Age Act's administrative-exhaustion requirement.

Response: Courts have long recognized that section 1557 authorizes a private right of action under any of the bases for discrimination. OCR declines to revise regulatory text to adopt a stance on the appropriate standards that apply to private litigants. This is an issue appropriately addressed by the Federal judicial branch and not via agency rulemaking.

Comment: One commenter requested that OCR clarify whether providers caring for individuals with disabilities and relatives of such individuals have the ability to bring a civil rights action in appropriate cases, such as where the provider or relative are themselves harmed by the plan's discriminatory conduct.

Response: OCR cannot provide legal advice as to whether an individual can appropriately bring a private claim under section 1557. If an individual—

including providers and relatives of a plan holder—believes they have experienced discrimination prohibited by section 1557, they are able to file a complaint with OCR. OCR will conduct a case-by-case analysis to determine its jurisdiction over the complaint allegations.

Comment: Some commenters urged OCR to increase enforcement capacity through coordination among agencies within the Department, and that the final rule should authorize OCR to empower other Department components, such as CMS, to investigate and enforce section 1557 claims.

Response: As a law enforcement agency with specialized knowledge and delegated authority over section 1557 enforcement, OCR is the agency within the Department that investigates and enforces section 1557 complaints. However, OCR continues to work with other agencies on many different initiatives and issues, including to promote compliance with Federal civil rights laws such as section 1557.

Comment: Some commenters suggested that OCR should pair enforcement with robust outreach and education. Several commenters requested that OCR postpone any enforcement action until after OCR provides education resources and technical assistance, to allow time for different practices to come into compliance without penalty.

Several commenters requested that OCR use enforcement discretion for particular groups of providers. For example, one commenter asked OCR to provide assurances that pharmacists can use reasonable clinical judgment to treat patients within their scope of practice, and not be subject to additional administrative burden and legal liability. Another commenter requested that OCR use enforcement discretion and not penalize physicians for failing to provide interpreter services as long as they make reasonable efforts to satisfy the final rule's requirements. This commenter also requested that OCR provide guidance and support for physicians in rural and other hard to reach areas for procuring and using the necessary technology to connect with remote interpreters. Specifically, this commenter pointed to concerns with physician practices in remote areas where interpreter availability is inconsistent and remote connectivity to interpreter services is either substandard or non-existent due to the lack of necessary broadband.

Response: We appreciate the commenters' concern, but section 1557 has been in effect since 2010 and OCR declines to postpone enforcement past the effective date of 60 days after publication of the final rule. We note, however, that we have provided delayed implementation dates for a number of provisions. Further, prior to taking an enforcement action (*i.e.,* terminating Federal financial assistance or referring a matter to DOJ for enforcement), OCR must attempt to achieve a covered entity's voluntary compliance with the law, such as through providing technical assistance and reviewing policies and procedures.[384]

Comment: Some commenters recommended adding a new provision requiring OCR to publish general information about the number and types of complaints received and resolved on a yearly basis and to publicly post information regarding resolution agreements within 14 days of resolving a complaint.

Response: Much of the information requested is already provided to Congress annually through OCR's Congressional Justifications and these annual justifications are also available on OCR's website.[385] In addition, OCR posts its resolution agreements to its website, available to anyone to review. We intend to continue with this practice as more cases are resolved.

Comment: Some commenters were also concerned with mandatory arbitration agreements and recommended that OCR include a specific provision prohibiting insurers from requiring binding arbitration as the exclusive means to resolve a complaint arising under section 1557. These commenters were concerned that binding arbitration greatly favors defendants, particularly large corporations.

Response: OCR appreciates concerns with regards to arbitration but notes that agreements between private parties is beyond the scope of this rulemaking.

Summary of Regulatory Changes

For the reasons set forth above and in the Proposed Rule and considering the comments received we are finalizing the provisions as proposed in § 92.301, without modification.

[384] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities* (June 16, 2023), *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html.*

[385] Current and past OCR Congressional Justifications can be found at *https://www.hhs.gov/ocr/about-us/budget/index.html.*

Notification of Views Regarding Application of Federal Religious Freedom and Conscience Laws (§ 92.302)

In proposed § 92.302, OCR proposed an administrative process under which recipients can notify OCR of their views that they are exempt from certain provisions of section 1557 due to an applicable Federal conscience or religious freedom law. This proposed provision was not in either the 2016 or 2020 Rule.

Proposed § 92.302(a) provided that a recipient may notify OCR of its view that it is exempt from certain provisions of this part due to the application of a Federal conscience or religious freedom law. Proposed § 92.302(b) provided that once OCR receives such notification from a particular recipient, OCR shall promptly consider those views in responding to any complaints or otherwise determining whether to proceed with any investigation or enforcement activity regarding that recipient's compliance with the relevant provisions of this part. We further explained that any relevant ongoing investigation or enforcement activity regarding the recipient shall be held in abeyance until a determination has been made under § 92.302(c).

Proposed § 92.302(c) provided that based on the information provided in the notification under Proposed § 92.302(a), OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part, or whether modified application of the provision is required with respect to specific contexts, procedures, or health care services, based on an applicable Federal conscience or religious freedom law. In doing so, we further explained that OCR will assess whether there is a sufficiently concrete factual basis for making a determination and will apply the applicable legal standard of the relevant law. Proposed § 92.302(c) also provided that OCR will communicate its determination to the recipient. Proposed § 92.302(d) provided that if OCR determines that a recipient is exempt from the application of certain provisions of this part or modified application of the provision is required as to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law, that determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

The comments and our responses regarding § 92.302 are set forth below.

Comment: Many commenters expressed support for the proposed provision primarily because, in their view, § 92.302 would balance the need to protect both the religious and conscience views of recipients and the civil rights protections for patients, providers, and consumers. In commenting on the purpose of section 1557, one religious, organizational commenter stated that it ''strongly supports the principle of nondiscrimination in health programs and activities established by the ACA and the promulgation of regulations to ensure that principle is implemented robustly'' because ''[a]ccess to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual.'' Another religious, organizational commenter stated that ''[e]nsuring access to health coverage and health care, and removing barriers to these, is without question a laudable goal.''

Response: OCR appreciates these commenters' views and agrees that § 92.302 allows OCR to fully consider and uphold religious freedom and conscience laws as well as civil rights laws for patients, providers, and consumers, to ensure broad access to health care for all individuals.

Comment: Many other commenters opposed the addition of § 92.302. Commenters maintained that the process for notifying OCR of their exemption requests would burden religious entities and favor the interests of third parties. Some commenters raised concerns that claims of third-party harms can be used by opponents of religious liberty as a basis for denying any religious exemption. Additionally, a few commenters asserted that any investigation by OCR that excludes consultation with the Conscience and Religious Freedom Division will lead to religious and conscience objectors losing to claims of third-party harms. Commenters thus requested that OCR explain the types of harm that may overcome religious objections.

Response: OCR appreciates commenters' objections to § 92.302 and recognizes the request for guidance and clarification. In response to commenters who stated that the notification process itself burdens religious entities, OCR has added clarifications to the regulatory text stating that recipients may rely on the protections in religious freedom and conscience laws or seek further assurance of these protections from OCR, if they wish. OCR notes that under revised § 92.302, recipients are not required to seek assurance of an exemption in advance but may raise a claim under an applicable Federal religious freedom and conscience protection in the context of an OCR investigation or enforcement action. Also, we have revised § 92.302(a) to make clear that, insofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. This language is consistent with language added to § 92.3(c) and has been interpreted by courts to support the Department's position that it ''will abide by RFRA in any enforcement of Section 1557'' and that the Department ''has never enforced section 1557 to require a provider with a religious objection to perform gender transition services.'' *Am. Coll. of Pediatricians* v. *Becerra,* 2022 WL 17084365 (E.D. Tenn. 2022) (citing to this language from the 2016 Rule as support).

In making determinations under § 92.302, OCR will faithfully apply the legal standards set forth in the Federal religious freedom or conscience law at issue. For example, RFRA provides that the Federal Government may not substantially burden a person's exercise of religion unless ''it demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.'' 42 U.S.C. 2000bb–1(b). Further, while case law interpreting RFRA requires consideration of any potential third-party harms, such harms, where relevant, are one of several factors that will be considered. Other Federal religious freedom and conscience laws set forth different tests. For example, a provision of the Church Amendments, 42 U.S.C. 300a–7, states that the receipt of Federal financial assistance (under certain statutes implemented by HHS) ''by any individual or entity does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions,'' *id.* 300a–7(b)(1). When administering its exemption process, OCR will carefully apply the text of these statutes and judicial precedents interpreting them, including by being mindful of the ways in which the texts of these statutes differ from one another.

We continue to believe that this approach is most consistent with the Federal religious freedom and conscience protections. In addition, OCR has consulted with the appropriate Department staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage staff during OCR's enforcement of the final rule.

Comment: Many commenters said that by not allowing a categorical pre-enforcement exemption and instead making the exemption process case-by-case, OCR will increase doubt among providers, inviting constant reliance upon administrative adjudication and litigation that will cost unnecessary time and money. Some commenters asserted that OCR's consideration of claims on a case-by-case basis is problematic for large health care systems with multiple sites of care. These commenters raised concerns that hospital systems would be deprived of the clarity and certainty needed to adhere to their religious principles and to establish compliance with policies covering all member hospitals, such that the health system would ensure that claimed exemptions were being appropriately and narrowly applied. These commenters claimed that because a recipient would be left with significant uncertainty until OCR considered any enforcement action, the process of claiming a pre-enforcement exemption with OCR affords few assurances of future enforcement protections.

Still, many other commenters supported the § 92.302 process because, in their view, such a case-by-case inquiry allows OCR an opportunity to consider objections in the context-specific manner that Federal religious freedom laws like RFRA require. Many commenters emphasized that in the context of health care under section 1557, the government has a compelling interest in not only preventing discrimination but ensuring taxpayer dollars are not used to further discrimination. Other commenters, however, asserted that RFRA imposes an affirmative obligation on the government to respect and protect religious liberty and is not a defensive argument for individuals to raise on a case-by-case basis.

Response: OCR understands some commenters' concerns and opposition to the proposed provision requiring case-by-case determinations. OCR maintains an important civil rights interest in the proper application of Federal conscience or religious freedom protections, which requires taking a case-by-case approach to such determinations. Among other things, this allows OCR to determine whether the government has a compelling

interest in denying an exemption to a particular party; [386] to consider, when relevant under the applicable legal standard, any harm an exemption could have on third parties, including other recipients, providers, patients, and the public; and to evaluate whether imposing burdens on a covered entity is the least restrictive means of furthering a compelling government's interest.[387]

However, to address commenters' concerns, OCR has revised § 92.302(a) to state that a recipient may ''rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required where such protections apply.'' When a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant religious freedom and conscience protections (*e.g.,* RFRA), OCR will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b). But if OCR determines, after an investigation, that the recipient does not satisfy the legal requirements for an exception, it will seek forward-looking relief as appropriate under the facts.

If the recipient wishes to receive an assurance from OCR regarding an exemption under any applicable religious freedom and conscience laws, it may do so under § 92.302(b) either prior to, or during the course of, an investigation. We understand that there was some confusion regarding the ''case-by-case approach'' discussed in how OCR proposed to evaluate exemption requests under § 92.302(b). We clarify here that a recipient may seek assurance of an exemption applying to specific contexts, procedures, or health care services generally. When OCR makes a case-by-case determination, this refers to the evaluation of the exemption assurance request as a whole—which may be requesting assurance of an exemption from a category of procedures or health care services. Thus, when we indicate that exemption requests will be evaluated on a case-by-case basis, this does not mean that a recipient must seek assurance of an exemption each time such procedure or health care is sought if an exemption already applies. Rather, a recipient may demonstrate that it is entitled to an exemption due to a religious or conscience objection to a particular provision in this part, as applied to specific contexts, procedures, or health care services.

A recipient may obtain assurance of its exemption in multiple ways under § 92.302(b). For example, if a recipient is seeking assurance of an exemption while there is no investigation pending, the notification to the OCR Director under § 92.302(b) would include: (1) identification of the provision of care to which the covered entity objects, specifying whether the objection is to the service overall or to the provision of care in a specific circumstance (per item (1)); (2) an explanation of the legal basis supporting the claim (per item (2)); and (3) the factual basis supporting the claim (per item (3)). Thus, for example, if a Catholic hospital is seeking an assurance of an exemption from having to perform sterilization procedures that would conflict with the religious tenets of their institution, their notification under § 92.302(b) would potentially include: (1) the provision to which there is an objection and that the objection is to provision of a procedure overall, *i.e.,* sterilization procedures that are prohibited by their religious tenets; (2) that they should be exempt under a specified religious freedom or conscience law; and (3) evidence that it, for example, never provides sterilization in violation of a particular religious or conscience belief for any patient, no matter their sex.

Alternatively, if a covered entity is seeking assurance of an exemption during an OCR investigation, it may similarly submit a notification under § 92.302(b). This notification would include the same information, but the factual basis for the claim would also discuss the specific context of the investigation in question. Though raised in response to a specific complaint allegation, the recipient may use this same notification to seek assurance of an exemption for the same circumstances going forward.

To take an example drawn from enforcement experience, OCR investigated allegations that a Catholic hospital discriminated against the complainant when it refused to allow his physician to perform a hysterectomy as a form of gender affirming care at their facility. The hospital confirmed during the investigation: (1) it did not perform the particular type of care or procedure (hysterectomy) on any patient under the circumstances (as it performs ''direct sterilization'' only for ''the cure or alleviation of a present and serious pathology and a simpler treatment is not available''); (2) that it was raising a defense under RFRA, citing the relevant legal standard; and (3) the factual basis for not providing such medical care and how the hysterectomy request conflicted with the exercise of its religious beliefs. OCR evaluated the complaint and the hospital's response in light of its obligations under RFRA, and determined that to require the hospital to allow the procedure in question to take place at their facility would result in a substantial burden on their religious exercise. OCR further found that section 1557's prohibition on sex discrimination as applied to the facts of this case was not the least restrictive means of achieving the government's compelling interest in preventing discrimination and therefore closed the matter.

Comment: Some commenters who supported the provision expressed appreciation that the process outlined in § 92.302 would allow OCR to consider an exemption's potential harms to third parties, such as patients or the public. Many commenters believed that this type of exemption process is structured to promote equity and transparency, while ensuring compliance with relevant legal requirements. Multiple commenters shared stories about denials of care, including in medical situations in which patients were seeking emergency services. One commenter reported an instance in which a woman was forced to deal with serious health complications when her treatment was delayed after emergency room staff learned of her sexual orientation. In another example, a commenter recalled that a pediatrician's office refused to make an appointment for an infant because the patient's parents were lesbians. Other commenters said a hospital refused to allow doctors with admitting privileges to provide their patients with, for instance, medically necessary gender-affirming care inside their facilities. Many commenters stated that even where patients are able to obtain the services from another provider, the delay in receiving care may cause irreparable harm. Multiple commenters described that the stress of being denied medical care and the fear of facing similar denials in the future can have serious negative health outcomes.

Some commenters who supported proposed § 92.302 compared the provision to the title IX religious exception, explaining that they preferred an administrative process that

[386] *Fulton* v. *City of Phila.,* 593 U.S. 522, 541–42 U.S. (2021).

[387] *See Burwell* v. *Hobby Lobby Stores, Inc.,* 573 U.S. 682, 739 (2014) (Kennedy, J., concurring) (''Among the reasons the United States is so open, so tolerant, and so free is that no person may be restricted or demeaned by government in exercising his or her religion. Yet neither may that same exercise unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling.'').

protects religious liberty, such as that proposed in § 92.302, over an exception that might be too broad.

Response: OCR appreciates these comments and agrees that the § 92.302 exemption process is the better approach.

Although commenters compared the proposed § 92.302 process with the title IX religious exception when expressing their support, OCR makes clear that the process provided under § 92.302 is separate and apart from title IX and this new provision does not rely upon or effectuate title IX's religious exception. Rather, as explained above, this provision clarifies the applicability of religious freedom and conscience protections and provides a process for OCR to respect applicable Federal religious freedom and conscience laws for specific recipients, whether or not they are religious organizations, in its enforcement of section 1557.

Comment: Several commenters who opposed this provision requested that OCR provide recipients with a categorical exemption, similar to what, in their view, was captured by the 2020 Rule through the importation of the title IX religious exception. In these commenters' view, such importation would provide a categorical exemption from providing procedures that would violate their religious beliefs. Many commenters also argued for incorporation of the title IX religious exception to address their concerns over what they viewed as the complexities, inconsistencies, and unpredictable nature of the § 92.302 process.

Many other commenters also stated that the process at § 92.302 is too burdensome and unclear, and in their view, it would effectively prohibit a provider from abstaining from procedures that violate their religious convictions. Additionally, some commenters stated that these burdens were unfair to religious employers, especially small employers, who the commenters said will refrain from applying for Federal funding, further harming patients due to limited providers.

A few commenters stated that, as proposed, § 92.302 forces religious entities to expose themselves to potential sanctions by requesting an exemption. Requesting any exemption, commenters argued, makes the recipient a target for an agency that, in their view, is a ''bully'' to religious organizations. Several commenters expressed concerns that in requesting an exemption, the recipient will lose, in their views, its ''privacy and anonymity,'' which could have a chilling effect on its provision of health care services.

Response: OCR appreciates and respects commenters' concerns relating to their religious convictions. The § 92.302 process demonstrates OCR's concerted effort to enforce Federal antidiscrimination laws and apply Federal religious freedom and conscience laws. Section 92.302 provides an administrative process, not implemented in either the 2016 or 2020 Rule, which responds to the shortcomings of both rules. Through the § 92.302 process, OCR is committed to implementing a rule that clarifies legal obligations and maintains transparency about its enforcement mechanisms.

Moreover, as previously addressed, *supra,* at § 92.208, OCR complies with the protections in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws that provide religious freedom and conscience protections—§ 92.302 provides an administrative process through which providers may rely upon and assert these protections.[388] This provision helps ensure that recipients have an opportunity to seek assurance from OCR about the application of religious freedom and conscience protections. OCR does not seek to deprive a recipient of their ''privacy or anonymity,'' and the information requested is only that which is necessary to provide assurance of the exemption or modification that the recipient is seeking.

To clarify further, recipients may seek an assurance of an exemption under these Federal religious freedom and conscience laws at various points in time, including prior to an investigation or during an ongoing OCR proceeding. To begin, as explained above, a recipient may avail itself of the general application of § 92.302(a) and ''rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required.'' Should the recipient seek an assurance, it may—prior to any administrative investigation and enforcement—do so by filing a notification with OCR under § 92.302(b). OCR will then acknowledge receipt of the notification within 30 days, and the recipient may rely on a temporary exemption, per § 92.302(c)(1), while OCR adjudicates the assurance of exemption request. In instances where OCR has already initiated an investigation, the recipient may, during the pendency of that investigation, similarly notify OCR of their belief they are entitled to an exemption under the process provided at § 92.302(b). The notification will serve as a defense to the relevant investigation or enforcement activity, and a temporary exemption will then be in place per § 92.302(c)(2), pending OCR's determination regarding the request for assurance of the exemption or the conclusion of the investigation.

Finally, OCR disagrees with and respectfully objects to the characterization that it seeks to ''bully'' religiously affiliated recipients or expose them to potential sanctions. Religiously affiliated hospitals and health care facilities play a large role in the health care system, and OCR recognizes the critical patient care needs they provide, particularly in reaching underserved communities. As previously stated, the 2022 NPRM provided factual findings with respect to health care accessibility in the United States based upon health care capacity by providers, population demands, and geographic limitations. 87 FR 47840. A detailed discussion about these considerations can be found in the Regulatory Impact Analysis. In addition, OCR seeks to ensure Federal civil rights protections are fulfilled and has consulted with the appropriate staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage such staff during OCR's enforcement of the final rule.

Comment: Many commenters inquired about OCR's timeline for reaching a determination on a recipient's request. Specifically, commenters objected to the language in proposed § 92.302(c) that provides that, ''OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part'' because, in their view, this leaves open-ended the start and end points of the process. Some commenters opined that this uncertainty could result in disruptions or inappropriate denials of care while a recipient awaits a determination. Other commenters suggested that OCR amend § 92.302(c) to clarify what is intended by the clause ''may determine at any time'' because it may conflict with the provision in § 92.302(b) that such determinations will be made ''promptly.''

Many commenters recommended that OCR publish the anticipated timeframe for OCR's review of exemption requests, notify the requesting individuals/organizations about when OCR anticipates their review will be

[388] *See also* U.S. Dep't of Health & Hum. Servs., *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* Final Rule, 89 FR 2078 (Jan. 11, 2024).

complete, and instruct the requesting individual/organization to notify patients if they will not be offering the service or treatment under review during that period. Commenters expressed the need to set a reasonable timetable to ensure that requests for exemptions are processed quickly to not impede or delay patient care. Some commenters also proposed that OCR publicize de-identified data on conscience claims and their respective review timelines to ensure public and private entities can monitor any access issues, should they occur.

Many commenters who opposed the process described in § 92.302 explained that the provision lacks the guidance or clarity necessary for recipients to comply. For example, several commenters noted that in proposed § 92.302(a), OCR merely invites health care entities to express their views on whether their Federal religious freedom and conscience rights would be violated but provides no information about when a response should be expected. Some commenters explained that proposed § 92.302(b) appears to contemplate that recipients would wait until they are investigated or subject to an enforcement action before notifying OCR of their view that Federal religious freedom and conscience laws protect them. According to commenters, as proposed, § 92.302 provides no incentive for recipients to notify OCR any earlier than that, since the subsection appears to impose no obligation on OCR to weigh the notification or request until such an investigation or enforcement action is live.

Other commenters pointed to the purported lack of guidance regarding the types of records and facts that would assist OCR in reaching a determination on the exemption request. Some commenters asserted that § 92.302(c) also does not explain how OCR will make final determinations and omits discussion of a recipient's potential recourse for appeal in the event of an adverse decision from OCR.

Response: OCR appreciates commenters' suggestions and concerns and understands the desire for additional clarity and an established timeline under which OCR will process requests for assurances of exemptions and notify recipients of any determination. We agree that there is value in providing more detail regarding what obligations OCR and recipients have during this process, and so have revised § 92.302. These revisions provide, among other things: (1) a general application provision stating that a recipient may rely on applicable Federal protections for religious freedom and conscience; (2) clarity on what a notification for an assurance of a conscience or religious freedom exemption must contain; (3) a temporary exemption that will take effect upon the recipient's submission of the notification, regardless of whether the recipient is being investigated, and that will remain valid during the pendency of OCR's review of the request and any administrative appeal; (4) a general timetable under which OCR will acknowledge and begin to evaluate requests for assurances of exemptions; (5) additional clarity with regard to the scope of an exemption that has been assured under § 92.302(d); and (6) an administrative appeal process for recipients receiving adverse determinations.

First, § 92.302(a) now provides that a recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required, and does not violate section 1557 if it so relies.

Second, § 92.302(b) now provides that a recipient may notify OCR of its view that it is exempt from certain provisions of this part due to the application of Federal protections for religious freedom and conscience and seek assurance of that exemption. This notification must be in writing directed to the OCR Director and the notification must include (1) the particular provision(s) of this part to which the recipient objects; (2) the legal basis supporting the assurance of exemption request, including the standards governing the applicable conscience or religious freedom law; and (3) the factual basis supporting the recipient's view that it is exempt, including identification of the conflict between the recipient's conscience or religious beliefs and the application of a provision in this part, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their conscience or religious beliefs overall.

Third, § 92.302(c) now provides that a recipient's notification and request for an assurance of an exemption to OCR will trigger the extension of a temporary exemption to the recipient. This exemption will cover the period of time it takes OCR to reach a determination on the request. The temporary exemption shall apply only to the provision(s) as applied to specific contexts, procedures, or health care services identified in the recipient's notification to OCR and will exempt conduct that occurs during the pendency of OCR's review and determination regarding the assurance of exemption request. In the event that there is an investigation or enforcement activity regarding the recipient related to the specific provisions for which an assurance of exemption has been requested, the temporary exemption will serve as a defense through the investigation or until OCR has made a determination on the assurance of exemption request, or through the administrative process if the recipient seeks an appeal under § 92.302(e). During this time, a recipient's temporary exemption shall remain effective. OCR will work promptly to reach a determination regarding the request.

Fourth, with respect to OCR's expected timetable for review, § 92.302(c) now provides that for pre-enforcement requests for an assurance of an exemption, OCR shall provide the recipient with email confirmation within 30 days of a recipient's notification acknowledging receipt of their request and stating that OCR will work expeditiously to reach a determination. If the request for an assurance of religious freedom and conscience exemption is received during the pendency of an investigation, it shall serve as a defense to the relevant investigation or enforcement activity until the final determination of the recipient's request, the conclusion of the investigation, and any relevant appeal. The temporary exemption shall exempt the recipient from the provision of care at issue in the investigation until a final determination is made on recipient's notification request or investigation, or during the pendency of any appeal.

Fifth, OCR has revised § 92.302(d) to clarify the effect of an exemption. The assurance of an exemption would exempt the recipient from OCR's administrative investigation and enforcement with regard to the application of a particular provision, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their conscience or religious beliefs. The exemption assurance will not apply to all contexts, procedures, or health care services. A recipient must otherwise have a legitimate, nondiscriminatory reason for denying or limiting service outside the scope of the granted exemption assurance, and any such decision must not be based on unlawful animus or bias, or constitute a pretext for discrimination. For example, a hospital with a religious exemption to not provide sterilizations outside of those permitted under their religious tenets may not rely on the exemption to broadly decline all health care services,

e.g., cancer treatments, to any individual if the hospital otherwise provides that care.

Sixth, § 92.302(e) now clarifies that a recipient may appeal an OCR determination under this section. The relevant revisions provide that recipients subject to an adverse determination of their request for assurance of an exemption may appeal OCR's determination of that request. Recipients who have been denied an exemption assurance under § 92.302 may raise their request before an administrative hearing examiner from the Department with the same procedural protections outlined for such administrative hearings under 45 CFR part 81. The temporary exemption granted under § 92.302(c) would remain in effect until completion of the administrative appeal process.

Comment: Many commenters supportive of the outlined process also urged OCR to revise proposed § 92.302 to require OCR to make publicly available, or publish on its website, all determinations for any exemptions claimed or granted under § 92.302. A few commenters made specific suggestions for what the public postings should contain. These commenters proposed that postings should include the name(s) of the recipient requesting the exemption, the factual basis asserted by that recipient demonstrating its eligibility under Federal law, OCR's analysis of those facts, and the specific provision(s) of the rule to which an exemption is recognized. A handful of other commenters raised the possibility of requiring exemption determinations to be published, within 10 days of issuance, in the **Federal Register** and on the Department's website. Commenters also suggested that the notice should be accompanied by an electronic link to documents that specifically state the nature, scope, and duration of the exemption granted.

Many commenters discussed that, in addition to promoting transparency, providing notice to the public of religious and conscience exemptions granted would provide guidance both to providers and patients regarding their rights and responsibilities under section 1557, reducing confusion that can impede equitable access to care, particularly for the vulnerable populations the rule is designed to protect. Many commenters stated that it is important that individuals seeking care or coverage know whether the health providers or issuers they are considering do, in fact, provide the services they need—including whether they will be presented with all available care options—and whether they will feel accepted and welcomed by the provider they see.

Response: OCR appreciates commenters' suggestions for revisions to the rule to provide notice to the public regarding assurances of exemptions granted under this provision, including through having OCR post information regarding such assurances. Consistent with our title IX regulations and those of other agencies,[389] OCR declines to revise § 92.302 to require affirmative notice of exemptions sought by or granted to recipients under this provision. OCR notes that nothing in this final rule prevents a recipient from providing public notice of any such exemption assurances it has sought or received and we encourage recipients to do so. We recognize that individuals are not always aware that the health care entities from which they seek care may be limited in the care they provide, and remain committed to working with recipients and the public to improve transparency, clarity, and access to health care through implementation of this rule. As noted above, OCR is also subject to FOIA, and information may be released to a requestor or made available for public inspection consistent with the agency's obligations under that statute and its implementing regulations.

Comment: Some commenters also criticized the process laid out in § 92.302 for failing to identify who will evaluate the exemption requests. One commenter stated that most recipients will likely wait to raise their religious defenses in litigation, as they see courts as the only neutral decisionmakers. A handful of commenters also raised concerns that the 2022 NPRM did not mention OCR's 2019 final rule, *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 84 FR 23170 (May 21, 2019), or its applicability to numerous Federal statutes protecting religious freedom and conscience in health care. As a result of this omission, these commenters expressed skepticism about OCR's ability to apply the regulatory provisions contained in that rule.

Several commenters also questioned the interaction between the proposed exemption process and private rights of action. They stated that while the § 92.302 process would apply to OCR investigations and enforcement, the provision did not address situations where a lawsuit has been filed, as there is no across-the-board requirement that the administrative process be exhausted before going to court. Commenters assumed that faith-based hospitals likely will be forced to litigate claims in the courts without the ability to stay proceedings pending OCR's consideration of their exemption claim—another factor, they argued, which undermined the usefulness of the proposal.

Response: OCR appreciates commenters' concerns regarding the process for review. OCR refers commenters to the six specific steps outlined above detailing what obligations OCR has, and what options are available to recipients. And as stated previously, OCR is committed to enforcing all Federal civil rights laws under its purview. While OCR appreciates comments regarding the 2019 *Safeguarding the Rights of Conscience as Protected by Federal Statutes* final rule, as a result of challenges to its legality, that rule has been vacated.[390] OCR has published its final rule on enforcement of religious freedom and conscience laws. *See Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 89 FR 2078 (Jan. 11, 2024). Finally, OCR would not open or continue an investigation under section 1557 against the recipient regarding compliance with a provision for which they have requested an exemption assurance while a temporary exemption under § 92.302(a) is in effect, or after a final determination is made that the recipient is entitled to an exemption. While such commenters are correct that a temporary or final assurance of an administrative exemption from OCR would not itself preclude any private lawsuit under section 1557, OCR notes that the recipient could still raise the relevant Federal conscience or religious freedom law as a possible defense in judicial proceedings in such private litigation. And in cases where OCR has assured the recipient an exemption under § 92.302, the recipient could argue that that assurance is evidence that a Federal religious freedom or conscience law likely applies to the recipient in any private litigation under this final rule.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the

[389] *See, e.g.,* 45 CFR 86.12 (no notice requirement); *see, e.g.,* 34 CFR 106.12 (Department of Education, same).

[390] *New York* v. *HHS,* 414 F. Supp. 3d 475, 580 (S.D.N.Y. 2019) (''Accordingly, as a remedy, the Court vacates the 2019 Rule in its entirety, pursuant to [the Administrative Procedure Act] § 706(2).''), *appeal dismissed without prejudice to reinstatement,* Nos. 19–4254 et al. (2d Cir.); *see also Washington* v. *Azar,* 426 F. Supp. 3d 704 (E.D. Wash. 2019), *appeal pending,* No. 20–35044 (9th Cir.); *City & Cnty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019), *appeal pending,* Nos. 20–15398 et al. (9th Cir.).

comments received, we are finalizing the provision as proposed in § 92.302, with modifications. First, we are adding a § 92.302(a), which provide that a recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3, application of a particular provision(s) of the part to specific contexts, procedures, or health care services shall not be required where such protections apply.

Second, we are revising the process laid out in proposed § 92.302(b) through (d) as follows. We are revising § 92.302(b) to provide that a recipient that seeks assurance consistent with § 92.302(a) regarding the application of particular provision(s) of the part to specific contexts, procedures, or health care services may do so by submitting a notification in writing to the Director of OCR. Notification may be provided by the recipient at any time, including before an investigation is initiated or during the pendency of an investigation, and provides details on what must be submitted in writing to the OCR Director. We are revising § 92.302(c) to provide that a temporary exemption from administrative investigation and enforcement will take effect upon the recipient's submission of the notification—regardless of whether the notification is sought before or during an investigation, and then delineates the scope and application of the temporary exemption. We are revising § 92.302(d) to provide that if OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of the part or that modified application of certain provision(s) is required, the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision as applied to the specific contexts, procedures, or health care services provided in the written determination. The determination does not otherwise limit the application of any other provision of the part to the recipient or to other contexts, procedures, or health care services.

Third, we are adding § 92.302(e) to provide an administrative appeal process for recipients subject to an adverse determination of its request for an assurance of religious freedom and conscience exemption. Fourth, we are adding § 92.302(f) to provide that a determination under this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

Procedures for Health Programs and Activities Conducted by Recipients and State Exchanges (§ 92.303)

Section 92.303 proposed the enforcement procedures related to health programs and activities conducted by recipients and State Exchanges.

In § 92.303(a), OCR proposed applying the procedural provisions in the title VI regulation with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, and disability under section 1557.

Proposed § 92.303(b) applied Age Act procedures to enforce section 1557 with respect to age discrimination complaints against recipients and State Exchanges.

Proposed § 92.303(c) stated that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach a voluntary resolution, find noncompliance with section 1557 and initiate the appropriate enforcement procedure, found at 45 CFR 80.8.

The comments and our responses regarding § 92.303 are set forth below.

Comment: Many commenters recommended that § 92.303(a) explicitly recognize claims of discrimination involving multiple grounds, and suggested adding the language ''or a combination thereof.''

Response: As discussed in § 92.101, OCR agrees with this recommendation and we have added ''or any combination thereof'' throughout the regulatory text.

Comment: Commenters generally supported adoption of title VI procedural provisions with respect to administrative enforcement actions; however, they noted that OCR proposed to process complaints alleging discrimination on the basis of age differently given the adoption of Age Act regulation requirements under § 92.303(b). These commenters recommended that OCR clarify that for administrative enforcement, it will treat claims involving multiple bases, such as age and other protected identities, under the same procedural provisions as title VI.

Response: The Proposed Rule followed the 2016 Rule's approach to administrative enforcement procedures for complaints on the basis of race, color, national origin, sex, and disability, applying the procedures found in the title VI regulation. The Proposed Rule proposed to apply the Age Act regulatory procedures to age-based complaints. The Age Act procedures uniquely contain a requirement that the Department refer all sufficient complaints to mediation upon receipt; unresolved complaints will be returned to the Department. 45 CFR 91.43. The timeline for mediation is generally 60 days, unless a resolution is reached sooner, or the mediator has extended the time period for no more than 30 days. *Id.* at § 91.43(e). The 60-day period counts as part of the 180 days the Department has to resolve a complaint before a court action can be filed by the complainant. 47 FR 57850, 57856 (Dec. 28, 1982). The mediation requirement derives entirely from the HHS Age Act regulations. The Age Act statute does not itself mandate referral for mediation. It merely directs agencies to publish regulations that ''provide appropriate investigative, conciliation, and enforcement procedures.'' 42 U.S.C. 6104(a)(4).

In adopting the mediation requirement, the Department stated that the Age Act regulations offered ''a unique opportunity to try [the] innovative approach'' to resolution of complaints and committed to monitoring the effectiveness of the mediation process. 47 FR 57850, 57856 (Dec. 28, 1982). According to the Department's 2021 Age Act Report, the Department referred 32 complaints for mediation, and two were successfully mediated (6 percent).[391] Eight of 21 (38 percent) cases were successfully mediated in 2020, and eight of 48 (17 percent) were successfully mediated in 2019.[392] Thus, the average success rate of mediation for complaints alleging age discrimination is roughly 18 percent. When a complaint is returned to the Department, it follows the title VI procedural provisions for investigations and enforcement. 45 CFR 91.47.

We agree that individuals filing complaints with OCR under any of the bases for discrimination, including on the basis of age, should not be subject to unnecessary administrative hurdles. Given that the Age Act mediation requirement is not required by statute, but rather was an ''innovative'' approach adopted by the Department under its administrative authority to implement the Age Act, we have determined that OCR has the authority to not import such a requirement into the section 1557 procedures. While

[391] *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2021,* p. 32, *https://www.hhs.gov/sites/default/files/age-act-2021-report.pdf.*

[392] *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2019,* p. 30, *https://www.hhs.gov/sites/default/files/age-act-2019-report.pdf*; *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2020,* p. 32, *https://www.hhs.gov/sites/default/files/age-act-2020-report.pdf.*

mediation may prove beneficial under certain circumstances, as reflected through the Department's reporting on Age Act enforcement, it is not successful in all cases.

Given concerns raised by commenters, the value OCR places on the efficient and timely resolution of complaints, and the potentially sensitive nature of complaints raised under section 1557, we revisited the proposal to require complainants to engage in mandatory mediation. After review, and in light of these considerations and a desire for consistency across section 1557 administrative enforcement, we are revising the regulatory text to strike proposed § 92.303(b), which would have applied the Age Act procedural provisions to administrative enforcement actions concerning age discrimination. We are also revising § 92.303(a) to apply the title VI procedures to all administrative enforcement actions brought under section 1557.

This means that a complaint filed under section 1557 alleging age discrimination would not require the complainant to engage in mediation before OCR can open an investigation and claims alleging multiple bases of discrimination would be subject to the same enforcement procedures under the final rule. We note that complainants that wish to engage in mediation to address a complaint against a recipient or State Exchange will be provided with the option to do so, as these complaints may also be addressed under the Age Act, consistent with 45 CFR 91.43.

Comment: Commenters suggested making the OCR complaint process more straightforward and accessible, especially since individual complaints remain the primary trigger for investigations and individuals often file without legal representation. Commenters suggested that the final rule offer clear, fully accessible complaint mechanisms, including directions written in plain language, for filing discrimination complaints. These commenters suggested that complainants should not be required to parse out how a covered entity perceived them or responded to differing aspects of their lives. Further, these commenters recommended that any complaint procedures include resource materials such as Frequently Asked Questions, process diagrams, and materials presented in alternative formats, including videos with instructions in ASL embedded into the website as well as a clear and simple complaint process for individuals with LEP. One commenter further suggested that OCR clarify in the final rule that citizenship status is not relevant to an enforcement process or complaint filing.

One commenter also recommended that the time allowed for filing a complaint without needing to show good cause be extended from 180 days to 6 years to account for the postpartum timeline. Another commenter urged OCR to consider putting the longest deadline on the complaint filing that it can, consistent with its statutory obligations. This commenter noted that it often takes people months to realize they have been discriminated against, decide to do something about that discrimination, and find out that there are laws against the discrimination and agencies like OCR where they can file complaints.

Response: OCR appreciates the comments regarding the complaint process. We understand the complaint filing process may be both perceived and experienced as challenging, and OCR welcomes suggestions on making the process more accessible. We currently offer resources on our website to provide the public with information about the process for submitting a complaint and what to expect once they have submitted a complaint to OCR.[393] In addition, OCR revises its own processes, as needed. The most recent updates to OCR's Civil Rights Discrimination Complaint Form and Portal, for example, include providing the form and portal in fifteen languages other than English, and inclusion of additional clarity regarding forms of discrimination to report, including sexual orientation, gender identity, pregnancy, and discrimination against individuals with LEP.[394] We consider changes to the OCR complaint process on an ongoing basis as we strive to simplify the process and make it more accessible to all.

OCR notes that the requirement that a complaint be filed no later than 180 days from the alleged discrimination is consistent with the enforcement mechanisms under title VI, which we adopt herein and have also been adopted under title IX, section 504, and the Age Act. OCR will continue to extend the 180-day filing deadline for good cause, as outlined in the title VI regulation at 45 CFR 80.7(b). Further, to make this information more widely available, we are reinstating a required Notice of Nondiscrimination (§ 92.10), which includes information on how to file a complaint with OCR should an individual believe they were discriminated against.

In response to the comments received, OCR also notes that citizenship status is not relevant to an enforcement process or complaint filing; an individual's citizenship or immigration status does not prevent or alter their ability to file a complaint or OCR's ability to enforce potential violations.

Comment: Some commenters indicated that OCR should initiate compliance reviews rather than wait on individual complaints and some noted that while a simple, accessible complaint system is helpful, it should not, and cannot be, the only means of enforcement. Commenters stated that robust enforcement must include agency-initiated oversight, monitoring, and investigations; and that OCR should proactively review medical providers' treatment of patients of color for patterns to help detect bias.

A few commenters stated that incorporating the title VI procedures in proposed § 92.303(a) means including requirements that covered entities submit compliance reports and data to OCR and authorizing OCR to conduct periodic compliance reviews of covered entities. These commenters argued that OCR is effectively declaring that its enforcement of these provisions will be based on the presumption that any business decision made by a covered entity is either intentionally discriminatory or has an impermissibly discriminatory effect, unless and until that entity can demonstrate otherwise to OCR's satisfaction. According to the commenters, this would have the effect of imposing an expansive, arbitrary, and capricious new regulatory regime.

Response: OCR appreciates the importance of compliance reviews and robust enforcement. While most OCR investigations are conducted based on complaints received, OCR also conducts compliance reviews, which may be based on, for example, news reports or other information received by OCR.[395]

[393] U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *Filing a Civil Rights Complaint, https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

[394] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Complaint Portal, https://ocrportal.hhs.gov/ocr/cp/complaint_frontpage.jsf*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Get Help in Other Languages, https://www.hhs.gov/ocr/get-help-in-other-languages/index.html*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Office for Civil Rights, Civil Rights and Conscience Complaint form* (Expiration Date: Dec. 31, 2025), *https://www.hhs.gov/sites/default/files/ocr-cr-complaint-form-package.pdf.*

[395] For example, on March 7, 2023, OCR announced that it had reached a Voluntary Resolution Agreement with Hillsborough County Fire and Rescue in Florida to improve access to care for communities of color. OCR initiated a compliance review of Hillsborough County Right and Rescue in response to public press reports indicating that its paramedics refused to transport

OCR disagrees with commenters' position that adopting the longstanding enforcement procedures of title VI creates a presumption that a covered entity is discriminating. Nor does the adoption of these procedures represent a new ''regulatory regime,'' as these procedures appear in the Department's title VI regulations, which were originally published in 1964[396] and have since been adopted in the Department's title IX and section 504 regulations. Section 92.303, adopting 45 CFR 80.6 (Compliance information), includes standard requirements related to civil rights enforcement, including seeking cooperation from recipients and State Exchanges in obtaining compliance; providing assistance and guidance to assist recipients and State Exchanges reach voluntary compliance; requiring records maintenance by recipients and State Exchanges so that they may demonstrate compliance with the conditions of their receipt of Federal funds; requiring access to pertinent records as needed to determine compliance; and sharing information with the public regarding protections against discrimination. As with all of its investigations, including compliance reviews, OCR acts as a neutral factfinder and does not presume discrimination by the covered entity.

Comment: Some commenters recommended that OCR consider creating a searchable database of complaints and provide status updates that clearly indicate where in the process a complaint stands. Commenters also noted that OCR should shorten the time between filing a complaint and resolution. They noted that lengthy timelines for resolution have been detrimental, as advocates are reluctant to file knowing the duration of an investigation, and covered entities feel less urgency to comply. Some commenters noted that an ongoing deterrent to filing administrative complaints with OCR is the lack of a mandatory response deadline from OCR in title VI procedures. These commenters recommended implementing a 90-day deadline for OCR to resolve most section 1557 complaints, and a 120-day deadline for ''more involved'' section 1557 complaints.

Response: OCR appreciates commenters' recommendation to create a searchable database of complaints, and will take that under advisement, though we cannot commit to doing so at this time. OCR works with finite resources to address complaints as quickly and efficiently as possible and will continue to do so. Title VI procedures require a prompt investigation whenever information indicates possible noncompliance. OCR intends to follow these enforcement procedures and promptly address and resolve outstanding compliance failures. Because each potentially discriminatory action involves unique facts and circumstances that must be independently investigated on a case-by-case basis before OCR can determine whether a challenged action is considered discriminatory, we decline to add a mandatory response deadline as requested by commenters.

Comment: One commenter recommended that OCR create a separate portal for complaints related to obstetric violence and obstetric racism.

Response: OCR currently uses one portal for all civil rights complaints. The portal allows complainants to select the ground(s) under which they believe they were discriminated against to help ensure their complaints are fully reviewed and considered by OCR.

Comment: Some commenters suggested merging proposed §§ 92.303 and 92.304 to help reduce confusion among complainants.

Response: While we appreciate the need to have clarity when filing complaints, maintaining two separate sections is necessary given that there are different procedures for OCR to follow depending on whether the complaint is against the Department itself, or a recipient or State Exchange. However, for the sake of additional clarity, OCR will revise § 92.303(a) to parallel § 92.304,

Comment: Some commenters recommended OCR include a provision in § 92.303 expressly stating that if OCR does not have jurisdiction over a complaint, it will refer it to the appropriate office or agency.

Response: Section 92.304 adopts the compliance procedures found in OCR's federally conducted section 504 implementing regulation, which includes a provision requiring OCR to make reasonable efforts to refer a complaint over which it does not have jurisdiction to the appropriate Federal Government agency. 45 CFR 85.61(e). There is no corresponding provision in the title VI procedures, which are adopted at § 92.303 and are applicable to recipients and State Exchanges. However, OCR's practice is to refer such complaints, and we believe this is important to reflect this in regulatory text. We have included a new provision, replacing the former age-discrimination related provision at proposed § 92.303(b), that reads: ''If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.''

A *Comment:* Some commenters recommended that any enforcement mechanism include monitoring, reporting, and ''actual penalties'' or fines.

Response: We appreciate the need for strong enforcement mechanisms to ensure compliance with section 1557. The enforcement mechanisms incorporated into the rule allow for investigations based on both complaints and OCR-initiated compliance reviews. Voluntary Resolution Agreements and Settlement Agreements resulting from investigations generally include a monitoring period and reporting requirement to ensure ongoing compliance. If a recipient or State Exchange does not come into voluntary compliance and is found in violation of section 1557, OCR can take compliance action by either initiating fund termination proceedings under 45 CFR 80.8 or by any other means authorized by law, including referral to DOJ for enforcement proceedings.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.303, with modifications. We are revising § 92.303(a) to read ''. . . administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof . . .'' This language applies the same procedural provisions to administrative enforcement actions under section 1557

---

an African American woman to the hospital because they assumed she could not afford the ambulance cost due to her race. *See* U.S. Dep't Health & Hum. Services, Off. for Civil Rts., *HHS Office for Civil Rights Reaches Agreement with Hillsborough County Fire and Rescue in Florida to Improve Access to Care for Communities of Color*, *https://www.hhs.gov/about/news/2023/03/07/hhs-office-for-civil-rights-reaches-agreement-with-hillsborough-county-fire-and-rescue-in-florida.html*. In June of 2022, OCR entered into a Voluntary Resolution Agreement with the University of Southern California (U.S.C.) and Keck Medicine of U.S.C. (collectively, the ''KMUSC Entities'') resolving a compliance review of KMUSC Entities' policies and procedures for responding to sex discrimination complaints made by students, employees, or patients employed by, or participating in, any KMUSC programs or activities receiving Federal financial assistance from HHS. *See* U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *HHS Voluntary Resolution Agreement with the University of Southern California Settles Title IX Compliance Review*, *https://www.hhs.gov/about/news/2022/06/15/hhs-voluntary-resolution-agreement-with-university-of-southern-california-settles-title-ix-discrimination-complaints.html*.

[396] 29 FR 16298, 16301–03 (Dec. 4, 1964).

regardless of the basis of alleged discrimination, acknowledges that discrimination experienced by individuals may involve multiple bases, and corrects a scrivener's error (an unnecessary placement of the word ''discrimination'' after ''disability''). We are also revising § 92.303(a) to parallel § 92.304, to now provide that the procedural provisions applicable to title VI apply with respect to administrative enforcement actions against health programs and activities of recipients and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, age, and disability discrimination under section 1557 or the part. These procedures are found at 45 CFR 80.6 through 80.11 and part 81 of the subchapter. Additionally, we are replacing the text at proposed § 92.303(b) with new language stating: ''If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.''

Procedures for Health Programs and Activities Administered by the Department (§ 92.304)

In § 92.304, OCR addressed procedures for all claims of discrimination against the Department under section 1557 or the part, as set forth in § 92.304(a).

Section 92.304(b) proposed making the existing procedures under the section 504 federally conducted regulation at 45 CFR 85.61 and 85.62 applicable to all such claims under Section 1557 for all protected bases (*i.e.,* race, color, national origin, sex, age, and disability).

Section 92.304(c) proposed requiring the Department to provide OCR access to information relevant to determining compliance with section 1557 or the part.

Section 92.304(d) proposed prohibiting the Department from retaliating against an individual or entity for the purpose of interfering with any right secured by section 1557 or the part, or because such individual or entity has participated in an investigation, proceeding, or hearing under section 1557 or the part.

The comments and our responses regarding § 92.304 are set forth below.

Comment: Some commenters recommended that this section explicitly recognize claims of discrimination involving multiple bases, and suggested amending § 92.304(a) to add ''or a combination thereof.'' Some commenters recommended providing clear procedures for the administrative enforcement of such intersectional claims.

Response: OCR agrees that including this language is consistent with the changes we have made throughout the text regarding claims of discrimination involving multiple bases and accepts this proposal with a minor modification, so that the rule reads ''of any combination thereof.'' Further, OCR appreciates the recommendation for providing clear procedures for the administrative enforcement of intersectional claims. As stated in § 92.301, administrative complaints under section 1557 alleging multiple grounds of discrimination are now subject to a single administrative process.

Comment: Commenters on § 92.304(d) supported its prohibition on retaliation by the Department, noting that this provision shows a commitment to preventing discrimination at all levels and ensuring a path to rectifying grievances.

Response: OCR appreciates the support for this provision and, as stated in the preamble, we think it is important to include because individuals should not face retaliation for asserting their civil rights or raising concerns regarding discrimination being experienced by others.

Comment: Some commenters encouraged OCR to be as proactive as possible in enforcing the regulations with respect to the Department's programs.

Response: OCR appreciates the need for proactive enforcement and proactive technical assistance. We will continue working with the Department components in providing technical assistance and assisting them in helping to resolve compliance issues with section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the provisions as proposed in § 92.304, with modification. We are revising § 92.304(a) and (b) to read ''. . . discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof . . . ,'' consistent with edits made at §§ 92.101(a)(1), 92.207(a) and (b)(1) and (2), and 92.303(a). In addition, as noted above, for clarity, we are revising § 92.304(b) to parallel § 92.303 to now provide that the procedural provisions applicable to section 504 at 45 CFR 85.61 and 85.62 shall apply with respect to administrative enforcement actions against the Department, including Federally-facilitated Exchanges, concerning discrimination on the basis of race, color, national origin, sex, age, or disability under section 1557 or the part. Also, where the section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability'' shall apply in its place.

III. Change in Interpretation—Medicare Part B Funding Meets the Definition of Federal Financial Assistance; Responses to Public Comment

The Department's longstanding position has been that Medicare Part B (''Part B'') funding does not meet the definition of ''Federal financial assistance'' for the purpose of title VI, title IX, section 504, the Age Act, and section 1557. *See, e.g.,* 81 FR 31375, 31383 (May 18, 2016). In the 2022 NPRM, we proposed to change that position after evaluating the Part B program and the definition of ''Federal financial assistance'', such that Part B funds will be considered Federal financial assistance when received by providers and suppliers.

The Department sought comment on the impact that this change in position may have on recipients subsidized only by Part B funds that do not receive any other form of Federal financial assistance from the Department. We also invited comment on the amount of time that should be allowed for recipients of Part B funds to come into compliance with the applicable statutes and their implementing regulations. We also sought comment on what resources the Department can provide to assist newly covered entities in coming into compliance.

The comments and our responses regarding this change in interpretation are set forth below.

Comment: Some commenters objected to the proposal. These commenters claimed that interpreting Part B as meeting the definition of ''Federal financial assistance'' would reduce access to care because forcing these providers to implement new requirements will discourage them from participating in federally funded health care programs. Other commenters who opposed this interpretation stated that Part B does not meet the definition of ''Federal financial assistance'' because the program requires participants to pay monthly premiums based on income. In this way, commenters maintained, Part B is merely a private health insurance plan for individuals with low incomes, and is not equivalent to a Federal welfare program. A few commenters discussed that including Part B among the programs to which section 1557 applies is a radical change to what

qualifies as Federal financial assistance, and that such a change will affect other civil rights laws.

Response: The Department's change in interpretation regarding Part B does not alter, change, or expand the definition of ''Federal financial assistance.'' As stated in the 2022 NPRM, the Department is revising its position regarding whether Part B payments constitute Federal financial assistance under the longstanding definition of ''Federal financial assistance'' in regulations implementing section 1557 and the four statutes referenced in section 1557: title VI, title IX, section 504, and the Age Discrimination Act. 87 FR 47828. After evaluating the definition of ''Federal financial assistance,'' the Department has concluded that Part B funds meet that definition. While we disagree that this change in interpretation changes the definition of ''Federal financial assistance,'' we do note that this change means that Part B payments are considered Federal financial assistance with respect to title VI, title IX, section 504, and the Age Discrimination Act, in addition to section 1557.

Moreover, the Department disagrees that Part B is the equivalent of private health insurance and therefore is not Federal financial assistance. Part B confers a benefit or subsidy on the recipient—namely, financial assistance to the provider in exchange for providing health care services. As discussed in the 2022 NPRM, ''the government is assisting providers of services by making available to them a segment of the patient population that either (a) would not have been able to afford any medical services, or (b) would not have been able to afford these specific providers.'' 87 FR 47890. The Federal Government, through Part B, offers providers a reliable source of payment for services given to eligible patients who otherwise would go without care. Although Part B enrollees may pay premiums to receive coverage, the Federal Government covers half of the cost of Part B benefits. Thus, the fact that enrollees may pay for a portion of their coverage does not change the fact that providers receive Federal financial assistance through the program. In this way, Part B is no different than Medicare Part A, which also offers financial assistance to providers and which has long been considered Federal financial assistance. We note, however, that private health insurance may be subject to this rule when a health insurance issuer receives Federal financial assistance for such coverage. For instance, issuers may receive Federal financial assistance through receipt of advance payments of the premium tax credit or cost-sharing reductions for qualified health plans, which are private health insurance plans sold on the Exchanges. Further, when a recipient health insurance issuer is principally engaged in the provision or administration of health insurance coverage or other health-related coverage as set forth under the definition of ''health program or activity'' at § 92.4, all of the issuer's operations are covered, including its other private health insurance coverage, such as coverage sold off the Exchange.

OCR is also unpersuaded by the argument that the Department's change in interpretation will reduce access to care by leading to physician disenrollment from Medicare participation or decreased participation in other federally funded government programs. Indeed, we are unaware of any evidence that supports this concern and commenters did not provide any. As stated in the 2022 NPRM, many providers who receive payments through Part B are already subject to section 1557 and the four civil rights laws referenced in section 1557 through receipt of other Federal financial assistance. 87 FR 47890.

For the reasons provided in the NPRM and restated here, the Department respectfully disagrees with commenters and reiterates its position that funds provided via the current Part B program meet the longstanding definition of ''Federal financial assistance''.

Comment: An overwhelming number of commenters supported the change in interpretation, the result of which is that the Part B funds will be considered Federal financial assistance. Many groups commented that applying section 1557 to Part B will help address past discrimination. For example, commenters discussed that excluding Part B from a Federal financial assistance designation exempted individual providers from any obligation to comply with the Civil Rights Act of 1964. This exemption of the Part B program from title VI's nondiscrimination requirements allowed doctors in many states to continue providing segregated health care services. Commenters stated that failing to consider Part B payments as Federal financial assistance created confusion for patients about whether civil rights laws applied to their individual health providers—many of whom refused to serve individuals on the basis of their race or national origin because title VI did not apply to them. Therefore, commenters suggested that discriminatory history warrants the Department's reassessment of whether Part B payments meet the definition of ''Federal financial assistance''. They also note that this change will align Part B with other portions of the Medicare program and bring uniformity across all Medicare providers, increasing access to quality health care.

Other commenters explained that many of Part B providers already receive other forms of Federal financial assistance, such that this change in interpretation will not subject them to new obligations. Some commenters stated that all providers enrolled in the Part B program are recipients of Federal financial assistance—regardless of whether they are ''participating'' or ''non-participating'' providers—because even those designated as ''non-participating'' agree to provide Medicare-subsidized health services to Part B enrollees.

Many other supportive commenters noted that because funds received under Medicare Part A and Part B are fundamentally similar and Medicare Part A payments have long been considered Federal financial assistance, it is reasonable for the Department to similarly consider Part B payments as Federal financial assistance. Therefore, the commenters argue, considering Part B payments to be Federal financial assistance will allow individuals additional options for bringing discrimination claims against discriminatory conduct in all health care settings.

Response: OCR appreciates commenters' views on the Department's change in interpretation regarding whether Part B payments constitute Federal financial assistance as defined by our civil rights regulations. The Department agrees with commenters that because Part B payments, like those of Medicare Part A, are Federal funds directly or indirectly received by providers, they squarely meet the definition of ''Federal financial assistance''. This position provides uniformity across the Medicare programs and will not only help address patient confusion regarding the funding streams of their respective Medicare programs, but also ensures that the Department is applying the definition of ''Federal financial assistance'' consistently across all of our federally funded programs.

The Department agrees that because many recipients of Part B funds are already recipients of some other form of Federal financial assistance, this change will not impose excessive burdens on those covered entities. For those newly covered entities, however, we are providing a delayed applicability date as discussed below.

Comment: Many other commenters expressed the view that this change in position by the Department reflects the evolution of how the Part B program operates today. Commenters explained that while Part B once served as contracts of insurance for those who qualified, today, individual providers directly bill and receive payment from the Federal Government itself.

Response: The Department acknowledges commenters' point that the current manner in which the Part B program is administered is a factor in our changed view on whether Part B funds meet the definition of ''Federal financial assistance''. As the commenters noted, a majority (⅔) of providers enrolled in Part B bill and are paid directly by the Medicare program. 87 FR 47889. However, this is not solely determinative regarding the change in interpretation. As noted in the 2022 NPRM, under *Grove City College* v. *Bell,* 465 U.S. 555, 569 (1984), Federal funds are Federal financial assistance regardless of whether they are provided directly by the Federal Government to an entity or are provided initially to beneficiaries (*i.e.,* program participants) for the specified purpose of assisting with payment for services.

Comment: Several commenters stated that this change in position will increase equity in access to quality health care for individuals with LEP, immigrants, and communities of color, as these groups are more likely to participate in Part B. Other commenters expressed the view that this interpretation allows the Department to align Part B providers' nondiscrimination obligations to Medicare Part A, which will result in better care for individuals with disabilities and will eliminate confusion for older adults who cannot determine whether their Part B provider receives any other type of Federal financial assistance. Other commenters stated that this will offer significant relief for older patients, individuals with disabilities, and LGBTQI+ adults by providing the same protections and rights regardless of the nature of the Medicare provider or the service they are receiving. These patients will no longer have to determine whether they are eligible for both Medicare and Medicaid, or whether they have Medicare or Medicaid, in order to assess what nondiscrimination protections they are afforded. A few commenters expressed the view that this will be particularly helpful for enrollees who rely on small specialty providers for care, such as medical equipment suppliers, that receive only Part B and no other form of Federal financial assistance. Several other commenters also explained that because many Medicare providers also serve people with other forms of health coverage, including private insurance, this change will increase access to quality health care for underserved communities who face disproportionate discrimination and barriers.

Response: The Department appreciates these comments and generally agrees that bringing all Medicare programs in line with other Federal financial assistance programs will bring about better health outcomes and increase equity in access to care. This position is also supported by the similarities across the Medicare programs and eliminates an inconsistency in the application of the definition of ''Federal financial assistance'' that the Department has determined is no longer justifiable.

Comment: A few commenters suggested that the Department should have a delayed date for when the revised interpretation regarding Part B payments as Federal financial assistance becomes effective. Some suggested at least 180 days and up to 365 days for newly covered providers to reach compliance for those practices that have not been subject to these requirements in the past. Several commenters stated that newly covered entities will need sufficient time to implement appropriate procedures, such as having a one-year applicability date or a safe-harbor compliance window of at least 6 months. However, one commenter expressed that the Department should impose the same implementation timeline for all covered entities, given that, in their view, very few entities will be providers who are not already Federal financial assistance recipients. This commenter explained that additional time is not necessary because OCR is also providing entities with technical assistance to reach compliance.

Response: The Department appreciates commenters' concerns and has amended the applicability date to give newly covered recipients sufficient time to come into compliance with civil rights obligations, as described below in the ''Summary of Changes.'' As this new designation of Part B applies to all Federal financial assistance-based civil rights statutes enforced by the Department, to the extent covered entities require assistance, OCR will provide adequate support.

Notice of Interpretation and Dates

A. *Notice of interpretation.*

The Department is finalizing its interpretation that Medicare Part B (''Part B'') funding meets the definition of ''Federal financial assistance'' for the purpose of title VI, title IX, section 504, the Age Act, and section 1557.

B. *Effective date.*

This interpretation is effective upon its publication in the **Federal Register**.

C. *Applicability date.*

The Department recognizes that that there are some recipients that do not receive any Federal financial assistance other than Part B funds and that these recipients be newly required to comply with section 1557 and other Federal civil rights laws enforced by OCR. The Department acknowledges that these recipients will require time to come into compliance as a result of this change in position. Therefore, while this revised interpretation is effective upon publication in the **Federal Register**, it will have a one-year delayed applicability date. Thus, compliance by entities whose Federal program participation has been limited to Part B must be in compliance with title VI, title IX, section 504, the Age Act, and section 1557 no later than May 6, 2025. An Assurance of Compliance, as required by 45 CFR 92.5, must be filed with the Department by entities whose Federal program participation has been limited to Medicare Part B no later than May 6, 2025. This can be completed via OCR's Assurance of Compliance portal at *https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf*. Similarly, if such a recipient accepts a form of Federal financial assistance other than Part B prior to May 6, 2025, they will be required to complete an Assurance of Compliance at that time, consistent with section 1557 and the other Federal civil rights laws enforced by OCR.

IV. CMS Amendments

In the 2022 NPRM, the Department proposed clarifying CMS provisions that govern Medicaid and CHIP; PACE; health insurance issuers, including issuers providing EHB and issuers of qualified health plans (QHPs), and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; and agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees into Exchange coverage so that they again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. The Department sought comments on CMS' proposal to explicitly mention only gender identity and sexual orientation in its amendments, while understanding that

discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is also prohibited sex discrimination.

We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Comment: The majority of commenters on the proposed CMS amendments in the 2022 NPRM supported the proposal to explicitly identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited types of sex discrimination. However, many of the commenters noted that the language in the CMS amendments did not match the language explaining what constitutes sex discrimination in the proposed section 1557 implementing regulation (proposed 45 CFR 92.101(a)(2)). Commenters encouraged the agency to adopt the language in proposed § 92.101(a)(2). Specifically, those commenters suggested that the CMS amendments should revise the term ''sex'' to ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; transgender status; and sex stereotypes)'' rather than ''sex (including sexual orientation and gender identity)'' as proposed for the various CMS regulations. Commenters argued that adopting the language from § 92.101(a)(2) in the CMS amendments would avoid confusion and ensure consistency of implementation and enforcement among the nondiscrimination protections in the CMS amendments and section 1557. In many contexts, CMS program regulations are more visible to some providers, patients, patient advocates, and other stakeholders than section 1557 requirements and are more readily translated into institutional policy, training, and patient awareness. Commenters asserted that the Department having a consistent description of sex discrimination would improve consistency across Department regulations, further the health and safety of program beneficiaries, and protect them from discrimination in health care. One commenter emphasized that a statement in the 2022 NPRM that CMS understands that discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is prohibited sex discrimination, without the inclusion of such language in the regulatory text, provides inadequate notice to entities required to comply with the CMS amendments.

Response: The Department is finalizing the proposed amendments to the CMS regulations, with a revision to the description of sex discrimination to conform to the language in 45 CFR 92.101(a)(2). We appreciate that so many commenters made this suggestion and raised important issues concerning avoiding confusion, ensuring consistent implementation, and providing greater clarity for compliance and enforcement. In the Proposed Rule, CMS noted in the preamble that it understands that sex discrimination includes discrimination based on sex stereotypes, sex characteristics, including intersex traits, and pregnancy or related conditions, but limited the explicit mention in the regulatory text to gender identity and sexual orientation, sought comments. 87 FR 47891. The Department agrees with commenters that the amendments in the regulation should reflect CMS' intended interpretation of sex discrimination to avoid confusion for regulated entities and to better address the barriers to obtaining health care, including those faced by LGBTQI+ people, that CMS noted in the Proposed Rule. As there are entities that must comply with both CMS nondiscrimination provisions and section 1557, adopting identical language will ensure consistency across the policies and requirements applicable to entities subject to all of the provisions. As finalized, these CMS regulations provide that discrimination based on ''sex'' includes discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. The list in the regulation text is not an exhaustive one that outlines all the ways (or the only ways) that discrimination can be based on sex but, rather, it only identifies examples; CMS interprets these regulations accordingly. However, nothing in this rule impedes regulated entities from taking nondiscriminatory actions based on current medical standards and evidence, such as individualized and nondiscriminatory decisions based on current medical standards and evidence about the timing or type of protocols appropriate for care. The rule does not (and cannot) require a specific standard of care or course of treatment for any individual, minor or adult.

Summaries of regulatory changes are outlined below, along with responses to comments. In the following sections, for brevity, all references to ''sex discrimination'' or ''discrimination on the basis of sex'' mean ''discrimination based on sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity, including transgender status; and sex stereotypes).''

A. Medicaid and Children's Health Insurance Program (CHIP)

In 42 CFR 438.3(d)(4) and 438.206(c)(2) (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a)), we proposed to restore regulatory text to prohibit Medicaid and CHIP managed care plans, which include managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case managers, and primary care case management entities in managed care programs, from discriminating on the basis of sexual orientation and gender identity, and to require managed care plans to promote access and delivery of services in a culturally competent manner to all beneficiaries regardless of sexual orientation or gender identity. Such text was finalized as part of §§ 438.3(d) and 438.206(c)(2) in the Medicaid and CHIP managed care final rule published in the **Federal Register** on May 6, 2016 (2016 Medicaid and CHIP Rule), 81 FR 27498, but was removed as part of the Department's second section 1557 rulemaking (2020 Rule), 85 FR 37160, 37219–37220.

Similarly, in 42 CFR 440.262, for fee-for-service Medicaid programs, we proposed to restore regulatory text to require States to promote access and delivery of services in a culturally competent manner to all beneficiaries regardless of sex, including sexual orientation or gender identity. Again, the text was finalized as part of § 440.262 in the 2016 Medicaid and CHIP Rule but the references to sexual orientation and gender identity were removed by the 2020 Rule. We also proposed to change ''unique'' in 42 CFR 440.262 to ''individualized'' to more accurately reflect Medicaid's goal of providing person-centered care. Finally, we proposed to incorporate 42 CFR 440.262 into CHIP regulations through a cross-reference at 42 CFR 457.495(e),

ensuring alignment across fee-for-service Medicaid and CHIP programs.

The comments received on these proposals and our responses are set forth below.

Comment: We received many comments in support of the reinstatement of prohibitions against discrimination based on sexual orientation and gender identity in Medicaid and CHIP. Commenters stated that restoring the regulation text at 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (and therefore in §§ 457.1201(d) and 457.1230(a)) would promote access to care and the delivery of services in a culturally competent manner, strengthen the Department's commitment to increasing equity, and address discrimination in health programs and activities that can lead to disparate health outcomes.

Response: We appreciate the support for our proposals and believe finalizing revisions to these provisions will be an essential step in promoting culturally competent care that improves access, quality of care, and ultimately health outcomes.

Comment: One commenter that asked CMS to adopt the more detailed description of ''sex discrimination'' in proposed § 92.101(a)(2) pointed out that CMS program rules provide different compliance mechanisms—including prospective as well as complaint-based mechanisms—that complement section 1557's fundamental but essentially retrospective, complaint-based enforcement scheme.

Response: We appreciate the commenter raising this important perspective. There are prospective and retrospective compliance mechanisms reflected as State and managed care plan responsibilities in the Medicaid managed care regulations at 42 CFR part 438. Some provisions explicitly address requirements that must be included in managed care plan contracts and others stipulate State responsibilities. A provision that particularly reflects State responsibilities for proactively monitoring their managed care programs to ensure compliance with Federal regulations is 42 CFR 438.66, which requires States to have a monitoring system for all Medicaid managed care programs that addresses all aspects of the program including the performance of each managed care plan. This provision also requires States to use the data collected from their monitoring activities to improve their program's performance. This example of a prospective and retrospective activity requirement demonstrates how the Medicaid managed care regulations may help states and their managed care programs complement OCR's enforcement actions related to the prohibition of discrimination by providing for more timely monitoring and enforcement of discrimination prohibitions. Consistent regulation text about what sex discrimination means in this context—specifically, it includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes—will maximize the effect of these benefits.

In addition, we believe it is critical to ensure consistency in the application of nondiscrimination requirements between Medicaid managed care and fee-for-service programs. Under section 1902(a)(19) of the Social Security Act, states must provide for such safeguards as may be necessary to assure access to care and services in a manner consistent with simplicity of administration and the best interest of beneficiaries. A Medicaid fee-for-service regulation (at 42 CFR 440.262) clarifying the meaning of the term ''sex'' in this context, particularly when that regulation is consistent with 42 CFR 438.3(d)(4) and 438.206(c)(2) facilitates simplicity in administration of nondiscrimination requirements and ensures the best interests of the beneficiaries are met across Medicaid delivery systems for all Medicaid beneficiaries. As we noted in the NPRM, the best interest of beneficiaries is appropriately met when access to care and services are provided in a non-discriminatory manner. A consistent approach on this issue will help protect beneficiaries from discrimination, avoid confusion, and provide for simplicity in administration of State Medicaid programs. To this end, we believe the reference to ''sex'' at 42 CFR 440.262 should be consistent with 42 CFR 438.3(d)(4) and 438.206(c)(2).

For this reason and those stated above, we are finalizing the proposed amendments to 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 with revisions to make the discussions of ''sex'' in them consistent with 45 CFR 92.101(a)(2). In 42 CFR 438.3(d)(4) (and therefore § 457.1201(d)), we also are finalizing revisions to improve the readability of the provision by replacing some of the commas with semicolons and moving ''disability'' after ''national origin.'' We have also removed unnecessary parentheses in 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262.

Comment: One commenter asserted that the Department based the Proposed Rule on general provisions of the Social Security Act requiring that health assistance be provided in the ''best interest of beneficiaries'' (for Medicaid programs) and that the statute cited by the Department does not indicate Congressional intent related to prohibiting discrimination.

Response: The Department undertook this rulemaking to better align the section 1557 regulation with the statutory text of 42 U.S.C. 18116, to reflect recent developments in civil rights case law, and to better address issues of discrimination that contribute to negative health interactions and outcomes. We believe aligning the Medicaid and CHIP regulations in 42 CFR parts 438, 440, and 457, subpart L, with the section 1557 regulations is critical to fulfilling the Department's mission of pursuing health equity and protecting public health. Access to health care that is free from discrimination benefits all communities and people, and is also vital to addressing public health emergencies, such as the COVID–19 pandemic.

CMS possesses statutory authority under section 1902(a)(4) of the SSA (codified at 42 U.S.C. 1396a(a)(4)), which authorizes the Secretary to adopt methods of administration necessary for the proper and efficient operation of the Medicaid State plan; section 1902(a)(19) of the SSA (codified at 42 U.S.C. 1396a(a)(19)), which requires the Medicaid State plan to provide safeguards as necessary to assure that covered services are provided in a manner consistent with the best interests of the recipients; and section 2101(a) of the SSA (codified at 42 U.S.C. 1397aa(a)), which permits provision of funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low income children in an effective and efficient manner. CMS interprets section 1902(a)(19) of the SSA as prohibiting discrimination in the delivery of services because such discrimination is inconsistent with the best interests of the Medicaid beneficiaries who are eligible for and receive services. CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of sex because such prohibitions on discrimination are necessary for the proper and efficient operation of a State plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner. For these reasons, we disagree with the commenter and continue to assert that adopting protection against discrimination to address disparities and, ultimately, health outcomes is within the authority granted to CMS by the Act.

Comment: One commenter stated that the proposed regulation text would prohibit physicians or other health professionals from categorically declining to provide gender-affirming treatments due to their religious or moral beliefs guaranteed them under the First Amendment to the U.S. Constitution and could require them to provide services and treatment procedures related to gender-affirming care that they object to performing.

Response: These regulations do not require the provision of any specific services. These regulations are neutral, generally applicable, and do not violate the Free Exercise Clause of the First Amendment. These regulations do not target religiously motivated conduct, but rather, are intended to prohibit sex discrimination generally in order to improve health outcomes for the LGBTQI+ community and fulfill the statutory command of the ACA to prohibit discrimination and remove unreasonable barriers to care. As noted previously in this rule, conduct does not constitute a violation of this rule's prohibition on sex discrimination if there is a legitimate, nondiscriminatory reason for the action. Also, HHS will respect religious freedom and conscience protections in Federal law, particularly with regard to the provision of certain health-related services. For example, when enforcing its nondiscrimination regulations, HHS will comply with laws protecting the exercise of conscience and religion, including RFRA (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements. Nothing in the nondiscrimination protections at 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a) and CHIP fee-for-service through a new cross-reference at § 457.495(e)), displaces those protections. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, the Department will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements. Finally, we note that physician licensing and discipline are outside the scope of this rulemaking.

Summary of Regulatory Changes

After consideration of the public comments, we are finalizing 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a)) with revisions to specify that discrimination based on ''sex'' includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. Similarly, where these regulations require actions to be taken regardless of sex, that includes actions regardless of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. We are also finalizing the change of ''unique'' to ''individualized'' in 42 CFR 440.262 as proposed.

B. Programs of All-Inclusive Care for the Elderly (PACE)

In 42 CFR 460.98(b)(3), CMS proposed to add sexual orientation and gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. Additionally, in 42 CFR 460.112, we proposed to add gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. This PACE provision is applicable one year after the effective date of this final rule.

Comment: CMS received numerous comments supporting our changes to both provisions.

Response: CMS thanks the commenters for supporting these important changes that will serve to protect CMS' beneficiaries.

Comment: Several commenters did not support CMS' proposal to add sexual orientation and gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. Some commenters objected to the protections against discrimination on the basis of gender identity, in particular. Some commenters, believing that the proposal requires coverage of gender-affirming care, stated that the Department can adequately protect people from discrimination without mandating this coverage.

Response: This rule does not require entities to cover any particular procedure or treatment. We clarify that, in finalizing the prohibition against discrimination on the basis of sex, the Department is not mandating that PACE organizations include coverage for any particular item or service not already covered. Rather, amending these sections to clarify discrimination on the basis of sex as including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes will better ensure that all individuals are treated fairly in their access to health care. Without protection from such sex discrimination, transgender individuals may face barriers or be denied medically necessary services that are classified as covered under PACE and made available to other enrolled individuals. These amendments will better clarify nondiscrimination protections for all individuals, while also addressing existing disparities for LGBTQI+ individuals seeking health care. For the reasons discussed here and in the preamble to the Proposed Rule, CMS believes it is important to ensure all PACE participants are protected against unlawful discrimination of any kind, including discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. Therefore, we are finalizing these revisions.

Summary of Regulatory Changes

We are finalizing the regulatory language with modifications based on comments received. Specifically, we are revising the reference to sex to include additional detail explaining that the reference to ''sex'' includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity, including transgender status; and sex stereotypes.

C. Insurance Exchanges and Group and Individual Health Insurance Markets

In the HHS Notice of Benefit and Payment Parameters for 2023 Proposed Rule (2023 Payment Notice NPRM),[397] the Department proposed amendments to the regulations applicable to Exchanges, QHPs, and certain issuers to prohibit discrimination based on sexual orientation and gender identity. The amendments were similar to those proposed in the 2022 NPRM. Those proposed amendments were not finalized in the Notice of Benefit and Payment Parameters for 2023 final rule published on May 6, 2022,[398] because the Department determined that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in the 2022 NPRM to ensure consistency across the policies and requirements applicable to entities subject to both

[397] U.S. Dep't of Health & Hum. Servs. Ctrs. for Medicare & Medicaid Servs., Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 584 (January 5, 2022).

[398] U.S. Dep't of Health & Hum. Servs. Ctrs. for Medicare & Medicaid Servs., Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208 (May 6, 2022).

those amendments and section 1557. 87 FR 27208. The clarifications finalized in this section of the rule will apply on or after the effective date of this final rule (60 days after publication).

In finalizing amendments to the CMS regulations in this final rule, the Department considered comments received in response to the 2022 NPRM, as well as comments received to similar proposals in the 2023 Payment Notice NPRM (collectively, the ''Proposed Rules''). The Department is also responding to comments we received in response to the Proposed Rules in this final rule. In section C.1. of this preamble, the Department responds to comments applicable to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b). Section C.2. provides a summary of regulatory changes for 45 CFR 155.120(c), 155.220(j), 156.200(e), and 156.1230(b); there were no unique comments applicable to those sections. Comments that relate specifically to 45 CFR 147.104 are addressed in section C.3. of this preamble.

As stated in the 2022 NPRM, if any of the provisions at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) are held to be invalid or unenforceable by their terms, or as applied to any person or circumstance, such provision shall be considered severable from its respective section or such application shall be considered severable from any valid or enforceable applications of such provision (87 FR 47895). The determination that a provision is invalid or unenforceable shall not affect either the remainder of its section or any other sections, and the determination that a provision is invalid or unenforceable as applied to any particular person or circumstance shall not affect the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, the Department will comply with laws protecting the exercise of conscience and religion, including, to the extent applicable, section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb-4) and all other applicable legal requirements.

1. Comments and Responses to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)

The Department proposed to amend 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) by removing the term ''sex'' and revising the term to read ''sex (including sexual orientation and gender identity).'' However, after considering all the public comments submitted in response to the Proposed Rules, the Department is finalizing a revision to the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).'' This revision is necessary to ensure consistency across the policies and requirements applicable to entities subject to both those amendments and section 1557.

Comment: The majority of commenters to the proposal in the 2023 Payment Notice NPRM expressed broad support for the proposal and agreed that amending the CMS regulations is warranted in light of the well-documented discrimination that LGBTQI+ individuals face in seeking health care and insurance coverage.

Commenters supporting the proposal asserted that all Americans deserve access to affordable, high-quality health care, and that Federal policies and nondiscrimination protections must reinforce equity of care for all patients regardless of socioeconomic and sociodemographic characteristics and insurance coverage. Commenters urged the Department to finalize the proposed nondiscrimination protections in light of persisting trends of pervasive discrimination in insurance coverage. Commenters said that it is well documented that LGBTQI+ individuals continue to face discrimination in seeking health care, and that the nondiscrimination protections will help address barriers to health equity for LGBTQI+ individuals and aid providers in providing effective care.

Many commenters supporting the proposal referred to copious bodies of research, including research identified in the 2022 NPRM, that demonstrate the many ways in which the LGBTQI+ community faces discrimination when seeking health care, resulting in poorer health outcomes. 87 FR 47833–47835 (2022). Commenters asserted that issuers have contributed to this discrimination by employing transgender-specific exclusions to deny coverage for medically necessary treatment and that this was exacerbated by the removal of protections on the basis of sexual orientation and gender identity in the 2020 Rule. Many of these commenters also highlighted how individuals who identify as part of the LGBTQI+ community disproportionately face health disparities and are at higher risk for many conditions.

Response: We firmly believe that clarifying the scope of sex discrimination can lead to improved health outcomes for LGBTQI+ individuals [399] and that these protections are consistent with our broader aim of improving health equity. Finalizing the amendments to the nondiscrimination protections to explicitly prohibit discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes is warranted to help remedy health care discrimination and to better address barriers to health equity for LGBTQI+ individuals.[400] The revisions to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) will support the Department's objective of ensuring consistency against employing discriminatory marketing practices and benefit designs.

Comment: Many of the commenters that supported the proposal in the 2023 Payment Notice NPRM suggested ways in which the Department could further strengthen or clarify the breadth of the nondiscrimination protections, such as by expressly prohibiting discrimination on the basis of sex characteristics, including intersex traits.

Many commenters also recommended that the Department clarify that gender identity discrimination includes discrimination based on gender expression and transgender status. Such commenters stated that entities often perpetuate discrimination against transgender people because of their gender expression or belief that they are transgender rather than their gender identity itself, which is often private information. These commenters argued that the inclusion of ''gender identity'' alone in nondiscrimination protections leaves room for confusion or evasion of legal obligations.[401] Commenters

[399] Brian W. Ward et al., U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, *National Health Statistics Report: Sexual Orientation & Health Among U.S. Adults: National Health Interview Survey,* 2013 (2014), *https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdfhttps://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.*

[400] Thu T. Nguyen et al., *Trends for Reported Discrimination in Health Care in a National Sample of Older Adults with Chronic Conditions,* 33 J. Gen. Internal Med. 291–297 (2017), *https://doi.org/10.1007/s11606-017-4209-5.*

[401] *See* U.S. Dep't of Health & Hum. Servs., *FAQs About Affordable Care Act Implementation (Part XXVI),* 6, Q5 (May 11, 2015), *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.* Section 2713 of the PHS Act and its implementing regulations require non-grandfathered group health plans and health insurance issuers offering non-

emphasized that expressly incorporating transgender status into Department regulations would provide additional clarity, and would conform the regulation to contemporary protections against discrimination.

Response: We agree with commenters that discrimination on the basis of sexual orientation and gender identity may present itself as discrimination on the basis of gender expression and transgender status, which are inextricably linked with one's gender identity. We believe that gender expression and transgender status are sufficiently addressed by the inclusion of gender identity in the description of discrimination based on sex that is being finalized.

Comment: Many commenters supported the proposal as consistent with the overarching intent of the ACA to improve access to health coverage and prohibit discrimination in health care, asserting that the removal of protections on the basis of sexual orientation and gender identity in the 2020 Rule frustrates this purpose by creating barriers to comprehensive care. Many commenters affirmed that the Department has broad authority to regulate in this area under various sections of the ACA independent of section 1557. Specifically, commenters acknowledged that section 1321(a) of the ACA [402] gives the Department broad rulemaking authority to regulate Exchanges and QHPs; section 1312(c) [403] gives the Department authority to establish procedures for States to allow agents or brokers to enroll individuals and businesses in QHPs; section 1302(b)(4) [404] directs the Department, in defining EHB, to ''take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups''; section 1311(c)(1)(A) [405] directs the Department to establish criteria for QHPs to ensure that they will ''not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs''; and section 2792 of the PHS Act [406] provides the Department with broad authority to promulgate regulations that may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, including the guaranteed availability provisions in section 2702,[407] added to the PHS Act by the ACA.

Response: We agree with commenters that clarifying the scope of sex discrimination aligns with the ACA's goals of improving access to health insurance and removing unreasonable barriers to care. We reiterate that we are relying on authority from sections 1311(c)(1)(A), 1312(e), and 1321(a)(1)(A), (B), and (D) of the ACA, as well as sections 2702 and 2792 of the PHS Act, to support this change. 87 FR 584, 596.

Comment: Some commenters objected to the protections against discrimination on the basis of gender identity, in particular, or stated that the Proposed Rule arbitrarily requires coverage of interventions for individuals diagnosed with gender dysphoria, but not for individuals seeking such procedures for other clinically indicated mental health conditions. Some commenters asserted the proposal is arbitrary and capricious because it requires issuers to provide coverage for a ''one-size-fits-all'' treatment to gender dysphoria that is unsupported by evidence. Such commenters, believing that the proposal requires coverage of gender-affirming care, stated that the Department can adequately protect people from discrimination without mandating this coverage.

Response: One of the primary goals of the proposals to clarify the scope of sex discrimination is to address the pervasive health care discrimination faced by LGBTQI+ patients.[408] When medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same such treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex. These types of exclusions, and other types of sex discrimination, can have the effect of discouraging or preventing the enrollment of LGBTQI+ individuals in health insurance coverage.

Issuers generally have discretion in designing their benefits packages, and this rule does not require entities to cover any particular procedure or treatment. We clarify that, in finalizing the prohibition against discrimination on the basis of sex, the Department is not mandating that health insurance issuers include coverage for any particular item or service not already covered. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide coverage for the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

Amending these sections to specify discrimination on the basis of sex includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes will help better ensure that all individuals are treated fairly in their access to health care. Without protection from such sex discrimination, transgender individuals may face barriers or be denied medically necessary services that are classified as covered under their plan and made available to other enrolled individuals. Regulations at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) already prohibit discrimination on a variety of bases, including on the basis of race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions. Amending these sections to describe sex discrimination will better clarify nondiscrimination protections for all individuals, while also addressing existing disparities for LGBTQI+ individuals seeking health care.

Comment: Many commenters that objected to the proposed clarification suggested that coverage of gender-affirming care and any corresponding treatments are unsupported by clinical evidence, harmful to patients, and incongruent with the belief that gender is immutably defined by one's biological sex. For example, many commenters asserted that due to the lack of clinical evidence, CMS decided in 2016 not to issue a National Coverage Determination

grandfathered group or individual health insurance coverage to provide coverage for certain recommended preventive health services without imposing any cost-sharing requirements. Under this requirement, the plan or issuer must provide coverage, without cost sharing, for a recommended preventive service that is medically appropriate for the individual, as determined by the individual's attending provider, regardless of the individual's sex assigned at birth, gender identity, or recorded gender.

[402] 42 U.S.C. 18041(a).

[403] 42 U.S.C. 18032(c).

[404] 42 U.S.C. 18022(b)(4),

[405] 42 U.S.C. 13031(c)(1)(A).

[406] 42 U.S.C. 300gg–92

[407] 42 U.S.C. 300gg–1.

[408] U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Statistics, *Chapter 25: Lesbian, Gay, Bisexual, and Transgender Health, Healthy People* 2020 (2016), *https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C25-LGBT.pdf*; Hudaisa Hafeez et al., *Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review,* 9 Cureus e1184 (2017), *https://doi.org/10.7759/cureus.1184*; Karen I. Fredriksen-Goldsen et al., *Health Disparities Among Lesbian, Gay, and Bisexual Older Adults: Results From a Population-Based Study,* 103 a.m. J. Pub. Health 1802–1809 (2013), *https://doi.org/10.2105/AJPH.2012.301110*; Billy A. Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities,* 107 a.m. J. Pub. Health e13–e21 (2017), *https://doi.org/10.2105/AJPH.2016.303630.*

(NCD) [409] for coverage of gender-affirming surgery for Medicare beneficiaries with gender dysphoria. Many objecting commenters also claimed that studies that reach different conclusions (for example, any studies showing efficacy or safety of gender-affirming care) are flawed.

Response: We believe that commenters citing the 2016 Medicare NCD decision are incorrectly interpreting the decision. In its final Decision Memorandum on the issue, CMS notes that it declined to issue an NCD specifically on gender-affirming surgery because the clinical evidence is inconclusive, specifically as it relates to the Medicare population (that is, generally individuals 65 or older). CMS clarifies that the result of the decision is not a national coverage prohibition, but rather a continuation of the current policy that coverage decisions for gender-affirming surgery will continue to be made by local Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) plans on a case-by-case basis based on whether gender-affirming surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances.

Furthermore, the Medicare program did not analyze clinical evidence for counseling or hormone therapy treatments for gender dysphoria and was not making an NCD determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria. Therefore, not only is the population for which the NCD applies distinct, but so is the scope of the NCD decision itself.

Claims made by opposing commenters regarding assertions of patient harm resulting from gender-affirming care, purported lack of evidence demonstrating efficacy of such care, alleged differences between ''biological sex'' and gender, and hypothetical medical scenarios are not germane to the proposed regulatory text acknowledging that sex discrimination includes discrimination on the basis of sexual orientation or gender identity. While claims about medical evidence and specific treatments may be relevant in evaluating whether a particular action constitutes unlawful discrimination, or whether a particular item or service is medically necessary, such assertions do not speak to the decision to clarify the scope of sex discrimination in the first place. We also acknowledge that there is a robust consensus in the medical community that gender-affirming care is safe, effective, and medically necessary when clinically indicated for a particular individual.

The amendments made concurrent with the 2020 final rule to the nondiscrimination protections in 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) were based on an erroneous assertion that the plain statutory meaning of ''sex'' does not encompass sexual orientation and gender identity, which is unsupported by *Bostock.* In addition, the 2020 amendments were based on the incorrect assertion that the denial of basic health care on the basis of gender-identity is not a widespread problem in the United States.

Comment: One commenter asserted that the proposed change to the description of sex discrimination is arbitrary and capricious because the Department did not compute the costs of the impact of the rule against the purported benefits of the proposal.

Response: As we explained in the 2022 NPRM and based on our experience with States selecting a new EHB-benchmark plan pursuant to 45 CFR 156.111,[410] CMS believes there will be minimal costs incurred based on amending these sections to clarify sex discrimination. Because these sections previously prohibited discrimination on the basis of sexual orientation and gender identity, many entities already comply with the prohibition on discrimination, as amended under this final rule. 87 FR 47898. We do not anticipate amending these sections to describe sex discrimination would impose substantial administrative costs on any regulated entities that did not subsequently revise nondiscrimination policies based on the 2020 Rule.[411] On balance, we believe any costs are justified in light of the potentially significant benefits provided by protecting individuals from discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. We refer readers to our cost benefit analysis in the Regulatory Impact Analysis of this final rule for additional discussion on the minimal cost impacts to plans and issuers to include nondiscrimination protections. 87 FR 47898.

Comment: Some commenters objected to a perceived lack of clarity in the Proposed Rules. Such commenters noted that the Proposed Rules did not appropriately discuss the breadth of which markets would be covered by this proposal, questioning whether it would apply to large group plans, fully insured group health plans sponsored by employers, health insurance issuers and third party administrators of self-insured plans.

Response: The amendments we are finalizing to the nondiscrimination regulations at 45 CFR 147.104(e) apply to health insurance issuers offering non-grandfathered group or individual health insurance coverage, and their officials, employees, agents, and representatives. The nondiscrimination amendments we are finalizing at 45 CFR 155.120(c) apply to States and Exchanges carrying out Exchange requirements. The nondiscrimination amendments we are finalizing at 45 CFR 155.220(j) apply to agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through an FFE. The nondiscrimination amendments we are finalizing at 45 CFR 156.200(e) apply to QHPs in the individual and small-group markets. Section 156.125(b) requires issuers providing EHB to comply with the requirements of 45 CFR 156.200(e), thereby extending the application to non-grandfathered health insurance coverage in the individual and small group markets that provide EHBs.

[409] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (CAG–00446N) (Aug. 30, 2016), *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282.*

[410] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Information on Essential Health Benefits (EHB) Benchmark Plans Colorado 2023 EHB- Benchmark Plan Actuarial Report, https://www.cms.gov/marketplace/resources/data/essential-health-benefits.* Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04 percent of the total allowed claims assuming utilization would be for adults.

[411] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* (2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf*; Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care,* 373 New Eng. J. Med. 1089 (2015), *https://www.nejm.org/doi/pdf/10.1056/NEJMp1509230?articleTools=true*; Jody L. Herman, The Williams Inst., UCLA Sch. of Law, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers,* p. 2, (Sept. 2013), *http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf*; William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

Lastly, the nondiscrimination protections we are finalizing at 45 CFR 156.1230(b) apply to issuers using direct enrollment on an FFE.

Comment: Some commenters noted concerns about how the nondiscrimination protections would apply to health care providers.

Response: The amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) do not apply to health care providers.

Comment: One commenter asked the Department to provide clarity on the interaction between the section 1557 requirement and the 2023 Notice of Benefit and Payment Parameters final rule regarding non-discriminatory benefit design and EHB.

Response: While the requirements of section 1557 and the requirements imposed on EHB are separate requirements, we are finalizing regulatory language in this rule to make compliance easier for entities that are subject to both standards. As we stated in the 2023 Notice of Benefit and Payment Parameters final rule, CMS continues to make refinements to our EHB nondiscrimination policy and will address non-discriminatory benefit design as it relates to EHB in future rulemaking.

Comment: Commenters objecting to a more detailed understanding of sex discrimination raised several legal concerns. Commenters stated that the Department's reliance on *Bostock* v. *Clayton County,* 590 U.S. 644 (2020), is inappropriate, misinterprets *Bostock,* and misapplies the case to section 1557. One commenter asserted that the rule is arbitrary and capricious because it inappropriately applies the title VII framework to health care. Other commenters stated that the proposal is based on a faulty interpretation of title IX. Commenters also asserted that although reverting the nondiscrimination sections to pre-2020 language would allow LGBTQI+ individuals to receive ''medically necessary'' care, the 2020 rule enforces the plain text enacted by the ACA, which prohibited the discrimination on the basis of sex only.

Other commenters cautioned that absent clear congressional authorization, the Department is not justified in promoting the view that sex or gender can be different than the sex assigned to an individual at birth. Other commenters asserted that the rule is arbitrary and capricious because it ignores that a person's sex is determined by biology and does not sufficiently specify what it means by ''sex'' and how it relates to gender dysphoria treatments.

Response: We disagree that the proposal to include nondiscrimination protections is arbitrary and capricious. We are not relying on or applying the title VII framework to the nondiscrimination protections we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b), nor are we relying on other Federal civil rights laws for statutory authority. As stated in the Proposed Rule, 87 FR 596, we are relying on authority from sections 1311(c)(1)(A), 1312(e), and 1321(a)(1)(A), (B), and (D) of the ACA to support the amendments at 45 CFR 155.120, 155.220, 156.200, and 156.1230. We also rely on authority from sections 2702 and 2792 of the PHS Act to support the amendments to 45 CFR 147.104 and 156.125. Section 2792 of the PHS Act provides the HHS Secretary with broad rulemaking authority to issue regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, including the guaranteed availability provision in section 2702 of the PHS Act, implemented at 45 CFR 147.104, and the EHB requirements in section 2707(a) of the PHS Act, implemented at 45 CFR 147.150 and 156.125. 87 FR 584, 596. We made these proposals and are finalizing these provisions due in large part to the pervasive health and health care disparities faced by people who identify as part of the LGBTQI+ community.[412]

The aim of this final rule is to address the reality of many consumers in the health care sector and how discrimination on the basis of sex by entities regulated under 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) impairs the ability of consumers to access or pay for quality care. We believe these changes are necessary to address the role of discrimination in perpetuating the pervasive health and health care disparities faced by people who identify as part of the LGBTQI+ community.

We also disagree with commenters contesting that these nondiscrimination proposals inappropriately align with *Bostock.* In *Bostock,* the Supreme Court held that discrimination on the basis of sex under title VII of the Civil Rights Act of 1964 includes discrimination on the basis of sexual orientation and gender identity. Under *Bostock's* reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity and sexual orientation.[413]

Furthermore, the inclusion of ''sex stereotypes'' is consistent with the Supreme Court's holding in *Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 250–51 (1989). The inclusion of ''pregnancy or related conditions'' is consistent with the Department's longstanding interpretation of sex discrimination under Title IX.[414] As noted earlier in this preamble, the Department is finalizing these amendments to ensure consistency across the policies and requirements applicable to entities subject to health insurance market and Exchange requirements and those subject to section 1557. Amending CMS nondiscrimination protections to better specify the meaning of sex discrimination is imperative to advancing health equity and ensuring individuals are able to receive health care that is free from discrimination as envisioned under the ACA.

Comment: Many commenters to the 2023 Payment Notice NPRM expressed concerns that the proposal infringed on the First Amendment and would lead to violations of the religious conscience of providers, issuers, brokers, agents, and religiously affiliated hospitals. Some of these commenters objected to the inclusion of sexual orientation or gender identity within nondiscrimination protections altogether. Other commenters asserted that it is unclear how CMS would implement RFRA protections in the context of the nondiscrimination protections, and that this lack of clarity would increase the chance of litigation. A few commenters asked for the final rule to include an exemption for any stakeholders with religious objections (including issuers,

[412] U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Statistics, Chapter 25: *Lesbian, Gay, Bisexual, and Transgender Health,* Healthy People 2020 (2016), *https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C25-LGBT.pdf*; Hudaisa Hafeez et al., *Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review,* 9 Cureus e1184 (2017), *https://doi.org/10.7759/cureus.1184*; Karen I. Fredriksen-Goldsen et al., *Health Disparities Among Lesbian, Gay, and Bisexual Older Adults: Results From a Population-Based Study,* 103 a.m. J. Pub. Health 1802–1809 (2013), *https://doi.org/10.2105/AJPH.2012.301110*; Billy A. Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities,* 107 a.m. J. Pub. Health e13–e21 (2017), *https://doi.org/10.2105/AJPH.2016.303630.*

[413] *See, e.g., Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *cert. denied,* 141 S. Ct. 2878 (2021) (''Although *Bostock* interprets Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e–2(a)(1), it guides our evaluation of claims under Title IX''); E.O. 13988, 86 FR 7023 (2021).

[414] *See* 45 CFR 86.21(c)(2) and (3); 86.40(b)(1), (4), and (5); 86.51(b)(6); 86.57(b) through (d) (Title IX regulation); *see also Conley* v. *Northwest Fla. State Coll.,* 145 F. Supp. 3d 1073 (N.D. Fla. 2015).

plan sponsors, or individual purchasers) or to clarify whether there will be a process for such stakeholders to claim an exemption under RFRA outside of litigation. One commenter requested a process under which issuers or the insured can receive an up-front exemption when they have a religious or conscience-based objection to paying for plans that cover benefits to which they object as being experimental and harmful.

Other commenters believed that the proposal takes the right approach in relation to moral and religious objections.

Response: These regulations are neutral, generally applicable, and do not violate the Free Exercise Clause of the First Amendment. These regulations do not target religiously motivated conduct, but rather, are intended to prohibit sex discrimination generally in order to improve health outcomes and fulfill the statutory command of the ACA to prohibit discrimination and remove unreasonable barriers to care. Certain protections already exist in Federal law with respect to religious or moral beliefs, particularly regarding the provision of certain health-related services. For example, when enforcing its nondiscrimination regulations, HHS will comply with laws protecting the exercise of conscience and religion, including RFRA and all other applicable legal requirements. Nothing in the nondiscrimination protections at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) displaces those protections, and an application of this rule will not be required if it would violate Federal religious freedom and conscience laws.

Although some commenters urged CMS to incorporate a categorical religious exemption into this final rule, a blanket religious exemption is not supported by the underlying statutes. We will apply the protections in existing laws in resolving any conflicts between religious beliefs and these nondiscrimination protections. An entity that believes that compliance with any of these provisions would violate their rights under RFRA or the Free Exercise Clause of the First Amendment should contact CMS, which is responsible for evaluating RFRA-based requests for requirements in the programs it operates or oversees.[415] An entity that believes that compliance with any provision of this rule would violate their rights under the religious freedom and conscience laws enforced by HHS's Office for Civil Rights should file a complaint with OCR.

As with any HHS program, if an entity alleges that HHS's actions have substantially burdened its religious exercise, the Department will apply the test set out by RFRA.[416] The RFRA analysis evaluates whether the actions of the Federal Government have substantially burdened an entity's exercise of religion; if so, the question becomes whether the action furthers a compelling interest and is the least restrictive means to further that interest. RFRA provides that when application of a Federal Government rule or other law would substantially burden a person's exercise of religion, the government must afford that person an exemption to the rule unless it can demonstrate that applying the burden to that person furthers a compelling governmental interest and is the least restrictive means of doing so.[417] Accordingly, under RFRA, we would assess whether a particular application of these rules substantially burdened a stakeholder's exercise of religion and, if so, whether the government has a compelling interest in denying the stakeholder's exemption assurance request and whether there are less restrictive alternatives available.[418] The government's compelling interest in prohibiting discrimination on the basis of sex is to improve health outcomes, including for the LGBTQI+ community, and fulfill the statutory command of the ACA to prohibit discrimination. Whether this prohibition imposes a substantial burden on an entity's exercise of religion and whether it is the least restrictive means of advancing the government's interest will depend on specific facts and circumstances.

The amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) prohibit discrimination on the basis of sex in the conduct of health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers subject to EHB requirements; and QHP issuers.

Lastly, we again reiterate that the amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) do not require regulated entities to cover any particular service not already covered.

2. Health Insurance Exchanges

a. Non-Interference With Federal Law and Nondiscrimination Standards (45 CFR 155.120)

In 45 CFR 155.120 we proposed to amend paragraph (c)(1)(ii) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 155.120 in paragraph (c)(1)(ii) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

b. Federally-Facilitated Exchange Standards of Conduct (45 CFR 155.220)

In 45 CFR 155.220 we proposed to amend paragraph (j)(2)(i) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 155.220 in paragraph (j)(2)(i) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

c. Essential Health Benefits Package: Prohibition on Discrimination (45 CFR 156.125)

In 45 CFR 156.200 we proposed to amend § 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' Section 156.125(b) would accordingly require issuers providing EHB to comply with such nondiscrimination requirements as it requires that an issuer providing EHB must comply with the requirements of § 156.200(e). We did not receive comments unique to this section.

[415] U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Delegation of Authority, 86 FR 67067 (Nov. 24, 2021).

[416] See 86 FR 67067 (Nov. 24, 2021) (delegation of authority under which all HHS components are to ensure full compliance with RFRA and other constitutional requirements).

[417] 42 U.S.C. 2000bb–1(b).

[418] *Fulton* v. *City of Phila.,* 593 U.S. (2021) (''The question, then, is not whether the City [of Philadelphia] has a compelling interest in enforcing its non-discrimination policies generally, but whether it has such an interest in denying an exception to [Catholic Social Services].'').

Summary of Regulatory Changes

Elsewhere in this rule, we amend 45 CFR 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).'' Paragraph (b) of 45 CFR 156.125 accordingly requires issuers providing EHB to comply with such nondiscrimination requirements as it states that an issuer providing EHB must comply with the requirements of § 156.200(e).

d. QHP Issuer Participation Standards (45 CFR 156.200)

In 45 CFR 156.200 we proposed to amend paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

e. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (45 CFR 156.1230)

In 45 CFR 156.1230 we proposed to amend § 156.1230 in paragraph (b)(2) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 156.1230 in paragraph (b)(2) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

3. Prohibition of Discrimination—Group and Individual Health Insurance Markets Guaranteed Availability of Coverage (45 CFR 147.104)

In 45 CFR 147.104 we proposed to amend paragraph (e) by revising ''sex'' to ''sex (including sexual orientation and gender identity).''

The comments and our responses regarding this proposal are set forth below.

Comment: Some commenters requested that CMS clarify that States, including State Attorneys General, may enforce section 1557 to the fullest extent granted by law. That request was in response to CMS' explanation in the Proposed Rule that it was not relying on section 1557 as authority to amend 45 CFR 147.104 because states would not have authority to enforce section 1557 and CMS is of the view that partial reliance on section 1557 could unnecessarily complicate enforcement efforts. 87 FR 47898.

Response: In the Proposed Rule, CMS explained that one of the primary reasons CMS did not propose to rely on section 1557 authority to amend 45 CFR 147.104 was the manner in which § 147.104 is enforced. As discussed in the Proposed Rule, under PHS Act section 2723, States have primary enforcement authority over issuers with respect to regulations that implement title XXVII of the PHS Act, which includes § 147.104. CMS has a responsibility to enforce such regulations if CMS determines that a State is not substantially enforcing or the State notifies CMS that it has not enacted legislation to enforce or is not otherwise enforcing such regulations; otherwise, the State retains primary enforcement authority. Because section 1557 is not codified in title XXVII of the PHS Act, PHS Act section 2723 does not provide States with the authority to enforce section 1557. Therefore, CMS continues to be of the view that partial reliance on section 1557 authority could unnecessarily complicate enforcement efforts of § 147.104.

For this reason and because § 147.104 applies to issuers that may not receive Federal financial assistance such that they would be subject to section 1557, CMS relies on its authorities under sections 2702 and 2792 of the PHS Act when amending § 147.104. Notwithstanding the foregoing, the Department clarifies that although States do not enforce the administrative procedures specified in the section 1557 regulation itself, States may utilize their independent enforcement authorities to pursue violations of law, including applicable Federal laws, by entities within their jurisdictions.

Summary of Regulatory Changes

We amend 45 CFR 147.104 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

V. Executive Order 12866 and Related Executive Orders on Regulatory Review

A. Regulatory Impact Analysis

We have examined the impacts of the final rule under E.O. 12866, E.O. 14094, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and E.O. 13132 on Federalism. E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of E.O. 12866 (as amended by E.O. 14094) defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. This final rule is a significant regulatory action, under sec. 3(f)(1) of E.O. 12866 (as amended by E.O. 14094).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs of the final rule are small relative to the revenue of covered entities, including covered small entities, and because even the smallest affected entities would be unlikely to face a significant impact, we are certifying that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) generally

requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, or disability.[419]

E.O. 13132 on Federalism establishes certain requirements that an agency must meet when it promulgates a Proposed Rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. In considering the principles in and requirements of E.O. 13132, the Department has determined that the final rule would not significantly affect the rights, roles, and responsibilities of the States.

The Congressional Review Act (CRA) defines a ''major rule'' as any rule that the Administrator of OIRA of the Office of Management and Budget finds has resulted in or is likely to result in: (A) ''an annual effect on the economy of $100,000,000 or more''; (B) ''a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions''; or (C) ''significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). Based on the analysis of this final rule under E.O. 12866, this rule is expected qualify under 5 U.S.C. 804(2)(A). The Department will comply with the CRA's requirements to inform Congress.

The Background and Reasons for the final rulemaking sections at the beginning of this preamble contains a summary of this final rule and describes the reasons it is needed.

1. Public Comments

Comment: OCR received some comments discussing the cost of notices and taglines [420] in addition to requests that OCR work with the health care industry to develop future regulations. One commenter explained how the cost of including taglines averages up to $8.91 per month per covered entity and upwards of $2 million a year for the health insurance industry. Another health insurer commenter stated that they have spent over $16 million on notices and taglines since 2016 and estimated that they have spent over $3 million in 2022 alone. However, neither commenter provided data explaining the source or more detail on the cost estimates. Another commenter noted that the Proposed Rule does not adequately answer complaints received in prior 1557 rulemakings on the frequency and volume of materials related to the notice and tagline sections of the rule but did not provide any data with their comment.

Response: Based on costs estimated in this analysis, OCR derives a monthly cost of notices ranging from $21.28 to $26.60 per entity depending on the prevalence of electronic delivery. These cost estimates include the total notices of nondiscrimination and notices of availability of language assistance services and auxiliary aids and services (''Notices of Availability''); OCR therefore finds the commenter's estimate of $8.91 per month for Notices of Availability as plausible and consistent with the estimates in section 2 of the Regulatory Impact Analysis. OCR also notes that the cost estimates that are given are averages, and it is expected that there will be some entities that would have costs that are well above or below average. Furthermore, it is expected that large entities would have higher than average costs due to the increased number of notices they would send to individuals.

Comment: A few commenters expressed general concerns on the potential for an increase in premiums and costs within the health care industry. Commenters suggested the final rule would create a moral hazard for individuals or made general statements without data that increasing coverage of goods and services would increase costs and resulting premiums. Other commenters focused on the harm to small business the rule would cause from raising the insurance costs for low-income individuals that small businesses employ. Commenters argued this would lead to layoffs of said employees and limit what services would be available.

Response: As discussed in section 2 of the RIA, OCR expects that there is a possibility of increased premiums and costs due to the rule, but the possible increase is expected to be a small percentage of the current costs due to the low utilization of gender-affirming care and supply of specialists capable of offering said services. OCR does not expect the final rule to have a significant economic impact on small entities based on the analysis in the Regulatory Flexibility Act (RFA).

Comment: A couple of commenters were concerned that the rule would make it more difficult for small entities to compete and remain compliant, which would give a competitive advantage to larger entities in the industry and lead to more consolidation of supplier and provider markets.

Response: OCR appreciates the concerns raised by these commenters; however, as discussed in the RFA, OCR does not expect a significant impact of costs on a substantial number of small entities.

Comment: A few commenters claimed that the final rule would lead to lower innovation within the health care industry due to an increased need to spend funds fighting discrimination instead of medical research.

Response: As discussed in section 2 of the RIA, OCR estimates that additional costs from the inclusion of nondiscrimination requirements will be a small percentage of the total cost due to the limited number of individuals that would seek gender-affirming care, thereby limiting any potential decrease in available funds for medical research.

Comment: A few commenters expressed concern that the final rule would limit rural health care because it would make it more difficult for rural entities to stay compliant and would worsen their financial positions, potentially resulting in closures.

Response: As discussed in section 2 of the RIA, OCR estimates that the costs associated with the final rule would be a small percentage increase in overall costs. Furthermore, OCR reviewed relevant literature and found no studies which suggested that rural hospitals would be particularly impacted by expanded health care services. Finally, as discussed in the small entity analysis section of this RIA, OCR does not estimate a significant economic impact on a substantial number of small entities.

Comment: Several commenters expressed concern that the final rule would lead to fewer health care professionals in the industry for a

[419] 2 U.S.C. 1503(2).

[420] Commenters referred to ''taglines,'' which were required in the 2016 Rule at former § 92.8(d). This final rule does not require ''taglines'' but instead requires a notice of availability of language assistance services and auxiliary aids and services (referred to as ''Notice of Availability'') at § 92.11.

variety of reasons. Some of the commenters stated that the final rule would lead to health care professionals leaving the industry from the lack of conscience or religious exemptions. A couple of commenters stated that future health care professionals would not enter the industry in the future as the final rule would require them to violate the Hippocratic Oath or their religious beliefs.

Response: As discussed in section 2 of the RIA and preamble of the rule, the final rule includes a variety of protections for religious freedom and conscience rights, including a process whereby entities may rely on these protections and seek assurance of them from HHS. See § 92.302.

Comment: Several commenters noted that portions of the data that were used in the RIA, such as the number of covered entities and number of small entities, are outdated and need to be updated for an accurate cost estimate to be made.

Response: OCR agrees with commenters that data sources could be updated from the Proposed Rule. In this final rule RIA, the data for the number of covered entities, number of entities with more than 15 employees, the number of small entities, and hourly wages have been updated to the most recent data available.

Comment: A few commenters expressed concern that the final rule would cause irreparable harm to individuals who regret transitions.

Response: Commenters do not provide supporting evidence or data on the frequency or cost of potential irreparable harm. OCR disagrees with the commenters and did not find studies providing evidence or data on the frequency or cost of what the commenters characterize as irreparable harm, and therefore makes no changes to the final rule.

Comment: One commenter expressed concern that long-term costs associated with gender-affirming care are not accounted for within the RIA and that the studies used may not be accurate. Due to this, the commenter stated that the supplementary information provided is at best speculative.

Response: The main source for costs related to gender-affirming care come from a peer reviewed article in the New England Journal of Medicine, a well-respected medical journal. The cost associated with gender-affirming care is based on actual cost data from the Defense Manpower Data Center, which is part of the Department of Defense (DOD). As noted, the final rule does not mandate the provision of or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

Comment: One commenter stated that the costs of algorithmic discrimination have been quantified and asked OCR to include examples of the costs of such discrimination.

Response: OCR includes a specific provision on algorithmic discrimination in the final rule and qualitatively discusses the potential costs to individuals from discriminatory application of algorithms and other decision support tools in the benefits section.

2. Summary of Costs and Benefits

This analysis quantifies several categories of costs to covered entities and to the Department under the final rule. Specifically, we quantify costs associated with covered entities training employees, revising policies and procedures, and costs associated with notices, including the Notice of Nondiscrimination and Notice of Availability. We quantify costs associated with provisions of the final rule related to documenting training activities performed under the final rule. We also quantify incremental costs associated with coverage for gender-affirming care (which, as noted above, is not mandated by the rule). Our analysis also addresses uncertainty in costs associated with notices and gender-affirming care, which is discussed in greater detail in the notices section of subsection B of section 2 of the RIA. We separately report a full range of cost estimates of about $523 million to $1,302.3 million using a 7 percent discount rate, and a full range of cost estimates of about $511.4 million to $1,290.7 million using a 3 percent discount rate. All cost estimates are in 2022 dollars. We conclude that the final rule would result in annualized costs over a 5-year time horizon of $646.5 million or $637.1 million, corresponding to a 7 percent or a 3 percent discount rate respectively.

In addition to these quantified cost estimates, the main analysis includes a discussion of costs that we do not quantify, and a discussion of the potential benefits under the rule that we similarly do not quantify. In addition to the impacts that we quantify, this final rule could also result in increases in premiums, which would result in increases in Exchange user fees and Federal expenditures for advance payments of the premium tax credit. These increases would be minimal due to the low utilization of gender affirming care and the availability of the services.

TABLE 1—ANNUALIZED COSTS OF THE FINAL RULE

[$ millions/year (percent)]

Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (percent)	Period covered
$646.5	$523	$1,302.3	2022	7	2024–2028
$637.1	511.1	1,290.7	2022	3	2024–2028

a. Baseline Conditions

Section 1557 prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an executive agency or any entity established under title I of the ACA.[421] On May 18, 2016, the Department published a final rule to implement section 1557 under the statute5 U.S.C. 301. 81 FR 31375. On June 19, 2020, the Department published a final rule that revised the Department's approach to implementing section 1557. 85 FR 37160. As described in greater detail in the Background section of this preamble, neither final rule was fully implemented as published, and certain provisions of the 2020 Rule remain the subject of ongoing litigation.

[421] 42 U.S.C. 18116.

The baseline scenario of no further regulatory action is substantially informed by the RIAs published with the 2016 and 2020 Rules. The 2016 RIA identified five sources of monetized costs: training and familiarization, enforcement, notice publication, sex discrimination policy and procedure changes, and language access plans. The bulk of the monetary impacts identified in the 2016 RIA occur in the first two years under the 2016 rule, with costs continuing in future years only for enforcement and language access plans.

The 2020 RIA adopted many of the assumptions contained in the 2016 RIA. For example, it assumed that many of the initial activities anticipated under the 2016 Rule were performed, and that the first two years of costs attributable to the 2016 Rule were incurred.[422] The 2020 RIA identifies cost savings only ''from the repeal of (1) the provision on the incentive for covered entities to develop language access plans and (2) the provisions on notice and taglines.'' 85 FR 37224. The 2020 RIA also identifies costs in the first year ''on covered entities' voluntary actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this final rule.'' 85 FR 37224.

In establishing a baseline scenario, this analysis similarly maintains a number of assumptions and estimates contained in prior analyses. For example, the baseline scenario includes some ongoing costs that are attributable to the 2016 Rule, such as the costs of enforcement. The 2016 RIA estimated that the costs of enforcement would be $108.8 million (reported in 2022 dollars), which we adopt as the costs under both the baseline and final rule scenarios. Similarly, we adopt the assumption in the 2020 RIA that covered entities continue to provide ongoing training attributable to the 2016 Rule, which was not impacted by the 2020 Rule. We include these ongoing training activities, including annual refresher training for returning employees and training for new employees, in the baseline scenario of no regulatory action.

The final rule analysis updates baseline conditions on the number of covered entities. The 2016 Rule, 2020 Rule, and 2022 NPRM all used 275,002 covered entities, and 41,250 covered entities that have 15 or more employees. This final rule updates the covered entities to 266,297 and the number of covered entities with 15 or more employees to 63,950. Table 2 presents the updated data on covered entities. To update this data, we identified the source of the original data being the 2012 Statistics of U.S. Businesses (SUSB) Annual Data Tables by Establishment Industry and found the 2020 version of the same dataset. Using the same NAICS codes from the Proposed Rule we identify the number of entities under these NAICS codes in addition to the number of firms with 15 or more employees.

TABLE 2—COVERED ENTITIES

NAICS code	Business type	Firm count 2020	Firms with 15 or more employees
62142	Outpatient mental health and substance abuse centers.	7,649	2,911
621491	HMO medical centers	84	21
621492	Kidney dialysis centers	449	216
621493	Freestanding ambulatory surgical and emergency centers.	4,554	2,204
621498	All other outpatient care centers	6,307	2,766
6215	Medical and diagnostic laboratories	7,200	1,892
6216	Home health care services	25,718	10,901
6219	All other ambulatory health care services	7,091	2,589
62321	Residential intellectual and developmental disability facilities.	6,674	3,628
6221	General medical and surgical hospitals	2,445	2,344
6222	Psychiatric and substance abuse hospitals	434	414
6223	Specialty (except psychiatric and substance abuse) hospitals.	301	280
6231	Nursing care facilities (skilled nursing facilities).	9,824	7,513
45611	Pharmacies and drug stores	19,346	3,436
6211	Offices of physicians	167,294	22,494
524114	Insurance Issuers	869	341
	Navigator grantees	58	
	Total Entities	266,297	63,950

In the next section, we discuss the incremental costs of the final rule, which exclude ongoing costs attributable to prior rulemaking.

b. Costs of the Final Rule

This analysis anticipates that the final rule would result in one-time costs to covered entities to process assurance of exemption requests and revise policies and procedures. The final rule would result in costs associated with a revised approach to notices, including the Notice of Nondiscrimination and Notice of Availability, costs to review new decision support tool requirements, and costs to training employees. The final rule would also result in costs associated with provisions related to documenting training activities performed under the final rule.

The final rule might result in additional costs associated with coverage for gender-affirming care. We discuss the potential costs associated with gender-affirming care coverage and the potential that some or all of these costs would be offset by reductions in spending on other types of care. We

[422] *E.g.,* 85 FR 37235 (''The Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs attributable to the 2016 Rule cannot be recovered.'').

reiterate that the final rule does not mandate the provision of or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

The analysis also discusses other potential costs of the final rule that we do not quantify.

Training

The Department anticipates that some covered entities would incur costs to train or retrain employees under the final rule. To calculate the costs related to training, we followed an approach common to both the 2016 and 2020 RIAs. Both analyses estimate that covered entities would train their employees on the requirements. This final rule uses the updated estimate of covered entities (266,297) as the basis for calculating the total costs. The 2020 RIA adjusted the number of covered entities downward by 50 percent, anticipating that some covered entities would not modify their procedures in response to the 2020 final rule, and would therefore not need to offer new training. Both RIAs anticipated that employers would most likely train employees who interact with the public and recognized that the percentage of employees that interact with patients and the public vary by covered entity. To account for this, the analyses adopted a central estimate of 50 percent of staff at covered entities that received one-time training on the requirements of the regulation.

Both RIAs reported the number of employees at covered entities by occupation category. To monetize the total costs of training, the RIAs adopted a value of time based on the average fully loaded wage rate for each occupation, combined with an assumption about the duration of the training. The 2016 RIA assumed that 50 percent of total employees at covered entities would receive training, while the 2020 RIA assumed that 25 percent of employees would receive training. Both RIAs assumed the typical training would last one (1) hour. For this analysis, we assume that 75 percent of total employees at covered entities would receive training, and that this training would last one (1) hour. This estimate is consistent with an assumption that all covered entities would revise their policies and procedures under the final rule and that most employees at covered entities would receive training.

As a necessary first step in calculating the incremental total costs of training attributable to the final rule, we have collected the most recent available data on the number of employees that would likely undergo training under the final rule, and data on the average wage rate by occupation for these employees.

The first category of health care staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The U.S. Bureau of Labor Statistics (BLS) Occupational code for this grouping is 29–1000, and the 2022 reported employment count for this occupational group is approximately 5.96 million, with average loaded wages of $114.42 per hour at the national level.[423]

The second category of health care staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 2.95 million employed individuals with average loaded wages of $51.18 per hour at the national level.[424] Technicians work in almost every area of health care: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), which includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staff (non-degreed, medical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates often required for degreed technical staff. There are approximately 6.79 million employed individuals in these occupations in the health care and social assistance sector, with average loaded wages of $34.20 per hour at the national level.[425]

The fourth category of health care staff that the Department assumes will receive training is health care managers (Occupation code 11–9111) and accounts for approximately 0.48 million employed individuals with average loaded wages of $123.06 per hour at the national level.[426]

The fifth category of health care staff that the Department assumes will receive training is office and administrative assistants (Occupation code 43–0000) and accounts for approximately 2.719 million employed individuals with average loaded wages of $41.16 per hour within the Health Care and Social Assistance sector.[427] These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. The Department assumes that outreach workers are included in the five categories listed above.

The Department estimates that there are a total 18.9 million employees at covered entities, of which we assume 14.2 million, 75 percent, would receive training attributable to the final rule. Across the five occupation categories, we estimate a weighted hourly wage rate of $32.70, or a weighted fully loaded hourly wage rate of $65.41. Assuming that the average training takes one (1) hour and adopting a value of time based on fully loaded wage rates, we estimate total first-year training costs for all covered entities to be approximately $927.3 million [428] As a sensitivity analysis, we considered the scenario of covered entities providing training to all employees, 18.9 million, not just employees who interact with the public, 14.2 million. Under this scenario, the total cost of training would increase to about $1.2 billion. These costs are likely overstated since this training may supplement or replace expected annual or other ongoing training activities at covered entities. To the extent that covered entities reduce time spent on other training activities, these costs would offset some of the total costs attributable to the final rule.

Lastly, the Department assumes that 91 investigators at OCR, who are equivalent to GS–12 Step 1 employees

[423] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.* The average loaded wage for Healthcare Diagnosing or Treating Practitioners is derived by multiplying the mean hourly rate by 200 percent to include the mean hourly wage, the cost of fringe benefits and overhead costs ($57.21 * 200% = $114.42).

[424] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[425] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[426] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[427] U.S. Bureau of Labor Statistics, *National Industry-Specific Occupational Employment and Wage Estimates, Sector 62- Health Care and Social Assistance, https://www.bls.gov/oes/current/naics2_62.htm#43-0000.*

[428] Numbers may not multiply due to rounding.

and whose average hourly loaded wage is $65.46, will receive a one-time training during the first year of the promulgation of this rule.[429] Each individual would receive 8 hours of training for a total of $47,655 (91 x 1 x $65.46) in training costs. This training would not occur in any subsequent years.

In addition to the first-year training costs, we anticipate that the final rule would result in additional costs associated with ongoing training, including annual refresher training for returning employees and training for new employees. As discussed in the Baseline Conditions section, we assume that many covered entities are routinely carrying out these activities, absent further regulatory action. However, we anticipate that the final rule would result in a larger share of employees at covered entities receiving such training. To quantify the change in training activities between the baseline scenario and the final rule scenario, we take the difference between the share of employees receiving training under the baseline scenario and the final rule scenario. We carry through an assumption from the 2016 RIA, which assumed that 50 percent of total employees at covered entities receive training and compare this to an assumption in this final RIA that 75 percent of total employees at covered entities would receive training. This yields an estimate of 25 percent of total employees at covered entities that would receive training in subsequent years under the final rule. We adopt the same weighted hourly wage estimate, number of employees, and estimate the total ongoing annual training costs as $309.1 million. This was calculated by multiplying the total number of employees at covered entities by .25 and multiplying by $65.41.

Finally, the Department assumes covered entities may require employees to undergo one (1) hour of training in response to in OCR investigation. As it is difficult to determine the type of employee that would be required go through additional training, we use the average loaded hourly wage of $65.41 to evaluate the opportunity cost of training time. To estimate the frequency with which covered entities may assume this cost, we reviewed OCR complaints from the 2023 calendar year and identified 60 cases investigated under section 1557 that were closed with a covered entity either engaging in voluntary corrective action in response to the investigation or entering into a Voluntary Resolution Agreement with the agency.[430] Using this as a baseline, the Department assumes that for every year of the observation period there would be 60 potential instances of this additional training, and that it would be conducted in each case. As a result, we estimate that covered entities would incur $3,924 in additional training costs for every year of the observation period.[431]

Revising Policies and Procedures

As discussed above in the previous section, the Department anticipates that all covered entities, or approximately 266,297 entities, would revise their policies and procedures under the final rule, with approximately half of these entities requiring less extensive revisions. For covered entities with more extensive revisions, we adopt the estimates contained in the 2020 RIA, with four (4) total hours spent on revisions per entity. Of these, three (3) would be spent by a mid-level manager equivalent to a first-line supervisor (Occupation code 43–1011), at a cost of $62.98 ($31.49 × 2) per hour after adjusting for the cost of fringe benefits and other indirect costs, while an average of one (1) hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $118.14 ($59.07 × 2) per hour at the national level, including the cost of fringe benefits and other indirect costs.[432] For covered entities with less extensive revisions, we assume two (2) total hours spent on revisions per entity. Of these, one (1) would be spent by a mid-level manager, and one (1) would be spent by executive staff.

We monetize the time spent on revising policies and procedures by estimating a total cost per entity of $307.08 or $181.12, depending on the extent of the revisions. For the 133,149 covered entities with more extensive revisions, we estimate a total cost of about $40.8 million. For the 133,149 covered entities with less extensive revisions, we estimate a total cost of about $24.1 million. We estimate the total cost associated with revisions to policies and procedures under the final rule of $65.0 million.

The above estimates of time and number of entities that would choose to revise their policies under the regulation are approximate estimates based on general BLS data. We are unable to precisely estimate the total number of covered entities that would choose to revise their policies and procedures under the new regulation or to what extent they would make these changes due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices.

In addition to the initial revisions of policies and procedures, the Department assumes some covered entities may elect or be required to revise their policies and procedures following an investigation. We assume that such revisions would cost the same as the original revision that occurs in the first year of the observation period. As discussed above, the Department estimates that during every year of the observation period, there would be an average of 60 instances in which corrective actions may be taken due to a 1557 investigation. As revising policies and procedures is a more significant corrective action compared to corrective training, the Department assumes that it will occur in response to only half of the investigations. The Department continues to use the assumption that half of the entities revising their policies and procedures would be major firms while the other half would be minor firms. The estimated total annual cost for revisions of policies and procedures in response to an OCR investigation is $7,323 ($307.08 × 15 + 181.12 × 15) in each year of the observation period.

Notices

The final rule requires the 266,297 covered entities to provide a Notice of Nondiscrimination to participants, enrollees, and beneficiaries, hereafter referred to as beneficiaries of its health program or activity, and members of the public. It also requires covered entities to provide a Notice of Availability. These provisions resemble elements of the 2016 Rule that were repealed in the 2020 Rule; however, the approach under the final rule provides a narrower set of situations where covered entities would be required to provide these notices. Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the covered entity's health program or activity website; and (4) in clear and prominent physical locations where the health program or activity interacts with the public.

[429] U.S. Off. of Personnel Mgmt., *Salary Table 2022–GS. GS–12 Step 1 Employee, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/GS_h.pdf/.*

[430] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Complaints Closed During Calendar Year 2023 within the Section 1557 Program Area.*

[431] $3,924 = ($65.41 × 1 × 60).

[432] U.S. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2022, 43–1011 First-Line Supervisors of Office and Administrative Support Workers, https://www.bls.gov/oes/current/oes431011.htm.*

The Notice of Availability is also required in the following electronic and written communications related to the covered entity's health programs and activities: (1) notice of nondiscrimination required by final § 92.10; (2) notice of privacy practices required by 45 CFR 164.520; (3) application and intake forms; (4) notices of denial or termination of benefits or services, including Explanations of Benefits (EOBs) and notices of appeal and grievance rights; (5) communications related to an individual's rights, eligibility benefits, or services that require or request a response from a beneficiary; (6) communications related to a public health emergency; (7) consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together); (8) discharge papers; (9) communications related to the cost and payment of care with respect to an individual, including good faith estimates and medical billing and collections materials; (10) complaint forms; and (11) patient and member handbooks.

For the purposes of the Notice of Availability analysis, we base our estimates of the number of communications containing these notices on a subset of the communications identified in the 2020 RIA. We include communications that are EOBs. The Department received feedback regarding the financial burden imposed by applying the Notice of Availability requirements to EOBs. EOBs are typically an individual's first, and often only, notice of a denial or termination of benefits or services, and as such, the Notice of Availability requirement is essential in this context to ensure timely and equitable access to appeals processes. The final rule at § 92.11(d) permits covered entities to provide individuals with the option to opt out of receiving the Notice of Availability on an annual basis, which will reduce the cost and burden associated with these requirements. In addition, as beneficiaries increasingly elect to receive EOBs and other types of communications electronically, we expect the cost of these requirements to decrease over time. We adopt the other estimates as a reasonable proxy for the number of communications that would be anticipated under the final rule. These estimates are intended to encompass all categories of Notices of Availability required under the final rule. We have increased the total number of communications containing notices by 10 percent to account for the additional communications related to the cost and payment of care with respect to an individual, including good faith estimates and medical billing and collections materials, which were not included in the Proposed Rule.[433]

Table 3 below reports the number of communications containing notices anticipated under the final rule and presents the costs of these communications. Our cost estimates reflect a wide range of uncertainty in the cost per communication. For our primary scenario, we adopt a central estimate of the average costs to print and fold paper forms containing prescribing information of $0.05 (calculated as the midpoint estimate of a range from $0.03 to $0.07), reported in 2010 dollars.[434] We explore the sensitivity of the overall cost estimates under a low-cost ($0.035 per unit) and high-cost ($0.32 per unit) scenario, reported in 2018 dollars, which matches the range contained in the 2020 RIA. We adjust these per-unit cost inputs for inflation to 2022 price levels using the Implicit Price Deflator, resulting in a primary per-unit cost estimate of about $0.067 and a full range of about $0.045 to $0.37.[435] Combining these per-unit cost estimates with the count of each notice results in a primary estimate of $93.2 million, with a range of estimates between $57.2 million and $522.8 million. Following the approach in the 2020 RIA, we adjust this figure downward by 50 percent to account for the lower cost of electronic communications. For this adjustment, we adopt a measure of the share of respondents reporting that they used a ''Digital (mobile app or website)'' method to contact or interact with their health insurance issuer or plan in the last year when viewing an online statement.[436] We anticipate that the share of communications occurring online will increase over time but have not accounted for a trend for the 5-year time horizon of this analysis. This adjustment results in a primary estimate of the adjusted annual total of $46.6 million, with a range of costs between $28.6 million and $261.4 million. These costs would occur in each year of the time horizon of the analysis.

TABLE 3—COST OF NOTICE PROVISIONS

[2022 Dollars]

Cost element	Count (millions)	Cost scenario ($ millions)		
		Low	Primary	High
Eligibility and enrollment communications	19.5	$0.8	$1.3	$7.2
Annual notice of benefits	135.3	5.5	8.9	49.9
Explanations of benefits—hospital admissions	105.6	4.3	6.9	39.0
Explanations of benefits—physician visits	1035.1	41.8	68.1	382.0
Medical bills—hospital admissions	12.1	0.5	0.8	4.5
Medical bills—physician visits	108.9	4.4	7.2	40.2
Total, Unadjusted	1416.5	57.2	93.2	522.8
Total, Adjusted for Electronic Delivery	1133.2	28.6	46.6	261.4

[433] This reflects the increase from 10 categories accounted for by communications and notices in the Proposed Rule RIA to 11 categories, or an increase of 10 percent.

[434] U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Electronic Distribution of Prescribing Information for Human Prescriptions Drugs, Including Biological Products,* Proposed Rule, 79 FR 75506 (Dec. 18, 2014).

[435] Fed. Reserve Bank of St. Louis, *Gross Domestic Product: Implicit Price Deflator* (GFPDEF), *https://fred.stlouisfed.org/series/GDPDEF.*

[436] Saurabh Gupta et al., *HFS Rsch. & Cognizant, Health Consumers Want Digital: It's Time for Health Plans to Deliver,* p. 4 (2021), *https://www.cognizant.com/en_us/general/documents/cognizant-hfs-health-consumers-want-digital-its-time-for-health-plans-to-deliver.pdf.*

Documentation Requirements

The final rule requires covered entities to contemporaneously document certain other activities performed under the final rule. This includes activities such as employees' completion of the training required by this section in written or electronic form. The final rule also requires covered entities to retain certain records. These and other requirements, and the associated cost estimates, are discussed in greater detail in the PRA section.

The costs associated with retaining records related to grievances filed with a covered entity is the time spent by the staff of covered entities to store the complaints for no less than three (3) years. We calculate the costs of labor as one (1) employee per covered entity with more than 15 employees (63,950) spending 10 hours to store complaints and the associated records required under final § 92.8(c)(2) each year.[437] We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $19.02 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of retaining records related to grievances filed at all covered entities would be $24.3 million annually ($19.02 × 2 × 10 × 63,950). This estimation approach will overstate the costs if many covered entities already retain complaint information.

The costs associated with documenting employee training is the time spent by the staff of covered entities to (a) create training attendance forms, and (b) store the training sign-up sheet. We calculate the costs of labor as one (1) employee spending 15 minutes (0.25 hours) to create the sign-up sheet during the first year and one (1) employee spending one (1) hour collecting and storing the attendance forms the first year and subsequent years. We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $19.02 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of documenting employee training would be $12.6 million in the first year ($19.02 × 2 × 1.25 × 266,297) and $10.1 million in subsequent years ($19.02 × 2 × 1 × 266,297).

Coverage for Gender-Affirming Care

In addition to the cost some covered health insurance issuers and plans may incur for revising policies and procedures to comply with the rule, there is a possibility that such issuers and plans may incur a de minimis cost related to the cost of coverage for gender-affirming care. Various studies, however, suggest that any such increased costs will likely be negligible, and that any increases may be offset by savings from decreased utilization of other services. The likelihood of significant costs is low both because transgender individuals make up a very small percentage of the population and because many transgender individuals do not seek gender-affirming surgeries or other types of care.[438]

In April 2012, the California Department of Insurance conducted an Economic Impact Assessment on Gender Nondiscrimination in Health Insurance that found that prohibiting discrimination on the basis of gender identity in health insurance plans would have an ''insignificant and immaterial'' impact on costs.[439] This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022 percent and 0.0173 percent.[440] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-affirming health care differs according to the needs and pre-existing conditions of each individual.[441] Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.[442] The Assessment notes the experience of one employer that initially established premium surcharges to cover the anticipated cost of gender-affirming care, reporting that the employer subsequently eliminated the surcharges because they found that the funds collected were nearly 15 times the amount expended on care.[443] While it did not analyze any original data, a 2018 analysis by the State of Wisconsin's Department of Employee Trust Funds cited numerous studies finding that the cost of coverage was minimal, and noted that ''[w]hile it is challenging to predict the costs of care averted for any condition, there is some evidence that the costs associated with providing transgender-inclusive plans is met with reduced costs related to comorbidities.'' [444] Other studies looking at both public and private sector plans have reached similar conclusions. One study published in the New England Journal of Medicine projected that the cost for providing gender-affirming care benefits to members of the military would result in an annual increase of 0.012 percent of health care costs, ''little more than a rounding error in the military's $47.8 billion annual health care budget.'' [445] A 2013 study of 34 public and private sector employers that provided nondiscriminatory health care coverage found that providing coverage of gender-affirming care had ''zero to very low costs.'' [446] An

[437] This estimate is consistent with the 2016 Rule's Regulatory Impact Analysis: ''Of the 275,002 covered entities, approximately 15 percent employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official.'' 81 FR 31375, 31452 (May 18, 2016).

[438] *See, e.g.,* U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Colorado 2023 EHB-Benchmark Plan Actuarial Report, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.* Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04 percent of the total allowed claims assuming utilization would be for adults.

[439] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 1 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[440] *Id.* at p. 3. More recent estimates indicate that a higher share of the population in the United States identifies as transgender (0.6 percent of the U.S. adult population). Andrew R. Flores et al., The Williams Inst., UCLA Sch. of Law, *Race and Ethnicity of Adults Who Identify as Transgender in the United States,* p. 2 (2016), *https://williamsinstitute.law.ucla.edu/wp-content/uploads/Race-Ethnicity-Trans-Adults-US-Oct-2016.pdf.*

[441] State of Cal., Dep't of Ins., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 8 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[442] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 9 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[443] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 6–7 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[444] Wis., Dep't of Employee Trust Funds, *Correspondence Memorandum Re: Transgender Services Coverage,* pp. 6–8 (Aug. 14, 2018), *https://etf.wi.gov/boards/groupinsurance/2018/08/22/item6a1/download?inline=.*

[445] Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care,* 373 New Eng. J. Med. 1089 (2015), *https://www.nejm.org/doi/pdf/10.1056/NEJMp1509230?articleTools=true.*

[446] Jody Herman, The Williams Inst., UCLA Sch. of Law, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers,* p. 2 (Sept. 2013), *http://*

additional study comparing costs and potential savings associated with covering gender-transition-related care concluded that ''additional expenses hold good value for reducing the risk of negative endpoints—HIV, depression, suicidality, and drug abuse'' and noted that ''provider coverage was cost-effective in 85 percent of simulations.'' [447] More recently, a 2021 survey of employers conducted by the Human Rights Campaign noted that most employers who covered gender-affirming care reported only ''marginal increases'' in cost, on the order of ''a fraction of a decimal point of cost calculations.'' [448]

In recent years, some legal challenges to coverage exclusions have also considered issues of cost and concluded that covering gender-affirming care does not significantly increase costs for plans. In discussing the parties' experts on the issue of the cost, one court noted that, ''[f]rom an actuarial perspective, there appears to be no dispute that the cost of coverage is immaterial.'' [449] Another court reviewing expert testimony called any cost savings from excluding coverage for gender-affirming care ''both practically and actuarially immaterial.'' [450]

Based on the studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment would have a small impact on the overall cost of care and on health insurance premiums in terms of the percentage of overall spending. We reiterate that the final rule does not mandate the provision or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule. The utilization rate of covered services, whatever those services may be, is likely to be extremely low because transgender individuals represent a small minority in the general population and because not all transgender individuals will seek medical care in the course of their transition.[451]

As described in this section, the costs associated with gender-affirming care are likely to be small on a percentage basis of total health care costs; however, when these estimates are combined with measures of overall health care spending, they would likely result in incremental costs that could be substantial. As an initial estimate, we pair the Belkin (2015) estimate of 0.012 percent of incremental health care costs with $4,255.1 billion in total health expenditures in calendar year 2021.[452] When this is grown to 2022 dollars, total health care costs are $4,550.0 billion. Combining these yields our upper-bound estimate of $546 million in annual costs associated with additional coverage. As a lower-bound estimate, we adopt an assumption that these costs will be fully offset by reductions in spending on other medical care. This lower bound of $0 is broadly consistent with a cost-effectiveness analysis that includes the probability of negative incremental costs associated with coverage.[453] For our primary estimate, we start with the midpoint of the lower-bound and upper-bound cost estimate of about $273.24 million annually. We reduce this figure by half to account for several factors, such as some covered entities already covering gender-affirming care under the baseline scenario. The coverage from § 92.207(b)(1) through (5) and (6) have delayed applicability dates of the first day of the first plan year beginning on or after January 1, 2025. Therefore, there is no cost from coverage in year 1 (2024). This results in a primary estimate of about $138 million per year starting in year 2 in incremental annual costs associated with additional coverage under the final rule, with a full range of cost estimates including $0 million and $546 million.

In addition, health plans and issuers could incur overall costs if total health care utilization increases as a result of this final rule. Any potential increase in costs as a result of increased health care utilization as a result of decreased discrimination could be passed on to beneficiaries in the form of increased premiums. However, this cost would be minimal due to the low utilization of gender affirming care along with the availability of the services.

Assessing Decision Support Tools for Discrimination

Section 92.210 sets a minimum requirement for each covered entity to make reasonable efforts to mitigate the risk of discrimination resulting from the covered entity's use of a decision support tool. This will impose a cost on covered entities to review for potential discrimination in their decision support tools and to then make reasonable steps to mitigate the risk of discrimination. To estimate the cost of review, the Department assumes that all covered entities, or 266,297 entities, would on average take 1 hour to review decision support tools in year 1 and 0.5 hours in each year 2–5. The Department assumes the time burden is halved after year 1 because entities would only be reviewing new decision support tools or changes made to preexisting ones in the past year. Evidence suggests that larger entities, such as insurers, health systems and national labs, are more likely to use decision support tools while some types of entities may not use them at all.[454] It is therefore likely that entities will have a large variance in time burden in practice as some entities will need to spend more time reviewing and others much less. OCR assumes that the hour of review consists of a 1557 coordinator (SOC code 43–4071) spending 0.5 hours coordinating a request for information on the potential for discrimination in decision support tools used by the covered entity and a Management Analyst (13–1111) or equivalent employee with knowledge of the decision support tools spending 0.5 hours responding to that request. After adjusting for fringe benefits and other indirect costs, the hourly wages for the Management Analyst and Section 1557 Coordinator come to $100.64 and $38.04 respectively. We monetize the time spent on reviewing decision support tools by estimating a total cost per entity

williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.

[447] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. of Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

[448] Hum. Rts. Campaign, *Corporate Equality Index 2021* (2021), *https://reports.hrc.org/corporate-equality-index-2021?_ga=2.206988627.1166715317.1639876655-819100514.1639876655.*

[449] *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[450] *Flack* v. *Wis. Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1021 (W.D. Wis. 2019); *see also Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *22 (finding that the cost of covering gender-affirming care ''pales in comparison'' to the Defendant state health plan's overall cash balance and that excluding such coverage would only save each plan member' ''about one dollar each'').

[451] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 2, 5 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[452] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Table 19. National Health Expenditure Accounts: Methodology Paper,* 2022, *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf.*

[453] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. of Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

[454] Xia Jing et al., *Availability and Usage of Clinical Decision Support Systems (CDSSs) in Office-Based Primary Care Settings in the USA,* BMJ Health Care Inform. (2019), *https://pubmed.ncbi.nlm.nih.gov/31818828.*

of $69.34 ($100.64 × 0.5 + $38.04 × 0.5). The estimated total cost to review decision support tools for all covered entities is $18,465,034 ($69.34 × 266,297) in year 1. In years 2–5, OCR estimates that the time burden will be half of what it was in year 1. This will lead to a total cost per entity of $34.67 ($100.64 × 0.25 + $38.04 × 0.25) in years 2–5. The estimated total cost to review decision support tools for all covered entities is $9,232,517 ($34.67 × 266,297) in each year 2–5.

If an entity reviews their decision support tools and determines that there is no evidence that use of the tools may result in discriminatory outputs, then it is likely that no further action will be taken, and no additional cost will be incurred. If the entity determines that there is evidence that the decision support tools used by the covered entity could result in discriminatory outputs, then the entity will have to make reasonable mitigation steps to be in compliance with the final rule. OCR has determined that there are a large variety of actions that a covered entity can take to satisfy the requirements of the final rule and that these steps likely depend on the specific scenario. One aspect that will affect what a covered entity would do is if the decision support tool that is being used is a third-party product that the covered entity pays for or was developed and is owned by the covered entity itself. In the first scenario, the covered entity could notify the third party that the decision support tool may result in outputs that could be in violation of the rule, take mitigation steps in the use of the tool to ensure decisions made using that tool account for the potential for bias, or switch to a different product if the cost to do so is not prohibitive. If the covered entity maintains their own decision support tool, then they might take time to update the decision support tool, change policies and procedures about its use, or take other reasonable mitigation measures to ensure that it is not used in a discriminatory manner. The cost of all these actions may vary greatly, and OCR does not have data to assess what the costs may be. Generally, OCR assumes that larger entities, such as multihospital health systems and insurers will have a higher cost to resolve these issues since they are more likely to use decision support tools.[455] In addition, OCR does not have data on how likely any given decision support tool is to be discriminatory and therefore necessitate taking reasonable mitigation steps. Due to these data limitations, OCR does not quantify the cost of taking reasonable mitigation steps.

Exemption Requests

We also identify a cost related to covered entities submitting a request for assurance of an exemption based on Federal conscience or religious freedom laws. We model this potential cost associated with exemption assurance requests as the time spent by covered entities to (a) assess the need for an exemption; (b) write the exemption assurance request; and (c) submit such a request to OCR. As an initial calculation, we assume that this would involve two (2) employees spending two (2) hours each assessing the need for an exemption and one employee spending three (3) hours writing and submitting the exemption assurance request to OCR. We further assume that legal personnel, including lawyers and legal assistants, would perform these functions. The mean hourly wage for these occupations is $70.55 per hour for each employee, which we double to account for overhead and other indirect costs. We multiply these factors together and estimate the cost per exemption request of $987.70 ($141.10 × 7 = $70.55 × 2 × 7).

OCR has revised the estimate of the number of religious exemptions from the Proposed Rule RIA, which assumed 27 religious exemptions. OCR has increased this estimate to provide a more conservative estimate of the cost of religious exemptions, given significant uncertainty in the number of requests that will be submitted. OCR revises its assumptions to assume that 707 religious hospitals and 2 percent of all other covered entities will request assurance of religious exemptions. This results in a total of 6,019 of such requests (707 + ((266,297 − 707) × 0.02)) in the first year. OCR estimates the cost to covered entities for the 6,019 of such requests as $5,944,792 (6,019 × $987.73).

We estimate the cost to OCR comprising the time it would take to review the request and determine if the exemption assurance should be given. We estimate that it would take a single lawyer equivalent employee (Occupation code 23–1011), with a wage of $70.55 per hour, 3 hours to complete this review. We double the mean hourly wage to account for overhead and fringe benefits. OCR estimates the cost to review 6,019 assurance of exemption requests as $2,547,768 ($141.10 × 3 × 6,019). The total estimated cost of this process is $8,492,559.

c. Total Quantified Costs

Table 4 below presents the total annual costs anticipated under the final rule for which estimates have been developed. For the purposes of this analysis, we assume that the regulatory requirements begin to take effect in the middle of 2024. In the first year under the final rule, these estimated costs include $927.4 million in training, $8.5 million to process religious assurance of exemption requests, $18.5 million to review decision support tools, and $65.0 million to revise policies and procedures. For all years in the analysis, we estimate recurring costs of $46.6 million related to notices. We estimate a first-year cost of $37 million related to documentation, with ongoing costs in future years of $10.1 million. We also report a primary recurring cost estimate of $136.6 million associated with coverage of gender-affirming care starting in year 2 and $9.2 million in reviewing decision support tools starting in year 2. The total costs in year 1 amount to $1,102.9 million, with ongoing annual costs of $511.7 million in subsequent years.

TABLE 4—PRIMARY ESTIMATE OF TOTAL ANNUAL COSTS

[$ Millions, 2022 dollars]

Cost element	2024	2025	2026	2027	2028
Training	$927.4	$309.1	$309.1	$309.1	$309.1
Policies and Procedures	65.0	0.0	0.0	0.0	0.0
Notices	46.6	46.6	46.6	46.6	46.6
Documentation	37.0	10.1	10.1	10.1	10.1
Gender-affirming Care Coverage	0	136.6	136.6	136.6	136.6

[455] Robert. S. Rudin & Shira H. Fischer, *Trends in the Use of Clinical Decision Support by Health System-Affiliated Ambulatory Clinics in the United States 2014–2016,* Am. J. of Accountable Care (2019), *https://www.ajmc.com/view/trends-in-the-use-of-clinical-decision-support-by-health-system-affiliated-ambulatory-clinics-in-the-united-states-20142016.*

TABLE 4—PRIMARY ESTIMATE OF TOTAL ANNUAL COSTS—Continued

[$ Millions, 2022 dollars]

Cost element	2024	2025	2026	2027	2028
Assurance of Exemption Requests	8.5	0.0	0.0	0.0	0.0
Decision Support Tool Review	18.5	9.2	9.2	9.2	9.2
Total Costs *	1,102.9	511.7	511.7	511.7	511.7

This rulemaking also revises the Department's interpretation of whether Medicare Part B payments constitute Federal financial assistance by answering that question in the affirmative. Thus, the requirements of section 1557 and other civil rights statutes apply to entities that receive payments through Medicare Part B. We are currently unable to quantify the number of covered entities that are enrolled in Medicare Part B but that receive no other forms of Federal financial assistance. The 2016 Rule discussed several of the challenges associated with estimating the number of these entities. For example, the 2016 Rule notes that, ''although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.'' We adopt the finding of the 2016 Rule that almost all practicing physicians were likely covered by the rule because they accept Federal financial assistance from sources other than Medicare Part B.[456]

3. Discussion of Benefits

Quantifying benefits for this final rule presents significant challenges. One notable challenge relates to attribution: several sources of benefits discussed in the preambles of the 2016 and 2020 Rules overlap with and may be attributable to prior existing civil rights regulation, to the ACA rather than the 2016 and 2020 rulemakings that implement section 1557, or to nondiscrimination policies based on State law or institutional policies prohibiting discrimination generally.

A second challenge relates to identifying a quantitative relationship between nondiscrimination policies and important outcomes such as improvements in public health outcomes. For example, we anticipate that this regulation would reduce the incidence of providers refusing to treat patients based on the patient's gender identity. This would result in fewer instances of delayed or denied care, which in turn would lead to reductions in mortality and morbidity risks. However, we are not able to estimate the changes in the magnitude of these discriminatory events that would be attributable to the final rule, and thus are unable to quantify or monetize these health improvements. Similarly, we anticipate that the final rule will result in other sources of benefits that we are unable to quantify. These include a reduction in suicidal ideation and attempts, improvements to mental health, reductions in substance use, and generally align with a discussion of the economic impacts of a California regulation relating to gender nondiscrimination in health insurance.[457]

In addition to these health improvements, we anticipate benefits to covered entities from additional regulatory clarity on how OCR will enforce the ACA's nondiscrimination protections, particularly in light of ongoing litigation related to the 2020 Rule, interpretation of the Supreme Court's *Bostock* decision, and the Department's Bostock Notification. The training provisions represent one mechanism by which the final rule would reduce discriminatory events. This would, in turn, reduce the number of enforcement actions, representing a potential cost-saving benefit for covered entities. We also anticipate benefits to covered entities from the establishment of a grievance process, which would reduce the number of complaints filed with OCR, though this may be offset somewhat from covered entities with fewer than 15 employees referring complaints to OCR in lieu of adopting their own grievance procedure.

We also anticipate that beneficiaries could benefit from reduced obstacles to accessing health care, including fewer language barriers and a reduction in discriminatory behavior related to sexual orientation and gender identity, resulting in a potential increase in overall health care utilization. These benefits relate to individuals' ability to access care and the quality of care they receive. For example, the provisions related to language access for individuals with LEP and accessibility for individuals with disabilities could reduce instances of negative outcomes, including death, due to a lack of understanding between patient and doctor or between patient and pharmacist, as well as lack of access to services. We also anticipate that the process by which individuals and recipients may seek assurance of an exemption based on Federal conscience or religious freedom laws will result in benefits from reduced litigation, which we do not capture in the benefit analysis. In addition, the prohibition on discrimination through the use of decision support tools is also likely to have a direct benefit on the health of individuals who are suffering from delayed or denied medical care due to discriminatory application of decision support tools. An example of this would be an incorrect diagnosis for skin cancer for a Black patient, which could lead to greater medical costs in the future and negative health outcomes for the patient.[458] Furthermore, the positive effects of using decision support tools, such as identifying those at risk for cardiovascular disease at an earlier date, will be a benefit across populations experiencing discrimination.[459]

4. Analysis of Regulatory Alternatives to the Final Rule

The Department considered various alternatives while developing this regulation, including adopting the compliance timeline of the Proposed Rule. As discussed in the preamble, the final rule will allow additional time for covered entities to comply with certain procedural requirements, as compared to the timeline of the Proposed Rule. For example, covered entities must comply with the § 92.9 Training requirements by no later than 300 days of effective

[456] 81 FR 31375, 31445–46 (May 18, 2016).

[457] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 9–11 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[458] Thomas Grote & Geoff Keeling, *On Algorithmic Fairness in Medical Practice,* Cambridge Quarterly of Healthcare Ethics, January 2022. *https://pubmed.ncbi.nlm.nih.gov/35049447/.*

[459] Rachel Gold et al., *Effect of Clinical Decision Support at Community Health Centers on the Risk of Cardiovascular Disease: A Cluster Randomized Clinical Trial,* JAMA Network Open (2022), *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788645.*

date. This revised timeline will postpone certain costs incurred by covered entities; however, since this analysis reports annual impacts, the revised timeline does not affect the quantified cost estimates. This section discusses several other alternatives OCR considered.

The Department analyzed several regulatory alternatives to the final rule related to the notice requirements. The first alternative considered retaining the 2020 Rule's repeal of the notices and taglines provisions. The Department considered concerns raised in response to the 2016 Rule notice and tagline requirements, as well as concerns raised in response to the removal of those requirements in the 2020 Rule. Though the Department acknowledges the burden placed on covered entities through the 2016 Rule notice requirements, the Department believes the 2020 Rule did not adequately consider the confusion and uncertainty placed on individuals or the unnecessary ambiguity that covered entities face by the 2020 Rule's repeal of the notices and taglines provisions in their entirety. As described earlier, we estimate that these provisions under the final rule would cost covered entities, as an aggregate, $46.6 million for each year. While excluding the provisions relating to the notices would reduce the cost of the final rule by $46.6 million, the Department rejected this option because it believes that the final provisions strike an appropriate balance between providing greater access for beneficiaries, while maximizing efficiency and economies of scale for covered entities.

The second alternative considered by the Department would require covered entities to provide notices only at their first encounter with a beneficiary. For this alternative, we adopt the quantity and cost estimates associated with eligibility and enrollment communication included in Table 5 above. Under our primary cost scenario, this policy alternative would result in annual costs of notices of $0.7 million, which is about $45.9 million lower than the final rule. The Department rejected this option however, because this policy alternative, while posing a significantly reduced cost and burden on covered entities, would be too narrow and substantially reduce the information available to beneficiaries, likely resulting in beneficiaries not being aware of their civil rights, including whether they have experienced a prohibited discriminatory practice by a covered entity.

The third alternative considered by the Department would require a more expansive notice provision, extending the requirements to include pharmacy-related notices. For this alternative, we adopt the 2020 RIA estimate of 3.2 billion annual pharmacy-related notices. This would result in $169.7 million in costs per year, or an increase of $123.1 million compared to the final rule. While this alternative related to notices would increase the number of notices available to beneficiaries, and therefore increase beneficiaries' opportunity to receive information regarding nondiscrimination and civil rights protections, the Department believes this alternative would neither address nor remedy the burden placed on covered entities through the 2016 Rule notice requirements. For this reason, the Department rejected this alternative.

Finally, the Department also considered not including a process for covered entities to submit a request for assurance of a religious or conscience exemption. As described in the cost section, we estimate that this policy alternative would reduce the quantified costs by $8.5 million. The Department did not choose this alternative because of its obligations to enforce a range of statutory protections, including Federal religious freedom and conscience laws. OCR remains committed to educating patients, providers, and other covered entities about their rights and obligations under these statutes, to protecting patients' health and dignity, and to providing a clear administrative process that respects the right to raise objections to the provision of certain kinds of care.

We have not quantified the benefits associated with this information for the final rule or for these policy alternatives.

Table 5 reports the total costs of these policy alternatives in present value and annualized terms, adopting a 3 percent and 7 percent discount rate. Table 6 reports the difference between the total cost of the alternatives compared to the provisions of the final rule, using the same accounting methods and discount rates. All estimates are presented in millions of year-2022 dollars, using 2024 as the base year for discounting.

TABLE 5—TOTAL COST OF POLICY ALTERNATIVES CONSIDERED

[$ Millions, 2022 dollars]

Accounting method discount rate	Present value		Annualized	
	3%	7%	3%	7%
Final Rule	$2,917.6	$2,650.8	$637.1	$646.5
Alternative 1: No Notice Provision	2,704.1	2,459.7	590.5	599.9
Alternative 2: Single Notice Provision	2,707.4	2,462.6	591.2	600.6
Alternative 3: Pharmacy-Related Notices	3,481.3	3,155.4	760.1	769.6
Alternative 4: No Exemption Provision	2,909.4	2,642.8	635.3	644.6

TABLE 6—COMPARISON OF ALTERNATIVES TO FINAL RULE

[$ Millions, 2022 dollars]

Accounting method discount rate	Present value		Annualized	
	3%	7%	3%	7%
Alternative 1: No Notice Provision	−$213.5	−$191.1	−$46.6	−$46.6
Alternative 2: Single Notice Provision	−210.2	−188.2	−45.9	−45.9
Alternative 3: Pharmacy-related Notices	563.7	504.6	123.1	123.1
Alternative 4: No Exemption Provision	−8.2	−7.9	−1.8	−1.9

The Department also considered whether to require covered entities to collect the self-identified race, ethnicity, primary language (spoken and written), sex (consistent with the categories of sex discrimination described at § 92.101(a)(2)), age, and disability status data for beneficiaries in any health program or activity. The Department believes, however, that our current authorities under section 1557, title VI, section 504, title IX, and the Age Act already provide us the ability to collect these data to ensure compliance.[460]

B. Regulatory Flexibility Act—Final Small Entity Analysis

The RFA requires agencies issuing a regulation to analyze options for regulatory relief of small businesses if a rule will have a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of ''small entity'').

OCR uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent for 5 percent or more of affected small entities. In instances where OCR judged that the final rule would have a significant impact on a substantial number of small entities, we considered alternatives to reduce the burden. To accomplish our task, we first identified all the small entities that may be impacted, and then evaluated whether the economic burden we determined in the RIA represents a significant economic impact.

1. Entities That Will Be Affected

OCR has traditionally classified most providers as small entities even though some nonprofit providers would not meet the definition of ''small entity'' were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields. The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms' tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

a. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are ''small'' if they meet the SBA's definition. The current size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111) is annual receipts of less than $16 million.[461] Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 16,361 entities or 9.8 percent of all physician offices defined as ''large.'' This left 150,933 offices or 90.2 percent as ''small.''[462]

b. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than $37.5 million. According to Census Statistics of U.S. Businesses, there are 19,346 pharmacy and drug store firms (North American Industry Classification System code 456110). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.[463] There are 17,160 pharmacy firms with fewer than 20 employees, representing 88.7 percent of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 17,160. As with the number of small physician offices, our method can only identify the minimum number of ''small'' pharmacies that meet the SBA size standard. We cannot determine the actual number of ''small'' pharmacies.

c. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of $47 million. Based on the analysis below, we conclude that there are few small health insurance issuers.

In 2021, there were 483 issuers in the U.S. health insurance market.[464] Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[465] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Due to the lack of recent Census data based on enterprise receipt size, HHS used the Census 2017 SUSB data as a proxy since it was the last year in which this data is available. Based on data from SUSB annual report submissions for the 2017 SUSB reporting year, approximately 443 out of 745 issuers of health insurance coverage nationwide, approximately 59.46%, had total premium revenue of $40.0 million or less.[466] OCR decided to use a value slightly higher than the 2017 SBA standard to account for slight changes in the industry in addition to inflation. We then apply this percentage to the current number of insurance Issuers to estimate the number of small entities for the business type, which is approximately 517 of 869 entities. However, this estimate may overstate the actual number of small health insurance issuers that may be affected due to changes in the health care industry since 2017. To produce a conservative estimate, for the purposes of this analysis, the Departments assumes 59.5 percent, or 517 issuers are considered small entities.

d. Local Government Entities

We also excluded local governmental entities from our count of small entities

[460] *See, e.g.,* 45 CFR 80.6, 86.71, 91.34, and 84.61.

[461] U.S. Small Business Admin., *Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Small Business Administration* (March 2023), *https://www.sba.gov/document/support-table-size-standards.*

[462] Physician practices may earn more than $16 million per year and that would increase the number of ''large'' practices in the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

[463] U.S. Census Bureau, *Statistics of U.S. Businesses, https://www.census.gov/programs-surveys/susb.html.*

[464] U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs. (2022), *Medical Loss Ratio Data and System Resources, https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[465] U.S. Small Business Admin., *Table of Size Standards* (March 17, 2023), *https://www.sba.gov/document/support--table-size-standards.*

[466] U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio Data and System Resources* (2017), *https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.*

because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small, covered entities we estimated could be affected by the final rule.

TABLE 8—SMALL ENTITIES

NAICS code	Business type	Small entities
62142	Outpatient mental health and substance abuse centers	7,649
621491	HMO medical centers	84
621492	Kidney dialysis centers	449
621493	Freestanding ambulatory surgical and emergency centers	4,554
621498	All other outpatient care centers	6,307
6215	Medical and diagnostic laboratories	7,200
6216	Home health care services	25,718
6219	All other ambulatory health care services	7,091
62321	Residential intellectual and developmental disability facilities	6,674
6221	General medical and surgical hospitals	2,445
6222	Psychiatric and substance abuse hospitals	434
6223	Specialty (except psychiatric and substance abuse) hospitals	301
6231	Nursing care facilities (skilled nursing facilities)	9,824
45611	Pharmacies and drug stores	17,160
6211	Offices of physicians	150,933
524114	Insurance Issuers	517
	Navigator grantees	58
	Total Entities	247,398

2. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

The Department generally considers a rule to have a significant impact on a substantial number of small entities if it has at least a 3 percent impact on revenue on at least 5 percent of small entities. We performed a threshold analysis to determine whether the quantified impacts of the final rule will exceed these thresholds. As described earlier in this analysis, we estimate the total annualized costs of the final rule would be about $637.1 million. Dividing these total costs by the 247,398 small entities gives a cost per entity of $2,575. This cost estimate would only exceed the 3 percent ''significant impact'' threshold on revenue for any covered small businesses with revenue below $85,836. We conclude that very few small businesses covered by the final rule will have revenues below $85,836, and that this number is very likely to be smaller than the 5 percent ''substantial number'' threshold.

As an additional consideration, we note that the costs of the final rule are mostly proportional to the size of the covered entity. For example, the costs associated with training, which account for more than 70 percent of the total costs of the final rule, are mostly proportional to the number of employees receiving training. In the main analysis, we estimate an incremental impact of one (1) hour per employee trained. The opportunity cost of training each employee represents 0.05 percent of a full-time employee's annual labor productivity, assuming a full-time employee works 2,080 hours per year.[467] This finding, that the cost of training represents 0.05 percent of the share of employees receiving training, is constant across firm size.

Because the costs of the final rule are small relative to the revenue of covered entities, including covered small entities, and because even the smallest affected entities would be unlikely to face a significant impact, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to E.O. 12250, the Department of Justice has the responsibility to ''review . . . proposed rules . . . of the Executive agencies'' implementing nondiscrimination statutes such as section 1557 ''in order to identify those which are inadequate, unclear or unnecessarily inconsistent.''The Department of Justice has reviewed and approved this final rule.

D. Paperwork Reduction Act

Information Collection Requirements

This final rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995.[468] In order to evaluate whether an information collection should be approved by OMB, the PRA requires that the Department solicits comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;

3. The quality, utility, and clarity of the information to be collected; and

4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.[469]

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department previously published a notice of a proposed data collection on August 4, 2022, at 87 FR 47907–08, as part of an NPRM entitled ''Nondiscrimination in Health Programs and Activities'' (RIN 0945–AA17), to invite public comment. OCR solicited comment on the issues listed above for the sections that contain ICRs. The following paragraphs describe these provisions, with an estimate of the annual burden, summarized in Table 1. OCR did not receive comments related to the previous notice but has adjusted the estimated respondent burden in this request to reflect revised assumptions based on updated information available at the time of the final rule's

[467] 40 hours per week × 52 weeks = 2,080 hours. 0.05% = 0.0005 = 1 hour ÷ 2080 hours.

[468] 44 U.S.C. 3501–3520.

[469] 44 U.S.C. 3506(c)(2)(A).

publication. This revision resulted in adjusted cost estimates that are consistent with the RIA presented in this final rule. The estimates covered the employees' time for reviewing and completing the collections required.

Consistent with the NPRM, the collections of information proposed by this final rule relate to §§ 92.5 (Assurances required); 92.7 (Designation and responsibilities of a Section 1557 Coordinator); 92.9 (Training); 92.10 (Notice of nondiscrimination); and 92.11 (Notice of availability of language assistance services and auxiliary aids and services). Respondents to this proposed information collection would include a variety of covered entities with a health program or activity including hospitals, ambulatory surgical centers, skilled nursing facilities, and physicians' offices. For a more detailed discussion concerning the potential costs' implications related to these collections of information, please see the Regulatory Impact Analysis.

1. ICRs Regarding Assurances (§ 92.5)

Section 92.5 retains the assurances obligations from the 2016 and 2020 Rules for covered entities to submit an assurance of compliance to the Department. As stated in the NPRM, OCR has previously obtained PRA approval (OMB control # 0945–0008) for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form), separate from this rulemaking. The requirement to sign and submit an assurance of compliance currently exists under section 1557 and other civil rights regulations (title VI, section 504, title IX, and the Age Act). Since the Department provides an online portal through which covered entities submit attestation of Assurance of Compliance, the Department has determined that this requirement imposes no additional reporting or recordkeeping requirements under the PRA.

OCR did not receive any comments in response to the ICRs related to this policy. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing this ICR as proposed.

2. ICRs Regarding Section 1557 Coordinator (§ 92.7) and Training (§ 92.9)

Section 92.7 requires covered entities with 15 or more employees designate a section 1557 Coordinator to coordinate their efforts to comply with and carry out their responsibilities under section 1557. The burden to coordinate efforts to comply with and carry out the responsibilities under section 1557 was estimated in the NPRM, at an annualized burden of 10 hours per covered entity to store complaints and the associated records required under § 92.8(c)(2) each year. We assumed that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation was $17.38 per hour, which we double to account for overhead and other indirect costs. In the 2022 NPRM, OCR estimated the number of covered entities with more than 15 employees to be approximately 15 percent or 41,250. Although in the 2022 NPRM, OCR estimated that the costs of retaining records related to grievances filed at all covered entities would be $14.3 million annually (($17.38 × 2) × 10 × 41,250), we noted that this estimation approach may overstate the costs if many covered entities already retain complaint information.

OCR has adjusted our estimated respondent burden in this request to reflect baseline conditions based on updated information available at the time of the final rule's publication. No changes were made to estimated personnel or staff time or to the assumption that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation, however, has increased to $19.02 per hour, which we double to account for overhead and other indirect costs. The Department estimates the number of covered entities with more than 15 employees to be approximately 15 percent or 63,950. Although we estimate the costs of retaining records related to grievances filed at all covered entities would be $24.3 million annually (($19.02 × 2) × 10 × 63,950)), this estimation approach will overstate the costs if many covered entities already retain complaint information.

The burden for documenting employee training as required under § 92.9(c) is the cost of covered entity staff time to (a) create training attendance forms; and (b) store the training sign-up sheet. The labor cost would include one (1) employee spending 15 minutes (0.25 hours) to create the sign-up sheet during the first year and one (1) employee spending one (1) hour collecting and storing the attendance forms the first year and in subsequent years. In the NPRM, we estimated that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation was $17.38 per hour. The labor cost was $6.0 million in the first year (($17.38 × 1.25) × 275,002 covered entities). In the 2022 NPRM, we estimated that the cost in subsequent years would be $4.8 million, which would represent an annual allotment of one (1) hour (($17.38 × 1) × 275,002 covered entities).

OCR has adjusted our estimated respondent burden in this request to reflect updated baseline conditions based on updated information not available at the time of the publication of the NPRM. No changes were made to the estimated personnel or staff time or to the estimate that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation, however, increased to $19.02 per hour. The estimated labor cost of documenting employee training would be $12.6 million in the first year (($19.02 × 2) × 1.25 × 266,297 covered entities). We estimate that the cost in subsequent years would be $10.1 million, which would represent an annual allotment of one (1) hour ((($19.02 × 2) × 1) × 266,297 covered entities).

OCR did not receive any comments in response to the ICRs related to this policy. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing these ICRs as proposed.

3. ICRs Regarding Notice of Nondiscrimination (§ 92.10) and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

Under §§ 92.10 and 92.11, OCR requires covered entities to notify the public of their nondiscrimination requirements, as well as the availability of language assistance services and auxiliary aids and services.

Section 92.10 requires covered entities to provide a Notice of Nondiscrimination relating to its heath programs or activities to beneficiaries of its health programs and activities and members of the public. To minimize the burden on covered entities, the provision proposes a covered entity may combine the content of the notice required by this section with the notice required by title VI, section 504, title IX, and the Age Act implementing regulations.

Section 92.11 requires covered entities to notify the public of their nondiscrimination requirements, as well as the availability of language assistance services and auxiliary aids and services. A covered entity must provide a Notice of Availability that, at minimum, states that the covered entity provides language assistance services and auxiliary aids and services free of charge

in its health programs and activities, in compliance with section 1557. This notice must be provided to beneficiaries of the covered entity's health program or activity and members of the public. The notice must be provided in English and at least the top 15 languages spoken by persons with LEP of the relevant State or States in which a covered entity operates (including territories) and must be provided in alternate formats for individuals who request auxiliary aids and services to ensure effective communication.

OCR also received comments on the cost of Notices of Nondiscrimination and Notices of Availability (referred to as ''taglines'' in the 2016 and 2020 Rules). One commenter explained how the cost of including taglines averages up to $8.91 per month per covered entity and upwards of $2 million a year for the health insurance industry. Another commenter stated that they have spent over $16 million on notices and taglines since 2016, and estimate that they have spent over $3 million in 2022 alone. As we noted in the RIA, neither commenter provided sources for their data nor additional detail on their cost estimates. Another commenter noted that previous complaints on the frequency and volume of materials related to the notice and tagline sections of the rule were not addressed, but no data were provided with their comment.

Based on costs estimated in the RIA, OCR derives a monthly cost of Notices of Nondiscrimination and Notices of Availability from $21.28 and $26.60 per entity depending on the prevalence of electronic delivery. These cost estimates include the total Notices of Nondiscrimination and Notices of Availability and therefore OCR finds the commenter's estimate of $8.91 per month for Notices of Availability as plausible and consistent with the estimates in the RIA. OCR also notes that these cost estimates are averages. It is expected that some entities, including larger entities, may have higher than average costs due to the increased number of notices they would send to individuals.

Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the homepage of the covered entity's health program or activity website; and (4) at conspicuous physical locations where the health program or activity interacts with the public.

In the NPRM, OCR estimated the burden for responding to the proposed notice requirements would be 34 minutes and that administrative or clerical support personnel would perform these functions. Because it was difficult to determine the exact number of communications that would be required to contain the notices anticipated under the 2022 NPRM, our cost estimates reflected a wide range of uncertainty in the cost. In the 2022 NPRM, the Department estimated an adjusted annual primary cost total of $4.5 million, with a range of costs between $2.7 million and $25.0 million. These costs would occur in each year of the time horizon of the analysis.

OCR has adjusted our estimated respondent burden in this request to reflect updated baseline conditions based on updated information not available at the time of the publication of the NPRM. Because it is difficult to determine the exact number of communications that would be required to contain the notices anticipated under the 2022 NPRM, our cost estimates reflect a wide range of uncertainty in the cost. OCR notes that the majority of associated costs for these requirements are from the materials, such as paper and ink, used in the notices and these costs are assumed to vary with the length of notices. No changes were made to the estimate that administrative or clerical support personnel would perform these functions. The estimated personnel and staff time, however, increased to 1.34 hours per year to perform these functions. The mean hourly wage for this occupation increased to $19.02 per hour, which we double to account for overhead and other indirect costs. The estimated labor cost to notify the public of their nondiscrimination requirements, as well as availability of language assistance services and auxiliary aids and services, would be $13.5 million (($19.02 × 2) × 1.34) × 266,297 covered entities). The Department estimates the total associated costs for these requirements as an adjusted annual total of $53.2 million, with a range of costs between $35.5 million and $292.6 million. These costs would occur in each year of the time horizon of the analysis.

OCR did not receive any comments in response to the ICRs related to § 92.10, and received the comments discussed above in response to ICRs related to § 92.11. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing the ICRs for §§ 92.10 and 92.11 as proposed.

We have submitted a copy of this final rule to OMB for its review of the rule's ICRs. These requirements are not effective until they have been approved by OMB.

TABLE 1—SUMMARY OF ESTIMATED ANNUALIZED BURDEN

Information collection	Number of respondents	Responses frequency (average)	Total responses	Burden hours per response (average)	Hourly rate	Burden cost [470]
§ 92.7 Coordination Efforts	[471] 63,950/ 266,297	1	330,247	[472] 10/1.25	[473] $38.04	$24,326,580/ 12,662,422
§§ 92.10 & 92.11 Notice	266,297	[474] 1	266,297	1.34	38.04	13,574,117
Total application collection	330,247	.....	596,544	12.59	.....	50,563,119

[470] The figures in this column are averages based on a range. Large entities with more than 15 employees may require more hours than those provided here due to their size and complexity, while small entities may require fewer hours to conduct certain compliance activities.

[471] Covered entities with 15 or more employees would be required to coordinate the retention of grievance complaints for no less than three years. We have estimated that this provision would apply to approximately 63,950 covered entities. All covered entities would be required to document employee training on section 1557. We estimated that this would apply to approximately 266,297 covered entities.

[472] We have estimated that covered entities with 15 or more employees would spend approximately 10 hours on efforts to coordinate their compliance efforts under section 1557 as required under § 92.7. We estimate that all covered entities would spend approximately 1.25 hours documenting employee training as required under § 92.9.

[473] The $38.04 wage, which includes $19.02 plus 100 percent for benefits, applies to the category ''Administrative or Clerical Support Personnel.''

[474] Because it is difficult to determine the exact number of communications which would be required to contain the notices anticipated under the Proposed Rule, our number of responses per respondent estimate reflects this uncertainty.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law.

The final rule would not negatively affect family wellbeing and would strengthen the stability of the family by promoting the ability of all individuals and families to receive health care free from discrimination. As research demonstrates that experiencing discrimination can have a negative impact on health and wellbeing, this rule addresses the immediate and long-term effects of discriminatory actions and establishes a set of practices to remove barriers to accessing care among entities that receive Federal funds. Addressing and preventing discrimination in health care can also improve the financial stability of the family unit by increasing access to nondiscriminatory health insurance coverage and other health-related coverage, aiding parents in their ability to provide for and nurture their children. The rule may be carried out only by the Federal Government because it would implement Federal nondiscrimination law, ensuring that American families have access to health care information and services, regardless of the State where they are located.

List of Subjects

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities

Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Sex discrimination.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 80

Civil rights, Individuals with disabilities, Sex discrimination, Vocational education.

45 CFR Part 84

Civil rights, Equal educational opportunity, Equal employment opportunity, Health care, Individuals with disabilities, Infants and children, Reporting and recordkeeping requirements.

45 CFR Part 92

Administrative practice and procedure, Aged, Citizenship and naturalization, Civil rights, Communications equipment, Health facilities, Health insurance, Health programs or activities, Healthcare, Individuals with disabilities, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Aged, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Taxes, Technical assistance, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

Dated: April 18, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR parts 438, 440, 457, and 460 and 45 CFR parts 80, 84, 92, 147, 155, and 156 as follows:

Title 42—Public Health

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 438.3 by revising paragraph (d)(4) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(d) * * *

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating on the basis of race; color; national origin; disability; or sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.

* * * * *

■ 3. Amend § 438.206 by revising paragraph (c)(2) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 4. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Revise § 440.262 to read as follows:

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their individualized needs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 6. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 7. Amend § 457.495 by adding paragraph (e) to read as follows:

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

* * * * *

(e) Access to and delivery of services in a culturally competent manner to all beneficiaries, as described in 42 CFR 440.262.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 8. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 9. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization shall not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, mental or physical disability, or source of payment.

* * * * *

■ 10. Amend § 460.112 by revising paragraph (a) introductory text to read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

* * * * *

Title 45—Public Welfare

PART 80—NONDISCRIMINATION UNDER PROGRAMS RECEIVING FEDERAL ASSISTANCE THROUGH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES EFFECTUATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

■ 11. The authority citation for part 80 continues to read as follows:

Authority: Sec. 602, 78 Stat. 252; 42 U.S.C. 2000d–1.

■ 12. Amend appendix A to part 80 under part 1 by adding entry 155 in numerical order to read as follows:

Appendix A to Part 80—Federal Financial Assistance To Which These Regulations Apply Part 1. Assistance Other Than Continuing Assistance to States

* * * * *

155. Supplementary medical insurance benefits for the aged (Title XVIII, Part B, Social Security Act, 42 U.S.C. 1395j–1395w–6).

* * * * *

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 13. The authority citation for part 84 continues to read as follows:

Authority: 20 U.S.C. 1405; 29 U.S.C. 794; 42 U.S.C. 290dd–2; 21 U.S.C. 1174.

■ 14. Amend appendix A to part 84 in subpart a, under Definitions, by revising section 2 to read as follows:

Appendix A to Part 84—Analysis of Final Regulation

Subpart A—General Provisions

Definitions * * *

2. ''Federal financial assistance''. In § 84.3(h), defining Federal financial assistance, a clarifying change has been made: procurement contracts are specifically excluded. They are covered, however, by the Department of Labor's regulation under section 503. The Department has never considered such contracts to be contracts of assistance; the explicit exemption has been added only to avoid possible confusion.

The proposed regulation's exemption of contracts of insurance or guaranty has been retained. A number of comments argued for its deletion on the ground that section 504, unlike title VI and title IX, contains no statutory exemption for such contracts. There is no indication, however, in the legislative history of the Rehabilitation Act of 1973 or of the amendments to that Act in 1974, that Congress intended section 504 to have a broader application, in terms of Federal financial assistance, than other civil rights statutes. Indeed, Congress directed that section 504 be implemented in the same manner as titles VI and IX. In view of the long established exemption of contracts of insurance or guaranty under title VI, we think it unlikely that Congress intended section 504 to apply to such contracts.

* * * * *

■ 15. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

Sec.

Subpart B—Nondiscrimination Provisions

Subpart C—Specific Applications to Health Programs and Activities

Authority: 42 U.S.C. 18116.

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

(a) *Purpose.* The purpose of this part is to implement section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in certain health programs and activities. Section 1557 provides that, except as otherwise provided in title I of the ACA, an individual shall not, on the grounds prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an executive agency or any entity established under title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Department-administered health programs or activities, and title I entities that administer health programs or activities.

(b) *Effective date.* The regulations in this part are effective beginning July 5, 2024, unless otherwise provided in the following schedule:

TABLE 1 TO PARAGRAPH (b)

Section 1557 requirement and provision	Date by which covered entities must comply
§ 92.7	Within 120 days of July 5, 2024.
§ 92.8	Within one year of July 5, 2024.
§ 92.9	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than one year of July 5, 2024.
§ 92.10	Within 120 days of July 5, 2024.
§ 92.11	Within one year of July 5, 2024.
§ 92.207(b)(1) through (5).	For health insurance coverage or other health-related coverage that was not subject to this part as of July 5, 2024, by the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.207(b)(6)	By the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.210(b) and (c)	Within 300 days of July 5, 2024.

§ 92.2 Application.

(a) Except as otherwise provided in this part, this part shall apply to:

(1) Every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department;

(2) Every health program or activity administered by the Department; and

(3) Every health program or activity administered by a title I entity.

(b) The provisions of this part shall not apply to any employer or other plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group, with regard to its employment practices, including the provision of employee health benefits.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) Neither section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available under title VI of the Civil Rights Act of 1964, title VII of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975.

(c) Insofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. For example, 42 U.S.C. 18023 provides (among other things) that nothing in section 1557 shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(d) Nothing in this part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at appendix A to 28 CFR part 36 on July 26, 1991, and republished as appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means 36 CFR part 1191, appendices B and D (2009), in conjunction with 28 CFR 35.151.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029) (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old a person is, or the number of elapsed years from the date of a person's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means a person who applies to participate in a health program or activity.

Auxiliary aids and services include, for example:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.104; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology (ICT); or other effective methods of making aurally delivered information available to persons who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to persons who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Companion means a family member, friend, or associate of an individual seeking access to a service, program, or activity of a covered entity, who along with such individual, is an appropriate person with whom a covered entity should communicate.

Covered entity means:

(1) A recipient of Federal financial assistance;

(2) The Department; and

(3) An entity established under title I of the ACA.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department, or their designee(s).

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of ''disability'' in the ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108.

Exchange means the same as ''Exchange'' defined in 45 CFR 155.20.

Federal financial assistance, as used in this part:

(1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal Government, directly or indirectly, provides assistance or otherwise makes assistance available in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real or personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including advance payments of the premium tax credit and cost-sharing reduction payments under title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health insurance coverage for payment to or on behalf of a person obtaining health insurance coverage from that entity or extended by the Department directly to such person for payment to any entity providing health insurance coverage.

Federally-facilitated Exchange means the same as ''Federally-facilitated Exchange'' defined in 45 CFR 155.20.

Health program or activity means:

(1) Any project, enterprise, venture, or undertaking to:

(i) Provide or administer health-related services, health insurance coverage, or other health-related coverage;

(ii) Provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage;

(iii) Provide clinical, pharmaceutical, or medical care;

(iv) Engage in health or clinical research; or

(v) Provide health education for health care professionals or others.

(2) All of the operations of any entity principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1) of this definition, including, but not limited to, a State or local health agency, hospital, health clinic, health insurance issuer, physician's practice, pharmacy, community-based health care provider, nursing facility, residential or community-based treatment facility, or other similar entity or combination thereof. A health program or activity also includes all of the operations of a State Medicaid program, Children's Health Insurance Program, and Basic Health Program.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. An individual with limited English proficiency may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be limited English proficient for other purposes (*e.g.,* reading or writing).

Information and communication technology (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and

(3) Written notice of availability of language assistance services.

Machine translation means automated translation, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.

National origin includes, but is not limited to, a person's, or their ancestors', place of origin (such as country or world region) or a person's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

OCR means the Office for Civil Rights of the Department.

Patient care decision support tool means any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide in-language oral language assistance as part of the person's current, assigned job responsibilities and who has demonstrated to the covered entity that they are:

(1) Proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and

(2) Able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by the covered entity.

Qualified interpreter for an individual with a disability means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance:

(1) Has demonstrated proficiency in communicating in, and understanding:

(i) Both English and a non-English language (including American Sign Language, other sign languages); or

(ii) Another communication modality (such as cued-language transliterators or oral transliteration);

(2) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement; and

(3) Adheres to generally accepted interpreter ethics principles including client confidentiality.

(4) Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language (qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages);

(2) Is able to interpret effectively, accurately, and impartially to and from such language(s) and English (or between two non-English languages for relay interpretation), using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement; and

(3) Adheres to generally accepted interpreter ethics principles, including client confidentiality.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Qualified translator means a translator who:

(1) Has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language;

(2) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original written statement; and

(3) Adheres to generally accepted translator ethics principles, including client confidentiality.

Recipient means any State or its political subdivision thereof; or any instrumentality of a State or political subdivision thereof; any public or private agency, institution, or organization; other entity; or any person, to whom Federal financial assistance is extended directly or indirectly, including any subunit, successor, assignee, or transferee of a recipient. Such term does not include any ultimate beneficiary.

Relay interpretation means interpreting from one language to another through an intermediate language. This mode of interpretation is often used for monolingual speakers of languages of limited diffusion, including select indigenous languages. In relay interpreting, the first interpreter listens to the speaker and renders the message into the intermediate language. The second interpreter receives the message in the intermediate language and interprets it into a third language for the speaker who speaks neither the first nor the second language.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means section 1557 of the ACA (42 U.S.C. 18116).

State includes each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

State Exchange means an Exchange established by a State and approved by the Department pursuant to 45 CFR part 155, subpart B.

Telehealth means the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

Title I entity means any entity established under title I of the ACA, as amended, including State Exchanges and Federally-facilitated Exchanges.

Title VI means title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title VII means title VII of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000e *et seq.*), as amended.

Title IX means title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

UFAS means the Uniform Federal Accessibility Standards (Pub. L. 90–480; 42 U.S.C. 4151 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies must, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which section 1557 or this part applies must, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health insurance issuer's or State's health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this section is the same as the duration of the assurances required in the Department's regulations implementing section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State Exchange has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, such recipient or State Exchange must take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 1557 or this part, require a recipient, in its health programs and activities, or State Exchange to take remedial action with respect to:

(i) Persons who are no longer participants in the recipient's or State Exchange's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Persons who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take nondiscriminatory steps, in addition to any action that is required by section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by persons on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation and responsibilities of a Section 1557 Coordinator.

(a) *Section 1557 Coordinator and designees.* A covered entity that employs fifteen or more persons must designate and authorize at least one employee, a ''Section 1557 Coordinator,'' to coordinate the covered entity's compliance with its responsibilities under section 1557 and this part in its health programs and activities, including the investigation of any grievance communicated to it alleging noncompliance with section 1557 or this part or alleging any action that would be prohibited by section 1557 or this part. As appropriate, a covered entity may assign one or more designees to carry out some of these responsibilities, but the Section 1557 Coordinator must retain ultimate oversight for ensuring coordination with the covered entity's compliance with this part.

(b) *Responsibilities of a Section 1557 Coordinator.* A covered entity must ensure that, at minimum, the Section 1557 Coordinator:

(1) Receives, reviews, and processes grievances, filed under the grievance procedure as set forth in § 92.8(c);

(2) Coordinates the covered entity's recordkeeping requirements as set forth in § 92.8(c);

(3) Coordinates effective implementation of the covered entity's language access procedures as set forth in § 92.8(d);

(4) Coordinates effective implementation of the covered entity's effective communication procedures as set forth in § 92.8(e);

(5) Coordinates effective implementation of the covered entity's reasonable modification procedures as set forth in § 92.8(f); and

(6) Coordinates training of relevant employees as set forth in § 92.9, including maintaining documentation required by such section.

§ 92.8 Policies and procedures.

(a) *General requirement.* A covered entity must implement written policies and procedures in its health programs and activities that are designed to comply with the requirements of this part. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with this part.

(b) *Nondiscrimination policy.* (1) A covered entity must implement a written policy in its health programs and activities that, at minimum, states the covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability; that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part; that the covered entity will provide reasonable modifications for individuals with disabilities; and that provides the current contact information for the Section 1557 Coordinator required by § 92.7 (if applicable).

(2) OCR considers it a best practice toward achieving compliance for a covered entity to provide information that it has been granted a temporary exemption or granted an assurance of exemption under § 92.302(b) in the nondiscrimination policy required by paragraph (b)(1) of this section.

(c) *Grievance procedures.* (1) A covered entity that employs fifteen or more persons must implement written grievance procedures in its health programs and activities that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by section 1557 or this part.

(2) A covered entity to which this paragraph applies must retain records related to grievances filed pursuant to the covered entity's grievance procedures required under paragraph (c)(1) of this section that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date the covered entity resolves the grievance. The records must include the grievance; the name and contact information of the complainant (if provided by complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; the date the grievance was resolved; grievance resolution; and any other pertinent information.

(3) A covered entity to which this paragraph (c) applies must keep confidential the identity of an individual who has filed a grievance under this part except as required by law or to the extent necessary to carry out the purposes of this part, including the conduct of any investigation.

(d) *Language access procedures.* A covered entity must implement written language access procedures in its health programs and activities describing the covered entity's process for providing language assistance services to individuals with limited English proficiency when required under § 92.201. At a minimum, the language access procedures must include current contact information for the section 1557 Coordinator (if applicable); how an employee identifies whether an individual has limited English proficiency; how an employee obtains the services of qualified interpreters and translators the covered entity uses to communicate with an individual with limited English proficiency; the names of any qualified bilingual staff members; and a list of any electronic and written translated materials the covered entity has, the languages they are translated into, date of issuance, and how to access electronic translations.

(e) *Effective communication procedures.* A covered entity must implement written effective communication procedures in its health programs and activities describing the covered entity's process for ensuring effective communication for individuals with disabilities when required under § 92.202. At a minimum, a covered entity's effective communication procedures must include current contact information for the Section 1557 Coordinator (if applicable); how an employee obtains the services of qualified interpreters the covered entity uses to communicate with individuals with disabilities, including the names of any qualified interpreter staff members; and how to access appropriate auxiliary aids and services.

(f) *Reasonable modification procedures.* A covered entity must implement written procedures in its health programs and activities describing the covered entity's process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability as required under § 92.205. At a minimum, the reasonable modification procedures must include current contact information for the covered entity's Section 1557 Coordinator (if applicable); a description of the covered entity's process for responding to requests from individuals with disabilities for changes, exceptions, or adjustments to a rule, policy, practice, or service of the covered entity; and a process for determining whether making the modification would fundamentally alter the nature of the health program or activity, including identifying an alternative modification that does not result in a fundamental alteration to ensure the individual with a disability receives the benefits or services in question.

(g) *Combined policies and procedures.* A covered entity may combine the content of the policies and procedures required by paragraphs (b) through (f) of this section with any policies and procedures pursuant to title VI, section 504, title IX, and the Age Act if section 1557 and the provisions in this part are clearly addressed therein.

(h) *Changes to policies and procedures.* (1) Covered entities must review and revise the policies and procedures required by paragraphs (b) through (g) of this section, as necessary, to ensure they are current and in compliance with section 1557 and this part; and

(2) A covered entity may change a policy or procedure required by paragraphs (b) through (g) of this section at any time, provided that such changes comply with section 1557 and this part.

§ 92.9 Training.

(a) A covered entity must train relevant employees of its health programs and activities on the civil rights policies and procedures required by § 92.8, as necessary and appropriate for the employees to carry out their functions within the covered entity consistent with the requirements of this part.

(b) A covered entity must provide training that meets the requirements of paragraph (a) of this section, as follows:

(1) To each relevant employee of the health program or activity as soon as possible, but no later than 30 days following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than 300 days following July 5, 2024;

(2) Thereafter, to each new relevant employee of the health program or activity within a reasonable period of time after the employee joins the covered entity's workforce; and

(3) To each relevant employee of the health program or activity whose functions are affected by a material change in the policies or procedures required by § 92.8 and any other civil rights policies or procedures the covered entity has implemented within a reasonable period of time after the material change has been made.

(4) For purposes of this section, ''relevant employees'' includes permanent and temporary employees whose roles and responsibilities entail interacting with patients and members of the public; making decisions that directly or indirectly affect patients' health care, including the covered entity's executive leadership team and legal counsel; and performing tasks and making decisions that directly or indirectly affect patients' financial obligations, including billing and collections.

(c) A covered entity must contemporaneously document its employees' completion of the training required by paragraphs (a) and (b) of this section in written or electronic form and retain said documentation for no less than three (3) calendar years.

§ 92.10 Notice of nondiscrimination.

(a) A covered entity must provide a notice of nondiscrimination to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public.

(1) The notice required under this paragraph (a) must include the following information relating to the covered entity's health programs and activities:

(i) The covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability;

(ii) The covered entity provides reasonable modifications for individuals with disabilities, and appropriate

auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, such as braille or large print, free of charge and in a timely manner, when such modifications, aids, and services are necessary to ensure accessibility and an equal opportunity to participate to individuals with disabilities;

(iii) The covered entity provides language assistance services, including electronic and written translated documents and oral interpretation, free of charge and in a timely manner, when such services are a reasonable step to provide meaningful access to an individual with limited English proficiency;

(iv) How to obtain from the covered entity the reasonable modifications, appropriate auxiliary aids and services, and language assistance services in paragraphs (a)(1)(ii) and (iii) of this section;

(v) The contact information for the covered entity's Section 1557 Coordinator designated pursuant to § 92.7 (if applicable);

(vi) The availability of the covered entity's grievance procedure pursuant to § 92.8(c) and how to file a grievance (if applicable);

(vii) Details on how to file a discrimination complaint with OCR in the Department; and

(viii) How to access the covered entity's website, if it has one, that provides the information required under this paragraph (a)(1).

(2) The notice required under this paragraph (a) must be provided in a covered entity's health program or activity, as follows:

(i) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(ii) Upon request;

(iii) At a conspicuous location on the covered entity's health program or activity website, if it has one; and

(iv) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

(b) A covered entity may combine the content of the notice required by paragraph (a) of this section with the notices required by 45 CFR 80.6(d), 84.8, 86.9, and 91.32 if the combined notice clearly informs individuals of their civil rights under section 1557 and this part, so long as it includes each of the elements required by paragraph (a)(1) of this section.

§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.

(a) A covered entity must provide a notice of availability of language assistance services and auxiliary aids and services that, at minimum, states that the covered entity, in its health programs or activities, provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part, to participants, beneficiaries, enrollees, and applicants of its health program or activities, and members of the public.

(b) The notice required under paragraph (a) of this section must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States in which a covered entity operates and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(c) The notice required under paragraph (a) of this section must be provided in a covered entity's health program or activity, as follows:

(1) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(2) Upon request;

(3) At a conspicuous location on the covered entity's health program or activity website, if it has one;

(4) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice; and

(5) In the following electronic and written communications when these forms are provided by a covered entity:

(i) Notice of nondiscrimination required by § 92.10;

(ii) Notice of privacy practices required by 45 CFR 164.520;

(iii) Application and intake forms;

(iv) Notices of denial or termination of eligibility, benefits or services, including Explanations of Benefits, and notices of appeal and grievance rights;

(v) Communications related to an individual's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;

(vi) Communications related to a public health emergency;

(vii) Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);

(viii) Discharge papers;

(ix) Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B–6 of the Public Health Service Act;

(x) Complaint forms; and

(xi) Patient and member handbooks.

(d) A covered entity shall be deemed in compliance with this section with respect to an individual if it exercises the option to:

(1) On an annual basis, provide the individual with the option to opt out of receipt of the notice required by this section in their primary language and through any appropriate auxiliary aids and services, and:

(i) Does not condition the receipt of any aid or benefit on the individual's decision to opt out;

(ii) Informs the individual that they have a right to receive the notice upon request in their primary language and through the appropriate auxiliary aids and services;

(iii) Informs the individual that opting out of receiving the notice is not a waiver of their right to receive language assistance services and any appropriate auxiliary aids and services as required by this part;

(iv) Documents, on an annual basis, that the individual has opted out of receiving the notice required by this section for that year; and

(v) Does not treat a non-response from an individual as a decision to opt out; or

(2) Document the individual's primary language and any appropriate auxiliary aids and services and:

(i) Provides all materials and communications in that individual's primary language and through any appropriate auxiliary aids and services; or

(ii) Provides the notice required by paragraph (a) of this section in that individual's primary language and through any appropriate auxiliary aids and services in all communications that are identified in paragraph (c)(5) of this section.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in title I of the ACA, an individual must not, on the basis of race, color, national origin, sex, age, disability, or any combination thereof, be excluded from

participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

(2) Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of:

(i) Sex characteristics, including intersex traits;

(ii) Pregnancy or related conditions;

(iii) Sexual orientation;

(iv) Gender identity; and

(v) Sex stereotypes.

(b) *Specific prohibitions on discrimination.* (1) In any health program or activity to which this part applies:

(i) A recipient and State Exchange must comply with the specific prohibitions on discrimination in the Department's implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 84, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term ''recipient,'' the term ''recipient or State Exchange'' shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(ii) The Department, including Federally-facilitated Exchanges, must comply with specific prohibitions on discrimination in the Department's implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 85, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term ''a recipient,'' the term ''the Department or a Federally-facilitated Exchange'' shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(2) The enumeration of specific prohibitions on discrimination in paragraph (b)(1) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency (including companions with limited English proficiency) eligible to be served or likely to be directly affected by its health programs and activities.

(b) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making ability of the individual with limited English proficiency.

(c) *Specific requirements for interpreter and translation services.* (1) When interpretation services are required under this part, a covered entity must offer a qualified interpreter in its health programs and activities.

(2) When translation services are required under this part, a covered entity must utilize the services of a qualified translator in its health programs and activities.

(3) If a covered entity uses machine translation when the underlying text is critical to the rights, benefits, or meaningful access of an individual with limited English proficiency, when accuracy is essential, or when the source documents or materials contain complex, non-literal or technical language, the translation must be reviewed by a qualified human translator.

(d) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including the effectiveness of the covered entity's written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to § 92.8(d).

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity must not, in its health programs and activities:

(1) Require an individual with limited English proficiency to provide their own interpreter, or to pay the cost of their own interpreter;

(2) Rely on an adult, not qualified as an interpreter, to interpret or facilitate communication, except:

(i) As a temporary measure, while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with an initial adult interpreter; or

(ii) Where the individual with limited English proficiency specifically requests, in private with a qualified interpreter present and without an accompanying adult present, that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, the request and agreement by the accompanying adult is documented, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with the minor child; or

(4) Rely on staff other than qualified interpreters, qualified translators, or qualified bilingual/multilingual staff to communicate with individuals with limited English proficiency.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's face and the participating person's face regardless of the person's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Audio remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through audio remote interpreting

services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time audio over a dedicated high-speed, wide-bandwidth connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(2) A clear, audible transmission of voices; and

(3) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the remote interpreting services.

(h) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity must take appropriate steps to ensure that communications with individuals with disabilities (including companions with disabilities), are as effective as communications with non-disabled individuals in its health programs and activities, in accordance with the standards found at 28 CFR 35.130 and 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''covered entity'' shall apply in its place.

(b) A covered entity must provide appropriate auxiliary aids and services where necessary to afford individuals with disabilities an equal opportunity to participate in, and enjoy the benefits of, the health program or activity in question. Such auxiliary aids and services must be provided free of charge, in accessible formats, in a timely manner, and in such a way to protect the privacy and the independence of the individual with a disability.

§ 92.203 Accessibility for buildings and facilities.

(a) No qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange must comply with the 2010 Standards if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility must comply with the 2010 Standards if the construction or alteration was commenced after January 18, 2018. If construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS, and the facility or part of the facility was not covered by the 2010 Standards prior to July 18, 2016, then it shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b). Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section must comply with the requirements for a ''public building or facility'' as defined in section 106.5 of the 2010 Standards.

(c) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with UFAS shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction or alteration was commenced before July 18, 2016, and such facility would not have been required to conform with a different accessibility standard under 28 CFR 35.151.

§ 92.204 Accessibility of information and communication technology for individuals with disabilities.

(a) A covered entity must ensure that its health programs and activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. If an action required to comply with this section would result in such an alteration or such burdens, a covered entity shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services of the health program or activity provided by the covered entity.

(b) A recipient or State Exchange shall ensure that its health programs and activities provided through websites and mobile applications comply with the requirements of section 504 of the Rehabilitation Act, as interpreted consistent with title II of the ADA (42 U.S.C. 12131 through 12165).

§ 92.205 Requirement to make reasonable modifications.

A covered entity must make reasonable modifications to policies, practices, or procedures in its health programs and activities when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term ''reasonable modifications'' shall be interpreted in a manner consistent with the term as set forth in the ADA title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

(a) A covered entity must provide individuals equal access to its health programs and activities without discriminating on the basis of sex.

(b) In providing access to health programs and activities, a covered entity must not:

(1) Deny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(2) Deny or limit, on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them

to discrimination on the basis of sex under a covered health program or activity;

(3) Adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity; or

(4) Deny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded.

(c) Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.207 Nondiscrimination in health insurance coverage and other health-related coverage.

(a) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof.

(b) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew health insurance coverage or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, disability, or any combination thereof;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof, in health insurance coverage or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care;

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex; or

(6) Have or implement benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities, including practices that result in the serious risk of institutionalization or segregation.

(c) Nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements. Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.208 Prohibition on sex discrimination related to marital, parental, or family status.

In determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex, as defined in § 92.101(a)(2), into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs and activities on the basis of the respective race, color, national origin, sex, age, or disability of the individual and another person with whom the individual or entity has a relationship or association.

§ 92.210 Nondiscrimination in the use of patient care decision support tools.

(a) *General prohibition.* A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the use of patient care decision support tools.

(b) *Identification of risk.* A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

(c) *Mitigation of risk.* For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

§ 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services.

A covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

The enforcement mechanisms available for and provided under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of section 1557 as implemented by this part.

§ 92.302 Notification of views regarding application of Federal religious freedom and conscience laws.

(a) *General application.* A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular

provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply.

(b) *Assurance of religious freedom and conscience exemption.* A recipient that seeks assurance consistent with paragraph (a) of this section regarding the application of particular provision(s) of this part to specific contexts, procedures, or health care services may do so by submitting a notification in writing to the Director of OCR. Notification may be provided by the recipient at any time, including before an investigation is initiated or during the pendency of an investigation. The notification must include:

(1) The particular provision(s) of this part from which the recipient asserts they are exempt under Federal religious freedom or conscience protections;

(2) The legal basis supporting the recipient's exemption should include the standards governing the applicable Federal religious freedom and conscience protections, such as the provisions in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of the Religious Freedom Restoration Act (RFRA); or any other applicable Federal laws; and

(3) The factual basis supporting the recipient's exemption, including identification of the conflict between the recipient's religious or conscience beliefs and the requirements of this part, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their religious or conscience beliefs overall or based on an individual patient matter.

(c) *Temporary exemption.* A temporary exemption from administrative investigation and enforcement will take effect upon the recipient's submission of the notification—regardless of whether the assurance is sought before or during an investigation. The temporary exemption is limited to the application of the particular provision(s) in this part as applied to the specific contexts, procedures, or health care services identified in the notification to OCR.

(1) If the notification is received before an investigation is initiated, within 30 days of receiving the notification, OCR must provide the recipient with email confirmation acknowledging receipt of the notification. OCR will then work expeditiously to reach a determination of recipient's notification request.

(2) If the notification is received during the pendency of an investigation, the temporary exemption will exempt conduct as applied to the specific contexts, procedures, or health care services identified in the notification during the pendency of OCR's review and determination regarding the notification request. The notification shall further serve as a defense to the relevant investigation or enforcement activity regarding the recipient until the final determination of recipient's exemption assurance request or the conclusion of the investigation.

(d) *Effect of determination.* If OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of this part or that modified application of certain provision(s) is required, OCR will provide the recipient its determination in writing, and if granted, the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or health care services provided. The determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

(e) *Appeal.* A recipient subject to an adverse determination of its request for an exemption assurance may appeal OCR's determination under the administrative procedures set forth at 45 CFR part 81. The temporary exemption provided for in paragraph (c) of this section will expire upon a final decision under 45 CFR part 81.

(f) *Final agency action.* A determination under this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

§ 92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.

(a) The procedural provisions applicable to title VI apply with respect to administrative enforcement actions against health programs and activities of recipients and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

(b) If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.

(c) When a recipient or State Exchange fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach voluntary resolution, find noncompliance with section 1557 or this part and initiate appropriate enforcement procedures, found at 45 CFR 80.8, including beginning the process for fund suspension or termination and taking other action authorized by law.

§ 92.304 Procedures for health programs and activities administered by the Department.

(a) The procedural provisions applicable to section 504 shall apply with respect to administrative enforcement actions against the Department, including Federally-facilitated Exchanges, concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 85.61 and 85.62. Where this section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability, or any combination thereof,'' shall apply in its place.

(b) The Department must permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or person, and the other agency, institution or person fails or refuses to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(c) The Department must not intimidate, threaten, coerce, retaliate, or otherwise discriminate against any individual or entity for the purpose of interfering with any right or privilege secured by section 1557 or this part, or because such individual or entity has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under section 1557 or this part. The identity of complainants must be kept confidential by OCR in accordance with applicable Federal law.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 16. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 17. Amend § 147.104 by revising paragraph (e) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 18. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 19. Amend § 155.120 by revising paragraph (c)(1)(ii) to read as follows:

§ 155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) * * *

(1) * * *

(ii) Not discriminate based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

* * * * *

■ 20. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes);

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 21. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 22. Amend § 156.200 by revising paragraph (e) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

* * * * *

■ 23. Amend § 156.1230 by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

[FR Doc. 2024–08711 Filed 4–26–24; 4:15 pm]

BILLING CODE 4153–01–P

FEDERAL REGISTER

Vol. 89 Monday,

No. 88 May 6, 2024

Part V

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 301

Clean Vehicle Credits Under Sections 25E and 30D; Transfer of Credits; Critical Minerals and Battery Components; Foreign Entities of Concern; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9995]

RIN 1545–BQ52; RIN 1545–BQ86; RIN 1545–BQ99

Clean Vehicle Credits Under Sections 25E and 30D; Transfer of Credits; Critical Minerals and Battery Components; Foreign Entities of Concern

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding Federal income tax credits under the Inflation Reduction Act of 2022 (IRA) for the purchase of qualifying new and previously-owned clean vehicles, including new and previously-owned plug-in electric vehicles powered by an electric battery meeting certain requirements and new qualified fuel cell motor vehicles. In addition, the final regulations provide guidance for taxpayers who purchase qualifying vehicles and intend to transfer the amount of any previously-owned clean vehicle credit or new clean vehicle credit to dealers that are entities eligible to receive advance payments of either credit. The final regulations also provide guidance for dealers to become eligible entities to receive advance payments of previously-owned clean vehicle credits or new clean vehicle credits, and rules regarding recapture of the credits. Finally, the final regulations provide guidance on the meaning of three new definitions added to the exclusive list of mathematical or clerical errors relating to certain assessments of tax without a notice of deficiency.

DATES:

Effective date: These regulations are effective on July 5, 2024.

Applicability dates: For dates of applicability, *see* §§ 1.25E–1(h), 1.25E–2(i), 1.25E–3(k), 1.30D–1(d), 1.30D–2(d), 1.30D–3(h), 1.30D–4(j), 1.30D–5(k), 1.30D–6(j), and 301.6213–2(c).

FOR FURTHER INFORMATION CONTACT: Rika Valdman or Maggie Stehn of the Office of Associate Chief Counsel (Passthroughs & Special Industries) at (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 25E and 30D of the Internal Revenue Code (Code), and to the Procedure and Administration Regulations (26 CFR part 301) under section 6213 of the Code.

I. Section 25E

Section 13402 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly known as the IRA, added section 25E to the Code. The credit under section 25E (section 25E credit) is a personal credit allowable under subpart A of the Code.

Section 25E(a) provides that, in the case of a qualified buyer who during a taxable year places in service a previously-owned clean vehicle, an income tax credit is allowed for the taxable year equal to the lesser of: (1) $4,000, or (2) the amount equal to 30 percent of the sale price with respect to such vehicle.

Section 25E(b)(1) sets a limitation based on modified adjusted gross income (Modified AGI) and provides that no credit is allowed for any taxable year if (A) the lesser of (i) the Modified AGI of the taxpayer for such taxable year, or (ii) the Modified AGI of the taxpayer for the preceding taxable year, exceeds (B) the threshold amount. The threshold amount is set forth in section 25E(b)(2) and varies based on a taxpayer's filing status. In the case of a taxpayer filing a joint return or who is a surviving spouse (as defined in section 2(a) of the Code), the threshold amount is $150,000. In the case of a taxpayer who is a head of household (as defined in section 2(b)), the threshold amount is $112,500. In the case of any other taxpayer, the threshold amount is $75,000. Section 25E(b)(3) defines Modified AGI as adjusted gross income (AGI) increased by any amount excluded from gross income under section 911, 931, or 933 of the Code.

Section 25E(c) defines certain terms for purposes of the section 25E credit. Section 25E(c)(1) defines ''previously-owned clean vehicle'' as a motor vehicle:

(A) the model year of which is at least 2 years earlier than the calendar year in which the taxpayer acquires such vehicle;

(B) the original use of which commences with a person other than the taxpayer;

(C) that is acquired by the taxpayer in a qualified sale; and

(D) that (i) meets the requirements of section 30D(d)(1)(C), (D), (E), (F), and (H) (except for section 30D(d)(1)(H)(iv)), or (ii) is a motor vehicle that (I) satisfies the requirements under section 30B(b)(3)(A) and (B), and (II) has a gross vehicle weight rating (GVWR) of less than 14,000 pounds.

Section 25E(c)(2) defines a ''qualified sale'' as a sale of a motor vehicle (A) by a dealer (as defined in section 30D(g)(8)); (B) for a sale price that does not exceed $25,000; and (C) that is the first transfer since the date of enactment of the IRA to a qualified buyer other than the person with whom the original use of such vehicle commenced.

Under section 25E(c)(3), ''qualified buyer'' means, with respect to a sale of a motor vehicle, a taxpayer (A) who is an individual; (B) who purchases such vehicle for use and not for resale; (C) with respect to whom no deduction is allowable with respect to another taxpayer under section 151 of the Code; and (D) who has not been allowed a section 25E credit for any sale during the 3-year period ending on the date of the sale of such vehicle.

Section 25E(c)(4) defines ''motor vehicle'' and ''capacity'' to have the meaning given such terms in section 30D(d)(2) and (4), respectively.

Section 25E(d) provides that no credit is allowed under section 25E(a) with respect to any vehicle unless the taxpayer includes the vehicle identification number (VIN) of such vehicle on the return of tax for the taxable year.

Section 25E(e) and (f) provide, respectively, that rules similar to the rules of section 30D(f) (without regard to paragraph (10) or (11) thereof) and the rules of section 30D(g) apply for purposes of section 25E. Section 13402(e)(2) of the IRA provides that the ability of a taxpayer to elect to transfer a section 25E credit under section 25E(f) applies to vehicles placed in service by the taxpayer after December 31, 2023.

Section 25E(g) provides that no section 25E credit is allowed with respect to a vehicle acquired after December 31, 2032.

II. Section 30D

A. In General

Section 30D(a) provides a credit (section 30D credit) with respect to each new clean vehicle that a taxpayer purchases and places in service. The credit is determined and allowable with respect to the taxable year in which the taxpayer places the new clean vehicle in service.

Section 30D was originally enacted by section 205(a) of the Energy Improvement and Extension Act of 2008, Division B of Public Law 110–343, 122 Stat. 3765, 3835 (October 3, 2008), to provide a credit for the purchase and placing in service of new qualified plug-in electric drive motor vehicles. Section 30D has been amended several times

since its enactment, most recently by section 13401 of the IRA.

The amount of the section 30D credit is treated as a personal credit or a general business credit, depending on the character of the vehicle. In general, the section 30D credit is treated as a personal credit allowable under subpart A of the Code. Section 30D(c)(2). However, the amount of the section 30D credit that is attributable to property that is of a character subject to an allowance for depreciation is treated as a current year business credit under section 38(b) instead of being allowed under section 30D(a). Section 30D(c)(1). Section 38(b)(30) lists as a current year business credit the portion of the section 30D credit to which section 30D(c)(1) applies. The IRA did not amend section 30D(c)(1) or (2).

B. IRA Amendments to Section 30D

1. Credit Amount and Critical Minerals and Battery Components Requirements

The IRA amends the rules for determining the amount of the section 30D credit. Prior to the amendments to section 30D made by section 13401(a) and (e) of the IRA, the amount of the section 30D credit was calculated based on the vehicle's battery capacity. The base amount was $2,500, plus $417 for a battery with a capacity of at least 5 kilowatt hours, and an additional $417 for each kilowatt hour of capacity in excess of 5 kilowatt hours, up to a maximum credit of $7,500 per vehicle. Section 13401(a) of the IRA amends section 30D(b) to provide a maximum credit of $7,500 per vehicle, consisting of $3,750 in the case of a vehicle that meets certain requirements relating to critical minerals and $3,750 in the case of a vehicle that meets certain requirements relating to battery components. The amendments made by section 13401(a) of the IRA apply to vehicles placed in service after the date on which the Secretary of the Treasury or her delegate (Secretary) issues proposed guidance described in new section 30D(e)(3)(B) of the Code relating to the new critical minerals requirements described in new section 30D(e)(1)(A) (Critical Minerals Requirement) and the new battery components requirements described in new section 30D(e)(2)(A) (Battery Components Requirement). *See* section 13401(k)(3) of the IRA.

New section 30D(e)(1)(A) provides that the Critical Minerals Requirement with respect to the battery from which the electric motor of a vehicle draws electricity is satisfied if the percentage of the value of the applicable critical minerals (as defined in section 45X(c)(6) of the Code) contained in such battery that were (i) extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or (ii) recycled in North America, is equal to or greater than the applicable percentage (as certified by the qualified manufacturer, in such form or manner as prescribed by the Secretary). The applicable percentage for the Critical Minerals Requirement is set forth in section 30D(e)(1)(B)(i) through (v), and varies based on when the vehicle is placed in service. In the case of a vehicle placed in service after the date of issuance of the proposed guidance described in new section 30D(e)(3)(B) and before January 1, 2024, the applicable percentage is 40 percent. In the case of a vehicle placed in service during calendar year 2024, 2025, and 2026, the applicable percentage is 50 percent, 60 percent, and 70 percent, respectively. In the case of a vehicle placed in service after December 31, 2026, the applicable percentage is 80 percent.

New section 30D(e)(2)(A) provides that the Battery Components Requirement with respect to the battery from which the electric motor of a vehicle draws electricity is satisfied if the percentage of the value of the components contained in such battery that were manufactured or assembled in North America is equal to or greater than the applicable percentage (as certified by the qualified manufacturer, in such form or manner as prescribed by the Secretary). The applicable percentage for the Battery Components Requirement is set forth in section 30D(e)(2)(B)(i) through (vi) and varies based on when the vehicle is placed in service. In the case of a vehicle placed in service after the date of issuance of the proposed guidance described in new section 30D(e)(3)(B) of the Code and before January 1, 2024, the applicable percentage is 50 percent. In the case of a vehicle placed in service during calendar year 2024 or 2025, the applicable percentage is 60 percent. In the case of a vehicle placed in service during calendar year 2026, 2027, and 2028, the applicable percentage is 70 percent, 80 percent, and 90 percent, respectively. In the case of a vehicle placed in service after December 31, 2028, the applicable percentage is 100 percent.

2. New Clean Vehicle Definition

Section 13401(c) of the IRA amends section 30D(d) of the Code by making the credit applicable to ''new clean vehicles,'' instead of ''new qualified plug-in electric drive motor vehicles.'' This amendment is applicable to vehicles placed in service after December 31, 2022. As amended by section 13401(c) and (g)(2) of the IRA, section 30D(d)(1) of the Code defines a ''new clean vehicle'' as a motor vehicle that satisfies the eight requirements set forth in section 30D(d)(1)(A) through (H) of the Code: the original use of the motor vehicle must commence with the taxpayer; the motor vehicle must be acquired for use or lease by the taxpayer and not for resale; the motor vehicle must be made by a qualified manufacturer; the motor vehicle must be treated as a motor vehicle for purposes of title II of the Clean Air Act; the motor vehicle must have a gross vehicle weight rating of less than 14,000 pounds; the motor vehicle must be propelled to a significant extent by an electric motor that draws electricity from a battery that has a capacity of not less than 7 kilowatt hours, and is capable of being recharged from an external source of electricity; the final assembly of the motor vehicle must occur within North America; and the person who sells any vehicle to the taxpayer must furnish a report to the taxpayer and to the Secretary, at such time and in such manner as the Secretary provides, containing specifically enumerated items.

With respect to the requirement that the motor vehicle must be made by a qualified manufacturer, the IRA creates new requirements for manufacturers of vehicles eligible for the section 30D credit that are applicable to vehicles placed in service after December 31, 2022. As amended by section 13401(c) of the IRA, section 30D(d)(3) of the Code defines a ''qualified manufacturer'' as any manufacturer (within the meaning of the regulations prescribed by the Administrator of the Environmental Protection Agency (EPA) for purposes of the administration of title II of the Clean Air Act (42 U.S.C. 7521 *et seq.*)) that enters into a written agreement with the Secretary under which such manufacturer agrees to make periodic written reports to the Secretary (at such times and in such manner as the Secretary may provide) providing vehicle identification numbers and such other information related to each vehicle manufactured by such manufacturer as the Secretary may require.

The IRA requires new clean vehicles to undergo final assembly in North America to be eligible for the section 30D credit. This requirement is applicable to vehicles sold after August 16, 2022. *See* section 13401(k)(2) of the IRA. New section 30D(d)(5) defines ''final assembly'' as the process by which a manufacturer produces a new

clean vehicle at, or through the use of, a plant, factory, or other place from which the vehicle is delivered to a dealer or importer with all component parts necessary for the mechanical operation of the vehicle included with the vehicle, whether or not the component parts are permanently installed in or on the vehicle.

The IRA provides that certain fuel cell vehicles may qualify for the section 30D credit. Section 13401(c) of the IRA adds new section 30D(d)(6) to the Code, which includes in the definition of the term ''new clean vehicle'' applicable to vehicles placed in service after December 31, 2022, any ''new qualified fuel cell motor vehicle'' (as defined in section 30B(b)(3)) that meets the requirements under section 30D(d)(1)(G) and (H) (North American final assembly and seller reporting requirements).

The IRA disqualifies certain vehicles from the section 30D credit if the battery of the vehicle contains critical minerals or battery components from a foreign entity of concern (FEOC). As amended by section 13401(e) of the IRA, section 30D(d)(7) of the Code excludes, after certain specified dates, vehicles placed in service with batteries containing certain critical minerals or battery components from a FEOC from the definition of the term ''new clean vehicle.'' In particular, amended section 30D(d)(7) (FEOC Restriction) provides that the term ''new clean vehicle'' does not include (A) any vehicle placed in service after December 31, 2024, with respect to which any of the applicable critical minerals contained in the battery of such vehicle (as described in section 30D(e)(1)(A)) were extracted, processed, or recycled by a FEOC (as defined in section 40207(a)(5) of the Infrastructure Investment and Jobs Act (42 U.S.C. 18741(a)(5))), or (B) any vehicle placed in service after December 31, 2023, with respect to which any of the components contained in the battery of such vehicle (as described in section 30D(e)(2)(A)) were manufactured or assembled by a FEOC (as so defined).

3. Elimination of Phaseout

The IRA eliminates the phaseout of the section 30D credit for vehicles made by manufacturers that have sold at least 200,000 vehicles eligible for the credit for use in the United States after December 31, 2009. Pursuant to section 13401(d) of the IRA this limitation does not apply to vehicles sold after December 31, 2022. *See* section 13401(k)(5) of the IRA.

4. Special Rules

The IRA adds four new special rules under section 30D(f) applicable to vehicles placed in service after December 31, 2022. First, section 30D(f)(8) permits only one section 30D credit to be claimed for each VIN. Second, section 30D(f)(9) requires taxpayers to include on the taxpayer's return for the taxable year the VIN of the vehicle for which the section 30D credit is claimed.

Third, section 30D(f)(10) denies the section 30D credit to certain high-income taxpayers. More specifically, section 30D(f)(10)(A) provides that no credit is allowed for any taxable year if (i) the lesser of (I) the Modified AGI of the taxpayer for such taxable year, or (II) the Modified AGI of the taxpayer for the preceding taxable year, exceeds (ii) the threshold amount. New section 30D(f)(10)(B) provides that the threshold amount is: (i) in the case of a joint return or a surviving spouse (as defined in section 2(a) of the Code), $300,000, (ii) in the case of a head of household (as defined in section 2(b) of the Code), $225,000, and (iii) in the case of any other taxpayer, $150,000. New section 30D(f)(10)(C) defines Modified AGI as AGI increased by any amount excluded from gross income under sections 911, 931, or 933.

Fourth, section 30D(f)(11) excludes from the section 30D credit vehicles that exceed certain manufacturer's suggested retail price (MSRP) thresholds. New section 30D(f)(11)(A) provides that no credit is allowed for a vehicle if the MSRP of the vehicle exceeds the applicable limitation. New section 30D(f)(11)(B) provides that the applicable limitation for each vehicle classification is as follows: in the case of a van, $80,000; in the case of a sport utility vehicle, $80,000; in the case of a pickup truck, $80,000; and in the case of any other vehicle, $55,000. New section 30D(f)(11)(C) authorizes the Secretary to prescribe such regulations or other guidance as the Secretary determines necessary to determine vehicle classifications using criteria similar to that employed by the EPA and the Department of the Energy (DOE) to determine size and class of vehicles.

5. Transfer of Credit

The IRA added new section 30D(g) to the Code, which allows the taxpayer to elect to transfer the section 30D credit in certain situations for vehicles placed in service after December 31, 2023.

Section 30D(g)(1) provides that subject to such regulations or other guidance as the Secretary determines necessary, a taxpayer may elect to transfer a section 30D credit with respect to a new clean vehicle to an eligible entity (credit transfer election).[1] If the taxpayer who acquires a new clean vehicle makes a credit transfer election under section 30D(g) with respect to such vehicle, the section 30D credit that would otherwise be allowed to such taxpayer with respect to such vehicle is allowed to the eligible entity specified in such election (and not the taxpayer).

Section 30D(g)(2) defines an ''eligible entity'' with respect to the vehicle for which the section 30D credit is allowed as the dealer that sold such vehicle to the taxpayer and that satisfies the following four requirements set forth in section 30D(g)(2)(A) through (D): (i) the dealer, subject to section 30D(g)(4), must be registered with the Secretary for purposes of section 30D(g)(2), at such time, and in such form and manner, as the Secretary prescribes; (ii) the dealer, prior to the credit transfer election and not later than at the time of sale, must have disclosed to the taxpayer purchasing such vehicle the manufacturer's suggested retail price, the value of the section 30D credit allowed and any other incentive available for the purchase of such vehicle, and the amount provided by the dealer to such taxpayer as a condition of the credit transfer election; (iii) the dealer, not later than at the time of sale, must have paid the taxpayer (whether in cash or in the form of a partial payment or down payment for the purchase of such vehicle) an amount equal to the credit otherwise allowable to such taxpayer; and (iv) the dealer with respect to any incentive otherwise available for the purchase of a vehicle for which a section 30D credit is allowed, including any incentive in the form of a rebate or discount provided by the dealer or manufacturer, must have ensured that the availability or use of such incentive does not limit the ability of a taxpayer to make a credit transfer election, and such election does not limit the value or use of such incentive.

Section 30D(g)(3) addresses the timing of the transfer and provides that any credit transfer election cannot be made by the taxpayer any later than the date on which the vehicle for which the section 30D credit is allowed is purchased.

[1] As discussed in section VIII of this Background section, on October 10, 2023, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–113064–23) in the **Federal Register** (88 FR 70310), that referred to this election as the ''vehicle transfer election.'' However, ''credit transfer election'' is a more descriptive and appropriate term, so these final regulations adopt the defined term ''credit transfer election'' to refer to the election by a taxpayer to transfer a section 25E or section 30D credit to an eligible entity.

Section 30D(g)(4) provides that upon determination by the Secretary that a dealer has failed to comply with the requirements described in section 30D(g)(2), the Secretary may revoke the dealer's registration.

Section 30D(g)(5) provides that with respect to any payment described in section 30D(g)(2)(C), such payment is not includible in the gross income of the taxpayer and is not deductible with respect to the dealer.

Section 30D(g)(6) addresses the application of certain other requirements to the transfer of credit and provides that in the case of any credit transfer election with respect to any vehicle: (i) the basis reduction and no double benefit requirements of section 30D(f)(1) and (2) apply to the taxpayer who acquired the vehicle in the same manner as if the section 30D credit determined with respect to such vehicle were allowed to such taxpayer; (ii) the election in section 30D(f)(6) to not take the section 30D credit does not apply; and (iii) the VIN requirement of section 30D(f)(9) is treated as satisfied if the eligible entity provides the VIN of such vehicle to the Secretary in such manner as the Secretary may provide.

Section 30D(g)(7)(A) provides for the establishment of a program to make advance payments to eligible entities in an amount equal to the cumulative amount of the credits allowed with respect to any vehicles sold by such entity for which a credit transfer election described in section 30D(g)(1) has been made. Section 30D(g)(7)(B) provides that rules similar to the rules of section 6417(d)(6) of the Code apply for purposes of the advance payment rules, and section 30D(g)(7)(C) provides that for purposes of 31 U.S.C. 1324, the payments under section 30D(g)(7)(A) are treated in the same manner as a refund due from a credit provision referred to in 31 U.S.C. 1324(b)(2).

Section 30D(g)(8) defines the term ''dealer'' as a person licensed by a State, the District of Columbia, the Commonwealth of Puerto Rico, any other territory or possession of the United States, an Indian tribal government, or any Alaska Native Corporation (as defined in section 3 of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(m)) to engage in the sale of vehicles. Section 30D(g)(9) defines an ''Indian tribal government'' as the recognized governing body of any Indian or Alaska Native tribe, band, nation, pueblo, village, community, component band, or component reservation, individually identified (including parenthetically) in the list published most recently as of the date of enactment of section 30D(g) (that is, August 16, 2022) pursuant to section 104 of the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 5131).

Section 30D(g)(10) provides that in the case of any taxpayer who has made a credit transfer election with respect to a new clean vehicle and received a payment from an eligible entity, if the section 30D credit would otherwise (but for section 30D(g)) not be allowable to such taxpayer pursuant to the application of the Modified AGI limitation of section 30D(f)(10), the income tax imposed on such taxpayer under chapter 1 of the Code for the taxable year in which such vehicle was placed in service must be increased by the amount of the payment received by such taxpayer.

Section 13401(k)(4) of the IRA provides that the ability for a taxpayer to elect to transfer a section 30D credit under section 30D(g) applies to vehicles placed in service after December 31, 2023.

6. Termination

The IRA added new section 30D(h) to the Code, which provides that no credit is allowed with respect to any vehicle placed in service after December 31, 2032.

III. Section 45W

Section 13403(a) of the IRA added section 45W to the Code, which is effective for vehicles acquired after December 31, 2022, and before January 1, 2033. A taxpayer can claim a section 45W credit for purchasing and placing in service a qualified commercial clean vehicle, as defined in section 45W(c), during the taxable year. Section 45W(e) provides that no section 45W credit is allowed with respect to any vehicle unless the taxpayer includes the VIN of such vehicle on the tax return for the taxable year.

IV. Section 6213(g)(2)

Section 6213(b)(1) authorizes the IRS to make certain assessments of mathematical or clerical errors without first issuing a notice of deficiency under section 6213(a). Section 13401(i)(4) of the IRA amended section 6213(g)(2) to provide the IRS with math error authority for the omission of a correct VIN required under sections 25E(d), 30D(f)(9), and 45W(e) to be included on a return. *See* section 6213(g)(2)(T)-(V).

V. Notice 2022–46

On October 24, 2022, the Treasury Department and the IRS published Notice 2022–46, 2022–43 I.R.B. 306. The notice requested general comments on issues arising under sections 25E and 30D. Regarding section 30D, the notice requested specific comments concerning: (1) definitions; (2) critical minerals; (3) battery components; (4) applicable values; (5) FEOCs; (6) recordkeeping and reporting; (7) tax-exempt entities; (8) registered dealers and eligible entities; (9) the final assembly requirement; (10) vehicle classifications; (11) elections to transfer and advance payments; and (12) recapture. Regarding section 25E, the notice requested specific comments concerning: (1) qualification as a ''previously-owned clean vehicle''; (2) the rules of section 30D(f) that should be applied under section 25E(e); (3) the rules of section 30D(g) that should be applied under section 25E; and (4) terms that may require definitions or further guidance. Stakeholders submitted more than 800 comments in response to Notice 2022–46. Those comments informed the development of the notices of proposed rulemaking relating to sections 25E and 30D discussed in section VII of this Background section.

VI. Revenue Procedures

On December 27, 2022, the Treasury Department and the IRS published Revenue Procedure 2022–42, 2022–52 I.R.B. 565, which sets forth the procedures under section 30D(d)(3) for qualified manufacturers to enter into a written agreement with the Secretary under which such manufacturer agrees to make periodic written reports to the Secretary providing VINs and such other information related to each vehicle manufactured by such manufacturer as the Secretary may require. The revenue procedure also provides the procedures for persons selling vehicles to report the information required to be reported to the IRS in order for such vehicles to be eligible for the section 25E credit or the section 30D credit.

On October 23, 2023, the Treasury Department and the IRS published Revenue Procedure 2023–33, 2023–43 I.R.B. 1135. The revenue procedure sets forth the procedures under sections 25E(f) and 30D(g) for the transfer of the section 25E credit and the 30D credit from the taxpayer to an eligible entity. In addition, the revenue procedure supersedes certain provisions of Rev. Proc. 2022–42.

On December 18, 2023, the Treasury Department and the IRS published Revenue Procedure 2023–38, 2023–51 I.R.B. 1544. The revenue procedure provides procedural rules for qualified manufacturers of new clean vehicles to comply with the reporting, certification, and attestation requirements regarding the excluded entity restriction, under which the IRS, with analytical

assistance from the DOE, will review compliance with the excluded entity restrictions. In addition, Rev. Proc. 2023–38 updates and consolidates the procedural rules for qualified manufacturers with respect to the section 25E credit, the section 30D credit, and the qualified commercial clean vehicle credit under section 45W. The revenue procedure supersedes certain provisions of Rev. Proc. 2022–42 and Rev. Proc. 2023–33.

On February 26, 2024, the Treasury Department and the IRS published Revenue Procedure 2024–12, 2024–9 I.R.B. 677. The revenue procedure provides a temporary extension of time to submit seller reports to the IRS under the procedures set out in Rev. Proc. 2022–42 and Rev. Proc. 2023–33 for the transfer of section 25E credits and 30D credits.

VII. Notice 2023–1, Notice 2023–16, and 30D White Paper

On January 17, 2023, the Treasury Department and the IRS published Notice 2023–1, 2023–3 I.R.B. 373, which describes definitions for certain terms in section 30D that the Treasury Department and the IRS intended to include in proposed regulations.

The Treasury Department also released a white paper on the anticipated direction of the proposed guidance on the Critical Minerals Requirement and Battery Components Requirement and the process for determining whether vehicles qualify under these requirements, as of December 29, 2022. *See* ''Anticipated Direction of Forthcoming Proposed Guidance on Critical Mineral and Battery Component Value Calculations for the New Clean Vehicle Credit,'' Dec. 29, 2022, *https://home.treasury.gov/system/files/136/30DWhite-Paper.pdf* (last accessed March 16, 2024).

On February 21, 2023, the Treasury Department and the IRS published Notice 2023–16, 2023–8 I.R.B. 479, which modifies Notice 2023–1 by revising the vehicle classification standard that the Treasury Department and the IRS intended to provide in proposed regulations.

VIII. Notices of Proposed Rulemaking

On April 17, 2023, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–120080–22) in the **Federal Register** (88 FR 23370), containing proposed regulations under section 30D (April Proposed Regulations). The April Proposed Regulations provided proposed definitions for certain terms related to section 30D; proposed rules regarding personal and business use of new clean vehicles and other special rules; and additional proposed rules related to the Critical Minerals and Battery Components Requirements of section 30D(e) in proposed § 1.30D–3.

On October 10, 2023, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–113064–23) in the **Federal Register** (88 FR 70310), which provided proposed guidance for elections to transfer clean vehicle credits under sections 25E(f) and 30D(g) (October Proposed Regulations). The October Proposed Regulations provided proposed guidance for taxpayers intending to transfer the section 25E credit and the section 30D credit to dealers that are entities eligible to receive advance payments of such credits. The October Proposed Regulations also provided proposed guidance for how dealers become eligible entities to receive advance payments of the section 25E credit and the section 30D credit. In addition, the October Proposed Regulations provided proposed guidance regarding basic and definitional provisions in for section 25E, recapture of the section 25E and section 30D credits, and math error authority under section 6213.

On December 4, 2023, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–118492–23) in the **Federal Register** (88 FR 84098), which provided guidance regarding the excluded entities limitation of section 30D(d)(7) (December Proposed Regulations). The December Proposed Regulations provided proposed definitions and proposed rules for qualified manufacturers of vehicles to determine eligibility for the section 30D clean vehicle credit regarding the excluded entity restrictions, under which vehicles placed in service beginning in 2024 are not eligible if the battery contains battery components manufactured or assembled by a FEOC, and vehicles placed in service beginning in 2025 are not eligible if the battery contains applicable critical minerals extracted, processed, or recycled by a FEOC.

IX. Department of Energy Guidance

Concurrently with the release of the December Proposed Regulations, the DOE released proposed guidance in the **Federal Register**, which provides proposed interpretations of certain terms used in the definition of FEOC set forth in section 40207(a)(5) of the Infrastructure Investment and Jobs Act (IIJA), and as cross-referenced in section 30D(d)(7). Concurrently with the release of these final regulations, the DOE is releasing final regulations under section 40207(a)(5) of the IIJA.

Section 40207(a)(5) of the IIJA defines FEOC to include foreign entities covered by specific designations, inclusions, and allegations by Federal agencies as described in section 40207(a)(5)(A), (B), and (D), as well as foreign entities ''owned by, controlled by, or subject to the jurisdiction or direction of a government'' of a covered nation under section 40207(a)(5)(C). Covered nations are defined in 10 U.S.C. 4872(d)(2) as the People's Republic of China, the Russian Federation, the Democratic People's Republic of Korea, and the Islamic Republic of Iran, as of the date of publication of the these final regulations and the DOE final guidance. Finally, section 40207(a)(5)(E) of the IIJA provides that a FEOC includes a foreign entity that the Secretary of Energy, in consultation with the Secretary of Defense and the Director of National Intelligence, determines is engaged in unauthorized conduct that is detrimental to the national security or foreign policy of the United States. The DOE final guidance provides an interpretation of section 40207(a)(5)(C) of the IIJA. In particular, the DOE final guidance provides definitions for the terms ''government of a foreign country,'' ''foreign entity,'' ''subject to the jurisdiction,'' and ''owned by, controlled by, or subject to the direction of.'' In general, an entity incorporated in, headquartered in, or performing the relevant activities in a covered nation would be classified as a FEOC. For purposes of these rules, an entity would be ''owned by, controlled by, or subject to the direction'' of another entity if 25 percent or more of the entity's board seats, voting rights, or equity interest are cumulatively held by such other entity. In addition, licensing agreements or other contractual agreements may also create control. Finally, ''government of a foreign country'' is defined to include subnational governments and certain current or former senior foreign political figures.

Summary of Comments and Explanation of Revisions

The Treasury Department and the IRS received over 180 written and electronic comments in response to the April Proposed Regulations, the October Proposed Regulations, and the December Proposed Regulations (collectively, the proposed regulations). A public hearing on the proposed regulations was held on January 31, 2024. Copies of written comments and the list of speakers at the public hearing are available at *https://www.regulations.gov* or upon request.

After full consideration of the comments received on the proposed regulations and the testimony presented at the public hearing, this Treasury Decision adopts the proposed regulations with clarifying changes and additional modifications in response to the comments and testimony as described in this Summary of Comments and Explanation of Revisions.

Unless otherwise indicated in this Summary of Comments and Explanation of Revisions, provisions of the proposed regulations for which no comments were received are adopted without substantive change. Comments that merely summarize the proposed regulations, recommend statutory revisions to section 25E, section 30D, or other statutes, address issues that are outside the scope of this rulemaking (such as proposed changes to other guidance), or recommend changes to IRS forms, are beyond the scope of these regulations and are not adopted. In addition, comments that relate to the revenue procedures or notices described in section VI and VII of this Background section are beyond the scope of these regulations and are not adopted. The final regulations include non-substantive modifications, including modifications that promote consistency across definitions, rules, and examples, rearrange provisions, and improve the overall clarity of the guidance. Such modifications are not addressed in the Summary of Comments and Explanation of Revisions.

Section I of this Summary of Comments and Explanation of Revisions addresses the comments and revisions applicable only to section 25E. Section II of this Summary of Comments and Explanation of Revisions addresses the comments and revisions applicable to both section 25E and section 30D. Section III of this Summary of Comments and Explanation of Revisions addresses the comments and revisions applicable only to section 30D. Section IV of this Summary of Comments and Explanation of Revisions addresses the comments and revisions applicable to section 6213. Section V of this Summary of Comments and Explanation of Revisions addresses the applicability dates of these final regulations.

I. Section 25E Credit

A. Definitions

1. Previously-Owned Clean Vehicle

Proposed § 1.25E–1(b)(5) defined the term ''previously-owned clean vehicle'' by reference to the statutory definition provided in section 25E(c)(1). A commenter noted that the proposed definition of ''previously-owned clean vehicle'' does not address whether a previously-owned vehicle purchased from a dealership would be eligible for the section 25E credit. Another commenter requested that the Treasury Department and the IRS provide a definition of ''vehicle.''

Section 25E(c)(1) provides a definition of ''previously-owned clean vehicle'' and criteria to be considered a ''motor vehicle.'' Section 25E(c)(4) defines ''motor vehicle'' by reference to section 30D(d)(2), which defines that term as any vehicle that is manufactured primarily for use on public streets, roads, and highways (not including a vehicle operated exclusively on a rail or rails) and that has at least four wheels. Further, section 25E(c)(2) defines ''qualified sale'' in part, as a sale of a motor vehicle by the dealer. Under the plain language of section 25E, a sale of a previously-owned clean vehicle by a dealer is eligible for the section 25E credit, provided the other requirements of section 25E are satisfied. Accordingly, the final regulations do not adopt these comments.

The final regulations clarify that vehicles that may qualify as previously-owned clean vehicles include battery electric vehicles, plug-in hybrid electric vehicles, fuel cell motor vehicles, and plug-in hybrid fuel cell motor vehicles.

2. Qualified Sale

i. Motor Vehicle Reference and Price Cap

Section 25E(c)(2) defines ''qualified sale'' as a sale of a motor vehicle by a dealer (as defined in section 30D(g)(8)), for a sale price that does not exceed $25,000, and that is the first transfer since August 16, 2022 (the date of enactment of section 25E), to a qualified buyer other than the person with whom the original use of such vehicle commenced. Proposed § 1.25E–1(b)(8)(i) tracked the statutory definition.

A commenter recommended that the final regulations substitute ''previously-owned clean vehicle'' for ''motor vehicle'' in the definition of ''qualified sale'' in proposed § 1.25E–1(b)(8)(i). In addition, multiple commenters requested changes to the $25,000 maximum sale price amount in the definition of ''qualified sale.''

Section 25E(c)(2) uses the term ''motor vehicle'' in the definition of ''qualified sale.'' In order to maintain consistency with the statutory definition of ''qualified sale,'' the final regulations do not adopt this comment. With regard to the comments suggesting a change to the sale price limitation, section 25E(c)(2)(B) provides that the sale price may not exceed $25,000. Because the $25,000 sale price limitation is statutory, the final regulations do not adopt this comment.

ii. First Transfer Rule

Proposed § 1.25E–1(b)(8)(ii) provided that to be a qualified sale, a transfer must be the first transfer since August 16, 2022, as shown by vehicle history, of a previously-owned clean vehicle after the sale to the person with whom the original use of such vehicle commenced. The proposed regulation further provided that the taxpayer may rely on the dealer's provision of the vehicle history in determining whether the first transfer rule is satisfied.

A commenter recommended that the final regulations change the term ''vehicle history'' to ''vehicle history report'' in proposed § 1.25E–1(b)(8)(ii) and define ''vehicle history report'' as a report ''issued by an approved provider at *www.vehiclehistory.bja/ojp.gov/nmvtis_vehiclehistory*.'' The website recommended by the commenter provides a list of National Motor Vehicle Title Information System (NMVTIS) approved data providers. This website is maintained by the Department of Justice. The commenter further suggested removing the dealer limitation from the last sentence of proposed § 1.25E–1(b)(8)(ii) and tying the vehicle history report to the time of sale.

Proposed § 1.25E–1(b)(8)(ii) identified ''vehicle history'' as the mechanism for verifying whether a transfer is the first transfer of the vehicle for purposes of the qualified sale definition. The Treasury Department and the IRS agree that substituting the term ''vehicle history report'' for ''vehicle history'' adds clarity to the rule. The Treasury Department and the IRS further agree that requiring the taxpayer to obtain the vehicle history report from the dealer is overly restrictive, and that the vehicle history report should be obtained at the time of sale or as part of the sale transaction in order to satisfy the first transfer rule. Accordingly, the final regulations adopt these comments. Further, the Treasury Department and the IRS have determined that vehicle history reports issued by NMVTIS-approved data providers may be used to verify whether a transfer is the first transfer of the vehicle. However, the Treasury Department and the IRS lack sufficient information to determine whether limiting vehicle history reports to those issued by NMVTIS-approved data providers would place an undue burden on taxpayers. As a result, the final regulations adopt the comment, in part, by adding a definition of ''vehicle

history report'' and clarifying that the term includes reports from NMVTIS-approved data providers.

Another commenter expressed concern that the proposed first transfer rule is more restrictive than the statutory language and could severely limit the applicability of the section 25E credit. The commenter suggested that the most straightforward way to determine if a car had previously been sold to a qualified buyer would be to exclude vehicles for which a credit under 25E had previously been claimed. The commenter recommended that the final regulations allow one section 25E credit per VIN (regardless of whether the credit is claimed with respect to the first transfer since August 16, 2022, or the first transfer to a qualified buyer) in place of the proposed first transfer rule.

One of the statutory requirements to be a qualified sale is that the sale be the first transfer to a qualified buyer since the enactment of section 25E, other than to the person with whom the original use of the vehicle commenced. The commenter's suggestion that the final regulations adopt a one section 25E credit per VIN rule is inconsistent with the statutory language and Congressional intent, because it would allow a transfer to a second qualified buyer to be eligible for the credit in situations where the first qualified buyer did not claim the section 25E credit or was not eligible to claim the credit (for example, if the first qualified buyer's MAGI exceeds the limitation). Further, the commenter's suggestion, if adopted, would be unadministrable because taxpayers have no way of verifying whether a section 25E credit has previously been claimed with respect to a prior sale of a particular vehicle. Such information is not part of a vehicle history report and is otherwise inaccessible to taxpayers. While the IRS has that information, it cannot share that information without violating the taxpayer confidentiality restrictions in section 6103. As a result, taxpayers making purchasing decisions would not know which previously sold vehicles were eligible for the section 25E credit in advance of their vehicle purchase, which would disincentivize the purchase of previously-owned clean vehicles. Accordingly, the final regulations do not adopt this comment.

As for the commenter's concern that the proposed first transfer rule is more restrictive than the statutory language, the first transfer rule is consistent with how Congress expected the statute to operate [2] and is necessary to protect confidential taxpayer information consistent with section 6103. Once there has been a sale of a previously-owned clean vehicle, there is no information source from which a subsequent buyer could ascertain or verify whether the prior sale was to a qualified buyer. For example, vehicle history reports do not include information as to whether a previous buyer was an individual, whether the previous buyer was a dependent, or whether the previous buyer had claimed the section 25E credit in the prior three years. As noted above, in cases where the previous buyer has claimed the section 25E credit, the IRS would have the information necessary to determine whether the prior transfer was to a qualified buyer, but such taxpayer information is protected from disclosure by statute, under section 6103. The first transfer rule, by allowing the section 25E credit to the first transfer after the date of enactment of 25E as determined by the vehicle's vehicle history report, provides certainty to buyers and dealers in a manner that is consistent with the taxpayer confidentiality mandates of section 6103. In addition, the proposed first transfer rule is consistent with Congressional intent to incentivize the deployment of clean vehicles.

The final regulations thus adopt the proposed first transfer rule without substantive change. As noted earlier, the first transfer rule is an element of the definition of ''qualified sale.'' The final regulations merge proposed § 1.25E–1(b)(8)(i) and (ii) and finalize the definition of ''qualified sale'' as § 1.25E–1(b)(14). Further, the final regulations move the language regarding taxpayer reliance on the vehicle history report from the definition of ''qualified sale'' to a standalone rule in § 1.25E–1(f), and clarify that reliance on a vehicle history report applies in the case where there has been a prior sale and return or resale described in § 1.25E–2(c). For additional clarity, the final regulations add an example that illustrates how the first transfer rule works in the context of dealer-to-dealer transfers.

3. Sale Price

Section 25E(a)(2) and (c)(2)(B) provide that the sale price of a previously-owned clean vehicle is taken into account for purposes of determining the amount of the section 25E credit and whether a particular sale is a qualified sale of the vehicle. Proposed § 1.25E–1(b)(9) defined the ''sale price'' of a previously-owned clean vehicle as the total sale price agreed upon by the buyer and dealer in a written contract at the time of sale, including any delivery charges and after the application of any incentives, but excluding separately-stated taxes and fees required by law. Under the proposed definition, the sale price of a previously-owned clean vehicle was determined before the application of any trade-in value. Proposed § 1.25E–1(b)(2) provided that for purposes of the definition of ''sale price,'' the term ''incentive'' means any reduction in total sale price offered to and accepted by a taxpayer from the dealer or manufacturer, other than a reduction, whether in the form of a partial payment or down payment for the purchase of a previously-owned clean vehicle or otherwise, pursuant to section 25E(f) and § 1.25E–3.

One commenter requested clarification regarding the term ''incentives,'' noting that manufacturer and distributor rebates and incentives are typically not available for previously-owned vehicles. The commenter did not reference the proposed definition of ''incentive'' in its comment letter. The proposed definition addresses the commenter's concern by broadly defining ''incentive'' to include reductions in price by manufacturers and dealers. In other words, the proposed definition does not limit incentives to price reductions provided by manufacturers and distributors. Therefore, no clarification is needed. However, because the term ''incentive'' is relevant to both sale price determinations for purposes the $25,000 sale price cap in section 25E(c)(2)(B) and the eligible entity definition in section 30D(g)(2)(B)(ii) and (D), the final regulations include separate definitions of ''incentive'' that apply to those provisions. In addition, with regard to the definition of ''incentive'' for purposes of sale price determinations, the final regulations clarify that an ''incentive'' means any reduction in price offered to and accepted by a taxpayer from the dealer or manufacturer. This clarification is necessary because the proposed definition only looked to incentives available to taxpayers from the dealer or manufacturer, which could disadvantage consumers by artificially lowering the $25,000 sale price cap in cases where the incentive was not accepted by the taxpayer.

Several commenters requested modifications to the proposed definition of ''sale price.'' Two commenters requested a narrower definition. Specifically, one commenter suggested that the proposed definition of sale

[2] See Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 117th Congress* (JCS–1–23), December 2023 at page 254.

price be amended so that fees and charges allowed by a state or locality, such as titling and registration charges for out-of-state buyers and charges associated with perfecting a lienholder's security interest, be excluded from the sale price because the amount of such fees is not easily knowable at the time of sale. Another commenter recommended modifying the proposed definition of ''sale price'' to exclude documentation fees because of long-standing practice in the automotive industry to charge such fees to cover a dealer's processing and administrative costs associated with a sale. The inclusion of dealer document fees and charges allowed by a state or locality in the sale price would allow dealers to allocate a portion of the sale price of the vehicle to such fees in order to avoid the $25,000 sale price cap in section 25E(c)(2)(B). Accordingly, the final regulations do not adopt these comments.

A commenter suggested the proposed definition of ''sale price'' be amended to include the total transaction amount, less any government-imposed taxes or fees, and including all add-ons and any non-government fees to prevent dealers from capturing a large portion of the credit as profit. The proposed definition already effectively does what the commenter suggests by excluding only separately-stated taxes and fees as required by law. Accordingly, the final regulations do not adopt this comment.

4. Other Definitions Applicable to Section 25E

The Treasury Department and the IRS received comments related to other definitions applicable to section 25E that are also applicable to section 30D. Section II of this Summary of Comments and Explanation of Revisions discusses comments received and modifications made to definitions applicable to both section 25E and section 30D.

B. Limitations Based on Modified AGI

The proposed regulations restated the Modified AGI limitation of section 25E(b) at proposed § 1.25E–1(b)(3) and (c)(1).

Several commenters suggested that the qualifying income threshold for the section 25E credit should be increased. Because these limitations are statutory, the final regulations do not adopt this comment.

C. Branded Title

Proposed § 1.25E–2(d) provided that a title to a previously-owned clean vehicle indicating that such vehicle has been damaged or is otherwise a branded title does not impact the vehicle's eligibility for a section 25E credit.

A commenter suggested that the section 25E credit program should not be used to incentivize consumers to purchase unsafe or unreliable vehicles, such as those that have been determined to be a total loss, salvage, or junk, and encouraged the Treasury Department and the IRS to consider making such vehicles ineligible for the section 25E credit. The commenter further suggested that title status reflected in the NMVTIS should be determinative because all states, insurance companies, and junk and salvage yards are required by law to regularly report information about vehicles that have been determined to be a total loss, salvage, or junk to NMVTIS.

Vehicle titles indicate whether the title is clean (meaning the vehicle has never been declared a total loss) or branded (indicating the vehicle has sustained serious damage, such as in the case of salvage title, or that there is some other significant problem with the vehicle, as in the case of a lemon title brand). State law generally governs the titling of vehicles. Each State and the District of Columbia has different standards for determining when a vehicle title must be branded. Further, although there are broad categories of title brands that are common across jurisdictions, such as salvage title, the thresholds for applying those title brands varies. These variations can lead to the practice of title washing, which is a method of removing a title brand by retitling the vehicle in a jurisdiction that does not recognize the title brand. The Treasury Department and the IRS do not want to incentivize the purchase of unsafe or unreliable vehicles. However, modifying proposed § 1.25E–2(d) to exclude certain title brands could lead to an increase in title washing, which, in turn, could lead to increased fraud regarding previously-owned vehicles. This would negatively impact consumers of previously-owned clean vehicles. Moreover, the statute does not exclude branded titles, and there is no indication that Congress intended to exclude such vehicles. Accordingly, the final regulations do not adopt these comments.

II. Crossover Provisions in Section 25E and Section 30D

A. Definitions

This section of the Summary of Comments and Explanation of Revisions addresses definitions that apply to both section 25E and section 30D. Unless otherwise specified, the final regulations move the definitions relating to section 30D from §§ 1.30D–2, 1.30D–3(c), 1.30D–5(a), and 1.30D–6(a) to § 1.30D–2(b).

1. Dealer

Section 25E(c)(2)(A) cross references section 30D(g)(8) with regard to the term ''dealer.'' Under section 30D(g)(8), the term ''dealer'' means a person licensed by a State, the District of Columbia, the Commonwealth of Puerto Rico, or any other territory or possession of the United States, an Indian tribal government, or any Alaska Native Corporation to engage in the sale of vehicles.

Proposed §§ 1.25E–1(b)(1) and 1.30D–5(a)(2) defined ''dealer'' as provided in section 30D(g)(8), except that the proposed term did not include persons licensed solely by a territory of the United States.[3] Under the proposed regulations, the term included a dealer licensed in any jurisdiction described in section 30D(g)(8) (other than one licensed solely by a territory of the United States) that makes sales at sites outside of the jurisdiction in which its licensed. The definition of dealer in the proposed regulations did not include persons licensed solely by a territory because clean vehicle credits generally are not allowed for vehicles used predominantly outside of the 50 States and the District of Columbia. *See* sections 30D(f)(4), 25E(e), 50(b)(1), and 7701(a)(9) of the Code.

A commenter suggested that the definition of ''dealer'' should include licensed dealers in territories or possessions of the United States, but only for purposes of vehicles sold for use and not for resale in the 50 states or the District of Columbia.

Such a rule would create verification issues for the IRS and place administrative burdens on certain dealers and purchasers of clean vehicles. At a minimum, buyers purchasing clean vehicles from dealers licensed in territories of the United States would be required to provide an attestation or certificate to the dealer indicating that the buyer intended to use the vehicle in the United States and not resell it. In addition, predominant use of the vehicle in a territory subsequent to such a statement of intent would make the vehicle ineligible for a clean vehicle credit. Pursuant to section 30D(g)(1), the Secretary has authority to prescribe necessary regulations with respect to that subsection. Accordingly, the final regulations do not adopt this comment.

[3] Section 30D(g)(8) uses the term ''territory or possession,'' but the proposed regulations and these final regulations use the term ''territory'' since both terms have the same meaning.

A separate comment requested guidance on the circumstances in which an original equipment manufacturer (OEM) is considered a ''dealer'' for purposes of section 30D(g)(8). In response to this comment, the Treasury Department and the IRS note that an OEM may be a dealer if licensed in any jurisdiction described in section 30D(g)(8) and §§ 1.25E–1(b) or 1.30D–2(b), as applicable.

2. Placed in Service

The year in which a vehicle is placed in service is relevant for a number of rules under section 25E and section 30D, including the applicable percentages for the Critical Minerals and Battery Components Requirements of section 30D(e) and the FEOC Restriction, which impose manufacturer sourcing requirements for the clean vehicle battery.

Proposed §§ 1.25E–1(b)(4) and 1.30D–2(e) provided that a vehicle is considered to be placed in service on the date the taxpayer takes possession of the vehicle. The proposed definition is consistent with the meaning of ''placed in service'' for purposes of other Code provisions. *See* § 1.46–3(d)(1)(ii) and (4)(i) and § 1.179–4(e) (property is considered placed in service when ''placed in a condition or state of readiness and availability for a specifically assigned function''); § 145.4051–1(c)(2) (''a vehicle shall be considered placed in service on the date on which the owner of the vehicle took actual possession of the vehicle''); *see also* § 1.1250–4(b)(2) (''property is placed in service on the date on which it is first used''); *Consumers Power Co.* v. *Commissioner,* 89 T.C. 710 (1987); *Noell* v. *Commissioner,* 66 T.C. 718, 728–729 (1976).

The proposed definition is also consistent with the IRS's and the Tax Court's interpretation of ''placed in service'' as used in section 30D(a), which was not amended by the IRA, and while not precedential or binding, reflects the prevailing view. *See e.g., Trout* v. *Comm'r of Internal Revenue,* T.C. Summ. Op. 2015–66, 2015 WL 7423818, at *4 (T.C. Nov. 19, 2015) (''[t]he Court will look at whether the vehicle was 'in a condition or state of readiness and availability' for the 'specifically assigned function' for which petitioners purchased it to determine when petitioners placed the [vehicle] in service.''); *Podraza* v. *Comm'r of Internal Revenue,* T.C. Summ. Op. 2015–67, 2015 WL 7423525 (T.C. Nov. 19, 2015) (same); IRS PLR 201312034 (Mar. 22, 2013) (''the taxable year in which the taxpayer may claim the credit on their return is defined as the year in which the vehicle is 'placed in service,' which requires that the taxpayer have actual possession of the vehicle. . .'').

The Treasury Department and the IRS received several comments regarding the definition of ''placed in service.'' One commenter suggested that for purposes of the section 30D credit, the definition of ''placed in service'' be modified to mean the date of vehicle manufacture. The commenter further noted that the proposed definition will cause significant confusion for consumers if the clean vehicle they want to buy is no longer credit-eligible because the vehicle was not placed in service at the correct time.

Several other commenters requested that ''placed in service'' be defined as the date of manufacture for purposes of the vehicle manufacturing requirements (specifically, the Critical Minerals and Battery Components Requirements and the FEOC Restriction) of section 30D. Another commenter raised concerns with the proposed definition of ''placed in service'' based on vehicle possession because some taxpayers: (1) may never take possession of the vehicle, such as cases involving leases and gifts, (2) may take possession before a vehicle is sold, (3) may take possession at the time a vehicle is sold, or (4) may take possession after a vehicle is sold, such as cases in which the taxpayer preorders a vehicle. The commenter recommended that the definition of ''placed in service'' be the date on which a vehicle is registered by a United States jurisdiction that administers on-road vehicle registration laws.

The final regulations adopt the definition in proposed §§ 1.25E–1(b)(4) and 1.30D–2(e), with minor clarifying changes, because the definition is consistent with existing guidance, as well as case law relating to when a vehicle is placed in service. Further, the Treasury Department and the IRS do not adopt a definition of ''placed in service'' for purposes of the Critical Minerals and Battery Components Requirements and the FEOC Restriction that differs from the definition for purposes of section 30D(a), because in cases in which the same term is used in a single section the term is presumed to have the same meaning throughout. *Mertens* v. *Hewitt Assocs.,* 508 U.S. 248, 260, 113 S.Ct. 2063, 124 L.Ed.2d 161 (1993). Accordingly, the final regulations do not adopt these comments.

3. Sale

The term ''sale'' is not defined in section 25E, section 30D, or the proposed regulations applicable to those sections. A commenter suggested that a definition of the term ''sale'' be added to the final regulations for purposes of sections 25E and 30D. The commenter recommended that the term ''sale'' be defined as ''an enforceable contract to transfer ownership of a vehicle from a dealer to a taxpayer.''

The term ''sale'' is relevant to the determination of whether there is a qualified sale for purposes of section 25E(c)(2) and the applicable recapture provisions under sections 25E and 30D. The commenter's proposed definition is overly broad and would not require that the transfer of ownership be made for consideration provided by the buyer. Further, section 25E(a) provides that the section 25E credit is only allowed for a qualified sale of a previously-owned clean vehicle. Section 25E(c)(2)(A) defines the term ''qualified sale,'' in part, as a sale by a dealer. Similarly, the credit transfer election framework incentivizes the purchase of previously-owned clean vehicles and new clean vehicles from dealers. Dealers have well-established practices with regard to vehicle sales and what constitutes a sale transaction. Based on the foregoing, the Treasury Department and the IRS have determined that a definition of ''sale'' is unnecessary. Accordingly, the final regulations do not adopt this comment.

B. Special Rules

1. Recapture

Section 25E(e) provides that, for purposes of section 25E, rules similar to the rules of section 30D(f) apply. Section 30D(f)(5) instructs the Secretary to provide regulations for recapturing the benefit of any section 30D credit with respect to any property that ceases to be eligible for the section 30D credit. Proposed §§ 1.25E–2(c) and 1.30D–4(d) provided corresponding rules under section 30D(f)(5) for cancelled sales, returns, and resales of the vehicle. The final regulations clarify that for purposes of section 30D(f)(5), and by extension, section 25E(e), the amount of the benefit recaptured due to such an event is considered an increase to tax imposed by chapter 1 of the Code.

i. Cancelled Sale

Proposed §§ 1.25E–2(c)(1)(i) and 1.30D–4(d)(1)(i) provided the Federal income tax consequences that apply if the sale of a vehicle between the taxpayer and seller is cancelled before the taxpayer places the vehicle in service (that is, before the taxpayer takes possession of the vehicle).

A commenter recommended that part of the definition of ''cancelled sale'' be changed from ''taxpayer places the

vehicle in service'' to ''the vehicle is placed in service.'' Section 25E(a) expressly requires the previously-owned clean vehicle to be placed in service by a qualified buyer. Similarly, section 30D(a) expressly requires the new clean vehicle to be placed in service by the taxpayer. Accordingly, the final regulations do not adopt this comment because a clean vehicle placed in service by someone other than the qualified buyer or taxpayer, as applicable, would not qualify for the credit.

ii. Vehicle Returns

Proposed §§ 1.25E–2(c)(1)(ii) and 1.30D–4(d)(1)(ii) addressed the Federal income tax consequences that apply if the taxpayer returns the vehicle to the seller within 30 days of placing the vehicle in service.

The Treasury Department and the IRS received multiple comments regarding the proposed vehicle return rules in proposed §§ 1.25E–2(c)(1)(ii) and 1.30D–4(d)(1)(ii). A commenter requested that the final regulations clarify that once a contract for the purchase of a clean vehicle is signed by the buyer and seller, the 30-day return period is for credit recapture purposes only and that state contract law governs whether the buyer can void the sale. One commenter agreed that 30 days is an appropriate length of time for qualified vehicle returns. Another commenter recommended deleting the 30-day limitation. That commenter also suggested changing ''of placing such vehicle in service'' to ''after it is placed in service'' and ''the vehicle history'' to ''a vehicle history report as of the date of such sale.'' In addition, a commenter recommended that, in general, the Treasury Department and the IRS regulate returns after the vehicle is registered.

Dealers generally have return policies that range from several days up to 30 days, so the proposed rules regarding returns within 30 days reflect industry practice. The final regulations maintain the 30-day return rule, with one modification. Specifically, the final regulations, for purposes of 25E, modify the reference to ''the vehicle history'' by changing it to ''a vehicle history report obtained on the date of such subsequent sale or as part of such subsequent sale transaction'' to conform with modifications to the definition of ''qualified sale'' described in section I.A.2 of this Summary of Comments and Explanation of Revisions. The final regulations also add a definition of ''vehicle history report'' and clarify that the term includes reports from NMVTIS-approved data providers. In addition, the Treasury Department and the IRS confirm that the vehicle return rules in the final regulations relate only to the section 25E and 30D credits and have no impact on the voidability of the sales contract for the clean vehicle, which is governed by state contract law. Otherwise, the final regulations do not adopt these comments.

2. Resales

Proposed §§ 1.25E–2(c)(1)(iii) and 1.30D–4(d)(1)(iii) treat the taxpayer as having purchased a clean vehicle with an intent to resell such vehicle if the resale occurs within 30 days of the taxpayer placing the vehicle in service.

A commenter noted that it largely agreed with the proposed resale rules, but suggested that for purposes of section 25E, the final regulations include an exception for subsequent sales by dealers that are unaware of prior resales as of the date of the subsequent sale. The commenter did not suggest an exception for purposes of section 30D resales given that a resale of a vehicle will render it used, thereby making the vehicle ineligible for the section 30D credit. The commenter also suggested changing ''placing the vehicle'' in service to ''it being placed'' in service. Another commenter stated that 30 days is an appropriate length of time for the resale rule.

The recapture rule in proposed § 1.25E–2(c)(1)(iii) did not address sales by dealers. Proposed § 1.25E–2(c)(1)(iii) addressed sales by individual buyers within 30 days and provided that recapture in the event of such resale is recaptured from the taxpayer, not the dealer. Accordingly, the final regulations retain the rules in proposed §§ 1.25E–2(c)(1)(iii) and 1.30D–4(d)(1)(iii) and do not adopt these comments.

3. Other Returns or Resales

Proposed §§ 1.25E–2(c)(1)(iv) and 1.30D–4(d)(iv) provided a rule for returns or resales occurring more than 30 days after the date on which the taxpayer places the vehicle in service. Generally, taxpayers returning or reselling a clean vehicle more than 30 days after the date the taxpayer places it in service will remain eligible for the section 25E or section 30D credit for the purchase of such vehicle. The proposed regulations provided that, in the case of a new clean vehicle that is returned or resold, the vehicle, once returned or resold, is not available for original use by another taxpayer and, therefore, is not eligible for a section 30D credit. Similarly, in the case of a previously-owned clean vehicle that is returned or resold, the vehicle, once returned or resold, is generally not eligible for the section 25E credit upon a subsequent sale pursuant to the first transfer rule described in proposed § 1.25E–1(b)(8)(ii). In the case of a return occurring more than 30 days after the date on which the taxpayer places the vehicle in service, the seller report is not required to be updated because the taxpayer generally will be eligible for the clean vehicle credit in this circumstance. In addition, in the case of a resale of such vehicle, the seller report is not required to be updated because the seller would not have knowledge of the subsequent resale. Finally, if the taxpayer made an election to transfer the clean vehicle credit, that credit transfer election remains in effect and the value of any transferred credit pursuant to the clean vehicle credit transfer rules generally is not subject to recapture and is not an excessive payment.

Although the proposed regulations did not provide an automatic clean vehicle credit recapture rule for returns or resales more than 30 days after a return or resale, the IRS may determine, based upon the facts and circumstances of a particular case, that a clean vehicle was purchased with the intent to return or resell and may disallow the clean vehicle credit in such case.

One commenter noted that dealers regularly place new clean vehicles in use for longer than 30 days as loaners, rentals, or company vehicles, and that the period of time the vehicle is in use varies but is normally longer than 30 days. The commenter suggested that the section 30D credit obtained by the dealer on its purchase of the vehicle should not be recaptured if, after a period of more than 30 days of use as a loaner, the dealer reclassifies the vehicle as used and subsequently sells it to a third party. The commenter requested the addition of an example to the final regulations addressing this scenario.

The final regulations adopt the comment and add an example to § 1.30D–4(e) that illustrates the application of the vehicle return rules to a scenario in which the dealer purchases a new clean vehicle, uses it as a demonstrator, and later sells the vehicle.

4. Recapture After Transfer Election

One commenter requested that an example be added to the final regulations that addresses who would be responsible for repaying a credit in the event the taxpayer made an election to transfer the credit and later learned that the sale of the previously-owned

clean vehicle to the taxpayer was not a qualified sale.

In general, whether the sale of a previously-owned clean vehicle is a qualified sale will be determined at the time of sale. For example, the taxpayer may rely on the vehicle history report obtained at the time of sale or as part of the sale transaction to determine whether the first transfer rule is satisfied. In the case of recapture, as described in §§ 1.25E–2(c) and 1.30D–4(e), responsibility for recapture of a clean vehicle credit depends upon the circumstances of recapture. In the case of a vehicle return within 30 days of placing a clean vehicle in service in which the taxpayer made a credit transfer election, the eligible entity must repay the amount of the credit as an excessive payment. In contrast, if the taxpayer resells the vehicle within 30 days of placing the clean vehicle in service rather than returning it to the eligible entity, the amount of the transferred credit is recaptured from the taxpayer.

Another commenter requested additional information about specific procedures regarding recapture, including clarification as to whether both parties would be notified, how such notification might occur, and when recapture would occur.

Generally, recapture is reported via self-assessment by the eligible entity or taxpayer. In the event of recapture from the eligible entity, the eligible entity must report the recapture via the dealer registration system as described in §§ 1.25E–3(c)(1) and 1.30D–5(c)(1), as finalized. In the event of recapture from the taxpayer, the taxpayer must report the recapture amount as an increase in tax imposed by chapter 1 of the Code on the taxpayer's Federal income tax return for the taxable year in which the recapture occurred.

A commenter requested that the final regulations clarify whether a taxpayer would be liable for repayment of the credit or a portion of the credit if a transfer election is made but the taxpayer's regular tax liability is less than the total amount of the credit transferred. With respect to the section 25E credit, this situation is addressed in proposed § 1.25E–3(e)(1)(i) and proposed § 1.25E–3(e)(5) Example 1. With respect to the section 30D credit, this situation is addressed in proposed § 1.30D–5(e)(1)(i) and § 1.30D–5(e)(5) Example 1. These provisions and examples are adopted in the final regulations at § 1.25E–3(e)(1)(i), § 1.25E–3(e)(5) Example 1, § 1.30D–5(e)(1)(i), and § 1.30D–5(e)(5) Example 1. Accordingly, no additional clarification is needed and the final regulations do not adopt this comment.

5. Requirement To File a Complete Income Tax Return

Proposed §§ 1.25E–2(f) and 1.30D–4(g) provided that taxpayers must file an income tax return, together with Schedule A (Form 8936), *Clean Vehicle Credit Amount,* or successor form, and any additional forms, schedules, or statements prescribed by the Commissioner for the purpose of making a return to report the tax under chapter 1 of the Code that includes all of the information required on the forms and in the instructions, for the taxable year in which the clean vehicle is placed in service to be entitled to the credit under section 25E or section 30D. The final regulations under section 30D clarify that this requirement also applies to information returns because a partnership or S corporation may claim a section 30D credit as a general business credit under section 38.

A commenter noted that some taxpayers may transfer a credit to a dealer and then fail to file a return or fail to attach Form 8936 to their return, and that dealers will have little incentive to inform taxpayers of their future filing obligations in order to qualify for the credit. The commenter recommended that the final regulations clarify that failing to file a return or failing to attach Form 8936 to a return will not alone subject the taxpayer to the credit recapture rules.

Proposed §§ 1.25E–3(h) and 1.30D–5(g) provide a reporting requirement for taxpayers who transfer a section 25E credit or section 30D credit to a dealer, but do not provide for recapture of the credit as a consequence of failing to fulfill these requirements. Although a taxpayer may not otherwise be required to file an income tax return for a particular taxable year, the taxpayer is required to file an income tax return and attach a Form 8936 and Schedule A (Form 8936) to ensure timely processing of their tax return and to demonstrate their eligibility for the credit. This reporting requirement assists the IRS in the collection of accurate information necessary to effectively administer the section 25E and section 30D credits. The statutory text provides the IRS with sufficient authority to impose this requirement to ensure program integrity, including the ability to recapture the credit where necessary. See sections 25E(f), 30D(g)(1) and 30D(g)(10); see also section 6011. Accordingly, a clarification has been made in the final regulations. The final regulations regarding credit transfer elections under section 30D also clarify that this includes information returns.

C. Transfer Rules

1. Disclosure and Assurance

Section 30D(g) generally establishes a set of rules under which a taxpayer may transfer a section 30D credit to certain dealers, referred to as eligible entities, in which case the eligible entity (and not the taxpayer) is allowed the section 30D credit. In exchange, the eligible entity must pay the taxpayer an amount equal to the transferred section 30D credit (with such payment being made either in cash or in the form of a partial payment or down payment for the purchase of the vehicle). Section 25E(f) provides that, for purposes of section 25E, rules similar to the rules of section 30D(g) apply.

Proposed §§ 1.25E–3 and 1.30D–5 provided transfer rules under section 30D(g) (and section 25E(f) by cross reference to section 30D(g)), including the establishment of an advance payment program for such transfers. The proposed regulations did not specifically address the requirements under section 30D(g)(2)(B)(ii) and (D) relating to the disclosure by the dealer of other incentives.

A commenter requested that the final regulations define the term ''incentive'' for purposes of the disclosure requirement and suggested a definition similar to the one in proposed § 1.25E–1(b)(2). The commenter also requested that the final regulations provide an attestation for dealers and taxpayers to use in conjunction with creditable sales to satisfy the assurance requirement.

The Treasury Department and the IRS agree that the final regulations should include a definition of ''incentive'' for purposes of section 30D(g)(2)(B)(ii) and (D). Because the section 30(g) credit transfer rules also apply to section 25E by reason of the cross reference in section 25E(f), the definition of ''incentive'' for the section 25E and 30D eligible entity requirements should align. Accordingly, the final regulations add a definition of ''incentive'' to §§ 1.25E–1(b) and 1.30D–5(b) that applies for purposes of the eligible entity requirements. Under that definition, ''incentive'' means any reduction in price available to the taxpayer from the dealer or manufacturer, including as in combination with other incentives, other than a reduction in the form of a partial payment or down payment for the purchase of a clean vehicle pursuant to section 30D(g)(2)(C).

2. Definitions

Proposed §§ 1.25E–3(b) and 1.30D–5(a) provided definitions that apply for purposes of the transfer of a clean vehicle credit.

i. Advance Payment Program

Proposed §§ 1.25E–3(b)(1) and 1.30D–5(a)(1) defined ''advance payment program'' as the program described in section 30D(g)(7) (and section 25E(f) by cross reference to section 30D(g)) and the proposed regulations under which an eligible entity may receive an advance payment from the IRS in the case of a credit transfer election made by an electing taxpayer. The advance payment program is the exclusive means by which an eligible entity may receive a transferred clean vehicle credit.

Several commenters requested that the section 25E and 30D credits be refundable regardless of tax liability. Other commenters requested that the credits be available for a taxpayer to use as a down payment at the time of the sale. In contrast, another commenter, requested that taxpayers without sufficient tax liability be required to repay the excess credit amount because, the commenter argued, Congress intended for the credit to be a non-refundable credit. One commenter requested clarification on how the credit will work in 2024 and beyond compared to previous years. Another commenter suggested that the proposed regulations allow 30D credits to be carried forward.

The section 25E and 30D credits are nonrefundable credits under the Code that cannot be carried forward; however, pursuant to sections 25E(f) and 30D(g), such credits may be transferred to an eligible entity beginning in 2024, regardless of the tax liability of the taxpayer or the eligible entity for the applicable tax year. Sections 25E(f) and 30D(g) do not provide for repayment in the event of insufficient tax liability. In exchange for the transferred credit, the eligible entity must pay the taxpayer an amount equal to the transferred clean vehicle credit, with such payment being made either in cash or in the form of a partial payment or down payment for the purchase of the vehicle. The proposed regulations described the transfer of the clean vehicle credits, including examples of cases in which a taxpayer may not have sufficient tax liability to claim the full amount of the credit (for example, Example 1 of proposed § 1.30D–5(d)(5)(i)). Accordingly, the final regulations do not adopt the comment to require repayment of an excess credit amount. Proposed §§ 1.25E–3 and 1.30D–5 already provided the other rules requested by commenters, and no additional clarification is needed. Accordingly, no changes are needed in the final regulations to address these comments.

ii. Electing Taxpayer

Under proposed §§ 1.25E–3(b)(3) and 1.30D–5(a)(4), ''electing taxpayer'' means the individual that purchases and places in service a clean vehicle and that elects to transfer a clean vehicle credit associated with that vehicle that would otherwise be allowable to that individual.

A commenter requested that businesses that purchase new clean vehicles be allowed to use the credit transfer option under section 30D(g). Because the election to transfer a credit under section 30D(g) is limited to the credit allowable under section 30D, the Treasury Department and the IRS have determined that a taxpayer may not elect to transfer a general business credit for a new clean vehicle allowable under section 38 pursuant to section 30D(c)(1). Proposed § 1.30D–1(b)(1) provided that in the event a depreciable vehicle's use is 50 percent or more business use in the taxable year the vehicle is placed in service, it will be creditable entirely under section 38 as a general business credit rather than under section 30D. Thus, the use of a new clean vehicle must be predominantly personal for a taxpayer to be able to make the election to transfer the credit under section 30D(g). Accordingly, the final regulations do not adopt this comment.

iii. Eligible Entity

Under proposed §§ 1.25E–3(b)(4) and 1.30D–5(a)(5), ''eligible entity'' means a registered dealer that meets certain requirements and, by reason of meeting those requirements, is eligible to receive advance payments from the IRS under the advance payment program.

A commenter suggested clarifying that an eligible entity is a registered dealer that is eligible to receive payments under the advance payment program by virtue of meeting the statutory and regulatory requirements. Proposed §§ 1.25E–3(b)(4) and 1.30D–5(a)(5) already provided the rule requested in this comment, and no additional clarification is needed. Accordingly, the final regulations do not adopt this comment.

iv. Time of Sale

Under proposed §§ 1.25E–3(b)(6) and 1.30D–5(a)(7), ''time of sale'' means the date the clean vehicle is placed in service. Under the proposed regulations, the date the clean vehicle is placed in service is the date the taxpayer takes possession of the vehicle.

A commenter suggested that ''time of sale'' be defined as the date of sale on the seller report, and noted that physical possession may occur before, after, or at the time of sale (or at no time) and is not relevant to when a sale has occurred. The date a taxpayer takes possession of the vehicle is a date certain that completes the transaction of purchasing a vehicle, whereas a date on the seller report does not guarantee the taxpayer will take possession of the vehicle and place it in service. As discussed in section II.A.2 of this Summary of Comments and Explanation of Revisions, defining ''placed in service'' as the date a taxpayer takes possession of the vehicle is consistent with other provisions of the Code and prior interpretations of section 30D(a). Accordingly, the final regulations do not adopt this comment.

3. Dealer Registration

Proposed §§ 1.25E–3(c)(2) and 1.30D–5(b)(2) provided rules regarding dealer tax compliance. Specifically, the proposed regulations provided that if the dealer is not in dealer tax compliance for any of the taxable periods during the most recent five taxable years, the dealer may register nonetheless to become a registered dealer. However, the proposed regulations provided that in such cases the dealer cannot receive advance payments under the advance payment program until the dealer's tax compliance issue is resolved. This is because the dealer, while registered, is not an eligible entity until it comes into dealer tax compliance.

One commenter suggested creating an exemption from the dealer tax compliance requirement to address the unique nature of its sales model in which all advance payments of transferred credits ultimately reside with the corporate parent and not with one of the subsidiaries in the organization structure that may be deemed out of tax compliance.

A commenter asserted that dealers play a purely ministerial role in the credit transfer process, and their tax compliance status does not impact the dealer's ability to facilitate a credit transfer. The commenter requested that to the extent the final regulations do not remove the dealer tax compliance provision, the compliance lookback period should be for a maximum of three years rather than the five provided in the proposed regulations. In addition, the commenter requested that the final regulations clarify that the dealer tax compliance requirement applies for

advance payment purposes only and has no impact on a registered dealer's sales or seller reporting.

Pursuant to section 30D(g)(1) and (g)(7), participation in the advance payment program is elective and is subject to the requirements and conditions that the Secretary determines necessary. An advance payment system for dealers presents unique tax administration challenges because it involves the IRS making payments to dealers regardless of their tax liability and doing so outside of the normal tax filing system, with its built-in compliance and enforcement mechanisms. The dealer tax compliance requirement ensures that the entities receiving advance payments have satisfied their own Federal tax obligations, which aids in fraud prevention and tax administration. For these reasons, the final regulations retain the dealer tax compliance requirement. Further, the final regulations retain the five-year lookback period because the longer period better facilitates the IRS's ability to determine whether there are enforcement concerns with regard to a particular dealer. The final regulations also add an express statement that dealer tax compliance is required before describing the consequences of noncompliance. No clarification is needed regarding the scope of the dealer tax compliance requirement because it is clear from the placement of the requirement in the provisions relating to the transfer of the section 25E and 30D credits that such requirement applies only for purposes of the advance payment program and not for other dealer activities, such as the issuance of seller reports.

4. Form of Payment From Eligible Entity to Electing Taxpayer

Proposed §§ 1.25E–3(e)(3) and 1.30D–5(d)(3) provided that the Federal income tax treatment of the payments associated with a credit transfer election are the same regardless of whether the payment is made in cash or in the form of a partial payment or down payment for the purchase of the clean vehicle.

A commenter noted that in some states, dealers are prohibited under state law to promise to pay or otherwise tender cash if a vehicle is financed. The commenter recommended that the credit transfer election be available only for a reduction in sale price without the payment of cash in states where cash payments from dealers for financed vehicles are prohibited under state law. Proposed §§ 1.25E–3(e)(3) and 1.30D–5(d)(3) included examples that illustrate the application of the payment rules referenced by the commenter. The examples in proposed §§ 1.25E–3(e)(5)(ii) and 1.30D–5(d)(5)(ii) address a scenario in which the eligible entity makes the payment to the electing taxpayer in the form of a reduction in sale price (rather than as cash) and concluded that the eligible entity is eligible to receive an advance payment. Although addressed in the examples, reductions in sale price are not explicitly addressed in proposed §§ 1.25E–3(e)(3) and 1.30D–5(d)(3), which articulate the rules illustrated in the examples. Accordingly, the final regulations adopt proposed §§ 1.25E–3(e)(3) and 1.30D–5(d)(3) with language clarifying that reductions in sale price are acceptable forms of payment by an eligible entity.

5. Vehicle Identification Number Requirement

Proposed §§ 1.25E–2(e)(4) and 1.30D–5(d)(4) impose certain additional requirements for credit transfer elections. Among those rules, the proposed regulations provided that the vehicle identification number requirements of section 30D(f)(9) and, by reason of section 25E(e), section 25E(d), would be treated as satisfied if the eligible entity provides the vehicle identification number of such vehicle to the IRS in the form and manner set forth in guidance published in the *Internal Revenue Bulletin*. The final regulations, consistent with the Secretary's general authority under section 30D(g)(1), provide that the electing taxpayer must provide its vehicle identification number with its Federal income tax return for the taxable year in which the vehicle is placed in service. Reporting of the vehicle identification number by both the electing taxpayer and the eligible entity is necessary to reconcile the advance payments under the credit transfer program with the eligibility of the electing taxpayer, which helps safeguard program integrity.

6. Increases in Tax

i. Recapture From Taxpayer

Section 30D(g)(10) provides that, in the case of any taxpayer who has made a credit transfer election and received a payment from an eligible entity, if the section 30D credit would otherwise (but for section 30D(g)) not be allowable to such taxpayer pursuant to the application of the Modified AGI limitation, the tax imposed on such taxpayer under chapter 1 of the Code for the taxable year in which such vehicle was placed in service will be increased by the amount of the payment received by such taxpayer. Because section 25E(f) cross references to section 30D(g), similar rules apply with respect to the section 25E credit.

Proposed §§ 1.25E–3(g)(1) and 1.30D–5(f)(1) provided that, in the case of a clean vehicle credit that would otherwise not be allowable to a taxpayer that made a credit transfer election because the taxpayer exceeds the limitation based on Modified AGI, the income tax imposed on the taxpayer under chapter 1 of the Code for the taxable year in which the vehicle was placed in service is increased by the amount of the payment received by the taxpayer pursuant to the credit transfer election. The taxpayer in such a case must report recapture of the additional amount on its income tax return for the taxable year during which the vehicle was placed in service.

A commenter suggested that §§ 1.25E–3(g)(1) and 1.30D–5(f)(1) should be revised to apply recapture to taxpayers purchasing clean vehicles for resale or for primarily nonpersonal use. Regarding the purchase for resale aspect of this comment, proposed §§ 1.25E–2(c)(1)(iii)(E) and 1.30D–4(f)(1)(iii)(E) provided that the value of any transferred credit will be collected from the taxpayer in the event the taxpayer resells the vehicle within 30 days of placing the vehicle in service. Therefore, the proposed regulations already addressed the purchase for resale aspect of this comment and further clarification is not necessary. Regarding the aspect of the comment related to recapture in the event of primary nonpersonal use of the vehicle, Revenue Procedure 2023–33 provides that a taxpayer must attest to the IRS under penalty of perjury that the taxpayer is an individual for purposes of section 25E, or that the taxpayer will use the vehicle predominantly for personal use for purposes of section 30D. Because nonpersonal use of vehicles is adequately addressed in sub-regulatory guidance, additional clarification is not necessary. Accordingly, the final regulations do not adopt this comment.

Another commenter requested that the final regulations clarify who is responsible for recapture and under what circumstances. The final regulations, as described in this section of the Summary of Comments and Explanation of Revisions, make clear who is subject to recapture. Accordingly, the final regulations do not adopt this comment.

Based on the foregoing, the final regulations adopt proposed §§ 1.25E–2(c)(1)(iii)(E) and 1.30D–4(f)(1)(iii)(E) without modification.

ii. Excessive Payment to an Eligible Entity

Section 30D(g)(7)(B) and section 25E(f) (by cross reference to section 30D(g)) provide that rules similar to the rules of section 6417(d)(6) apply for purposes of the advance payment program. Proposed §§ 1.25E–3(g)(2) and 1.30D–5(f)(2) provided that, in the case of any advance payment that the IRS determines constitutes an excessive payment, the tax imposed on the eligible entity by chapter 1 of the Code, for the taxable year in which such determination is made will be increased by the sum of the amount of the excessive payment, plus an amount equal to 20 percent of such excessive payment. The proposed regulations further provided that the rule applies regardless of whether such entity would otherwise be subject to chapter 1 tax. The additional amount of 20 percent, however, will not apply if the eligible entity demonstrates to the IRS that the excessive payment was due to reasonable cause, which is presumed to be the case for a clean vehicle returned within 30 days of placing such vehicle in service. *See* proposed §§ 1.25E–3(g)(2)(ii) and 1.30D–5(f)(2)(ii).

The proposed regulations provided that an excessive payment means, with respect to an advance payment to an eligible entity pursuant to a credit transfer election made by an electing taxpayer, an advance payment made to a registered dealer that fails to meet the requirements to be an eligible entity. Additionally, the proposed regulations define ''excessive payment'' as an advance payment to an eligible entity with respect to a clean vehicle to the extent the payment exceeds the amount of the clean vehicle credit that would be otherwise allowable to the electing taxpayer with respect to the vehicle. *See* proposed §§ 1.25E–3(g)(2)(iii) and 1.30D–5(f)(2)(iii). However, any excess payment attributable to a taxpayer exceeding the limitation based on Modified AGI is not treated as an excessive payment to an eligible entity.

A commenter requested clarification that ''reasonable cause'' includes an eligible entity's reliance on a manufacturer's calculations for purposes of the Critical Minerals and Battery Components Requirements, as shown on *https://fueleconomy.gov* or elsewhere. Specifically, the commenter requested that the final regulations clearly provide that eligible entities will not be liable for mistaken determinations with respect to those requirements.

Section 4.03 of Revenue Procedure 2022–42 provides that a taxpayer may rely on the information and certifications (which include certifications with respect to the Critical Minerals and Battery Components Requirements and the FEOC Restriction) contained in the qualified manufacturer's periodic written reports. Therefore, in the case of a mistaken calculation by the qualified manufacturer in a periodic written report, the taxpayer is not denied the section 30D credit. Accordingly, if that taxpayer transfers the credit under the advance payment program, the excess of the advance payment to the dealer over the credit otherwise allowable to the taxpayer would be zero, and there is no excessive payment under proposed § 1.30D–5(f)(2)(iii). Consequently, the eligible entity would have no liability and no need to demonstrate reasonable cause. For clarity, the final regulations incorporate the provisions of section 4.03 of Revenue Procedure 2022–42 regarding taxpayer reliance on manufacturer certifications regarding qualified manufacturer status, and certifications and information a qualified manufacturer provides to the IRS in periodic written reports. The final regulations also delineate what taxpayer reliance means in this context. In addition, the final regulations add an example to §§ 1.25E–2(g) and 1.30D–5(g)(3) that illustrate that an excessive payment does not arise in the situation described by the commenter.

7. Two Credit Transfer Elections per Year

Proposed §§ 1.25E–3(i) and 1.30D–5(h) provided that a taxpayer may make no more than two credit transfer elections per taxable year. The proposed regulations further provided that in the case of a joint income tax return, each spouse may make two transfer elections per taxable year, for a maximum of four credit transfer elections in a taxable year. These proposed rules were intended to ensure program integrity by limiting credit transfer elections to vehicle sales that appear to be for legitimate nonbusiness individual use.

A commenter recommended that the requirements of proposed §§ 1.25E–3(i) and 1.30D–5(h) be deleted because there is no basis in section 25E or section 30D for these restrictions. The commenter noted that an eligible entity working with a taxpayer on a credit transfer would have no ability to determine whether the taxpayer would have already made two transfer elections. Section 30D(g)(1) provides that the credit transfer election is ''[s]ubject to such regulations or other guidance as the Secretary determines necessary.'' Section 25E(f) adopts section 30D(g) by reference. Therefore, the Treasury Department and the IRS have the authority to regulate the credit transfer election to ensure program integrity and sound tax administration. Moreover, pursuant to Revenue Procedure 2023–33, the taxpayer will attest to the IRS directly that they have not made more than two transfer elections per year, and the dealer may rely on the taxpayer's attestation. Accordingly, the final regulations do not adopt this comment.

III. New Clean Vehicle Credit—Section 30D

A. Definitions

Section 1.30D–2 of the April Proposed Regulations provided general definitions related to the section 30D credit. Section 1.30D–3(c) of the April Proposed Regulations provided definitions applicable for purposes of the Critical Minerals and Battery Components Requirements. Section 1.30D–6(a) of the December Proposed Regulations provided definitions applicable for purposes of the FEOC Restriction. In the Explanation of Provisions to the December Proposed Regulations, the Treasury Department and the IRS noted that terms relevant to both the Critical Minerals and Battery Components Requirements described in proposed § 1.30D–3 and the FEOC Restriction of proposed § 1.30D–6 should be interpreted consistently between those provisions.

Consistent with this statement, the final regulations retain proposed § 1.30D–2, with certain modifications described in this section of the Summary of Comments and Explanation of Revisions, and generally move the definitions from proposed § 1.30D–3 and proposed § 1.30D–6 to § 1.30D–2(b). However, the final regulations, under § 1.30D–3, retain certain definitions that are directly relevant to the calculations under the Critical Minerals and Battery Components Requirements; those definitions are cross-referenced in § 1.30D–2(b). Section 1.30D–2(b) also cross-references definitions in proposed § 1.30D–5, which provides rules for the credit transfer election (described in section II.C of this Summary of Comments and Explanation of Revisions).

The discussion in this section of the Summary of Comments and Explanation of Revisions only addresses new definitions, definitions that have been modified, or definitions for which comments were received.

1. Applicable Critical Mineral

Proposed §§ 1.30D–3(c)(1) and 1.30D–6(a)(1), consistent with section

30D(e)(1), defined an ''applicable critical mineral'' as an applicable critical mineral defined in section 45X(c)(6).

In addition, proposed § 1.30D–6(c)(4)(ii)(A) provided that the determination of whether an applicable critical mineral is FEOC-compliant takes into account each step of extraction, processing, or recycling through the step in which such mineral is processed or recycled into a constituent material, even if the mineral is not in a form listed in section 45X(c)(6) at every step. Proposed § 1.30D–6(c)(4)(ii)(A) provided an exception to this general rule in the case of recycling (as discussed in this Summary of Comments and Explanation of Revisions at section III.A.25). Proposed § 1.30D–6(c)(4)(ii)(C) further provided that, for purposes of determining whether an applicable critical mineral is FEOC-compliant, an applicable critical mineral is disregarded if it is fully consumed in the production of the constituent material or battery component and no longer remains in any form in the battery.

Several commenters asked for clarification with respect to graphite. Specifically, the commenters requested clarification as to whether graphite that is of a purity of less than 99.9 percent graphitic carbon, but that is purified to a minimum purity of 99.9 percent carbon, is an applicable critical mineral under section 45X(c)(6) and thus section 30D. These comments were considered in the context of the section 45X proposed regulations. As explained in the Explanation of Provisions to the section 45X proposed regulations: ''Some stakeholders have questioned whether this definition could be interpreted to refer to a particular crystalline structure of carbon, that is, 99.9 percent carbon in a graphitic form. [. . .] Consistent with the general intent of section 45X, proposed § 1.45X–4(b)(14) would clarify that the term '99.9 percent graphitic carbon by mass' means graphite that is 99.9 percent carbon by mass.'' The Treasury Department and the IRS will continue to consider this issue as part of finalizing of the section 45X regulations. The form of graphite that is an applicable critical mineral for the purposes of section 30D will be the form that is determined to be an applicable critical mineral in the 45X final regulations.

Several commenters requested clarity as to whether synthetic graphite is an applicable critical mineral. Those commenters requested that the final regulations explicitly state that both graphite variations, synthetic and natural, qualify as an applicable critical mineral. A separate commenter suggested that, because natural and synthetic graphite have entirely different processing procedures, synthetic graphite should not be categorized as an applicable critical mineral. These comments were also considered in the context of the section 45X proposed regulations. Proposed § 1.45X–4(b)(14) would provide that ''[t]he term *graphite* means natural or synthetic graphite that is purified to a minimum purity of 99.9 percent graphitic carbon by mass.'' The Treasury Department and the IRS will continue to consider this issue as part of finalizing of the section 45X regulations. The form of graphite that is an applicable critical mineral for the purposes of section 30D will be the form that is determined to be an applicable critical mineral in the section 45X final regulations.

Several commenters requested clarification on whether other critical minerals are subject to the Critical Minerals Requirement and the FEOC Restriction. One commenter requested that the final regulations provide clarification with respect to hydrofluoric acid (HF). HF may be produced from fluorspar that is purified to a minimum purity of 97 percent calcium fluoride by mass. In these cases, the fluorspar is an applicable critical mineral (under section 45X(c)(6)(K)) and the HF would be an associated constituent material, both of which would be subject to the Critical Minerals Requirement and the FEOC Restriction. The commenter noted that in other cases, HF may be made with lower purity fluorspar or through phosphate mining (without fluorspar). The commenter requested clarification that such HF is still subject to the Critical Minerals Requirement and the FEOC Restriction. Similarly, another commenter requested clarity as to whether nickel, manganese, cobalt, and lithium that do not meet the purity requirements of section 45X(c)(6) are subject to the Critical Minerals Requirement and the FEOC Restriction. This commenter recommended that such lower-purity minerals not be subject to these rules.

One commenter recommended expanding the definition of ''applicable critical mineral'' to include other chemical forms of the critical minerals identified in section 45X(c)(6), such as nitrates, hydroxides, oxides, oxide hydroxides, carbonates, and chlorides. Another commenter stated that the critical minerals list excludes important minerals, such as iron and phosphorous, that are prevalent in FEOC-made batteries, and that this exclusion may introduce a loophole whereby FEOC-made batteries using non-listed critical minerals may be eligible for the critical mineral portion of the 30D credit. That commenter requested that the Treasury Department and the IRS issue additional rules to address non-U.S. critical minerals. Finally, one commenter noted that many minerals that enter battery supply chains prior to attaining the purity level listed in section 45X or becoming an associated constituent material come from FEOCs. That commenter expressed support for extending FEOC-compliance for critical minerals throughout production, even if the mineral is not in a final form listed in section 45X(c)(6) during each step.

In response to these comments, the Treasury Department and the IRS note that under the plain language of sections 30D(e)(1) and 45X(c)(6), minerals other than those specified in section 45X(c)(6) are not applicable critical minerals, and are therefore not subject to the Critical Minerals Requirement and the FEOC Restriction. In addition, the rules of proposed §§ 1.30D–6(c)(4)(ii)(A) and 1.30D–6(c)(4)(ii)(C) provided additional clarity regarding classification as an applicable critical mineral in cases in which the form of the mineral changes during the steps of extraction, processing, or recycling. The final regulations extend this clarification to the Critical Minerals Requirement by incorporating it into the definition of ''applicable critical mineral.''

The final regulations adopt the definition in proposed §§ 1.30D–3(a)(1), 1.30D–6(c)(1), 1.30D–6(c)(4)(ii)(A), and 1.30D–3(c)(4)(ii)(C), with the modification described above, consolidate it, and move it to § 1.30D–2(b) with the modification described previously. Specifically, the final regulations, like the proposed regulations, provide that ''applicable critical mineral'' means an applicable critical mineral defined in section 45X(c)(6). The final regulations clarify that the requirements under §§ 1.30D–3 and 1.30D–6 with respect to an applicable critical mineral take into account each step of extraction, processing, or recycling through the step in which such mineral is processed or recycled into an associated constituent material, even if the mineral is not in a form listed in section 45X(c)(6) at every step of production. The final regulations further clarify that an applicable critical mineral is disregarded for purposes of the Critical Minerals Requirement and the FEOC Restriction if it is fully consumed in the production of the constituent material or battery component and no longer remains in any form in the battery.

In addition, the final regulations incorporate the special rule for recycling in proposed § 1.30D–6(c)(4)(ii)(A) into the definition of ''recycling'' in § 1.30D–2(b). The final regulations also provide an example that illustrates when the determinations under the Critical Minerals Requirement and the FEOC Restriction take place with respect to an applicable critical mineral.

2. Assembly

Proposed §§ 1.30D–3(c)(2) and 1.30D–6(a)(2) defined ''assembly,'' with respect to battery components, as the process of combining battery components into battery cells and battery modules. The final regulations adopt the definition of ''assembly'' in proposed §§ 1.30D–3(c)(2) and 1.30D–6(a)(2), consolidate it into a single provision, and move it to § 1.30D–2(b).

One commenter stated that the definition of ''assembly'' could allow for abuse under the Battery Components Requirement by allowing a North American manufacturer, for example, to simply affix two Chinese batteries together, which would be considered assembly of a North American battery component. However, in this situation, the incremental value, for purposes of determining the total incremental value of North American battery components (that is, the numerator in the qualifying battery component content that is compared to the applicable percentages of section 30D(e)(2)(B)), would only be the value of the affixed batteries, less the value of the batteries prior to assembly. Because that incremental value would be minimal, the potential for abuse as described by the commenter would also be minimal. Accordingly, the final regulations do not adopt this comment.

3. Associated Constituent Materials

Proposed § 1.30D–6(c)(4)(ii)(B) provided that in determining whether an applicable critical mineral is FEOC-compliant, a constituent material is associated with an applicable critical mineral if the applicable critical mineral has been processed or recycled into a constituent material, even if that processing or recycling transformed the mineral into a form not listed in section 45X(c)(6).

The Critical Minerals Requirement under proposed § 1.30D–3 incorporated the same concept by providing that the portion of an applicable critical mineral that is a qualifying critical mineral must be determined separately for each procurement chain. Proposed § 1.30D–3(c)(14) defined ''procurement chain'' as a common sequence of extraction, processing, or recycling activities that occur in a common set of locations with respect to an applicable critical mineral, concluding in the production of constituent materials.

These determinations necessarily encompass steps in the procurement chain in which the applicable critical mineral is transformed into a form not listed in section 45X(c)(6). Accordingly, the final regulations add a definition of ''associated constituent material'' to § 1.30D–2(b), which provides that, with respect to an applicable critical mineral, an ''associated constituent material'' is a constituent material that has been processed or recycled from such mineral into the constituent material with which it is associated, even if that processing or recycling transformed such mineral into a form not listed in section 45X(c)(6).

4. Battery

Proposed §§ 1.30D–3(c)(3) and 1.30D–6(a)(3) defined ''battery,'' for purposes of a new clean vehicle, as a collection of one or more battery modules, each of which has two or more electrically configured battery cells in series or parallel, to create voltage or current. Under proposed §§ 1.30D–3(c)(3) and 1.30D–6(a)(3), the term ''battery'' did not include items such as thermal management systems or other parts of a battery cell or module that do not directly contribute to the electrochemical storage of energy within the battery, such as battery cell cases, cans, or pouches. The final regulations adopt the definition of ''battery'' in §§ 1.30D–3(c)(3) and 1.30D–6(a)(3), consolidate it into a single provision, and move the definition to § 1.30D–2(b).

The Treasury Department and the IRS received comments both in support of and in opposition to the proposed definition of ''battery.'' Several commenters requested a broader definition of ''battery,'' while other commenters criticized the definition of battery as too broad. Similarly, several commenters disagreed with the definition of ''battery'' and recommended that it be defined as a complete battery pack. The Explanation of Provisions to the April Proposed Regulations noted that the proposed definition of ''battery'' is consistent with the language and purpose of section 30D because battery modules and cells are the sources ''from which the electric motor of such vehicle draws electricity.'' *See* sections 30D(e)(1)(A) and (2)(A). Consistent with this, items that do not directly contribute to the electrochemical storage of energy within the battery are not the subject of the IRA's incentives to shift to more secure and resilient electric vehicle battery supply chains. Such items are generally low-value commodities that are specific to the end-use of the energy storage technology, rather than the process of storing energy. The proposed definition of ''battery'' is in keeping with the statutory purpose of incentivizing the resiliency and security of the highest-value and most specialized portions of the battery supply chain. In addition, the functional definition of ''battery'' in the proposed regulations allows for technological changes, as the definition will not be obsolete if battery pack structures change in the future, but is also consistent with current industry practice, as electrochemical batteries are currently standard. Accordingly, the final regulations do not adopt these comments.

In addition, one commenter requested that the definition of ''battery'' exclude thermal management systems and other components that do not directly contribute to energy storage. Because the definition of ''battery'' already excludes such systems and such other components, no modification to the definition of ''battery'' is required.

Finally, one commenter noted the necessity of future conversations about the definitions of ''battery'' and ''battery component'' to reflect technological advances. The Treasury Department and the IRS will continue to monitor technology in this area in coordination with the DOE. The Treasury Department and the IRS welcome additional comments in the future that discuss technological changes with respect to electric vehicle batteries.

5. Battery Cell

Proposed §§ 1.30D–3(c)(4) and 1.30D–6(a)(4) defined ''battery cell'' as a combination of battery components (other than battery cells) capable of electrochemically storing energy from which the electric motor of a new clean vehicle draws electricity. This proposed definition of battery cell encompassed the smallest combination of battery components necessary for the function of energy storage. The final regulations adopt the definition of ''battery cell'' in proposed §§ 1.30D–3(c)(4) and 1.30D–6(a)(4), consolidate it into a single provision, and move it to § 1.30D–2(b).

A commenter requested that the guidance align the definitions of ''battery cell'' and ''battery component'' with those in section 45X(c)(5). However, section 30D does not adopt those definitions by reference. As noted in section III.A.4 of this Summary of Comments and Explanation of Revisions, items that do not directly contribute to the electrochemical storage of energy within the battery, which are

generally low-value commodities, are not the subject of the IRA's incentives to shift to more secure and resilient electric vehicle battery supply chains. For this reason, the Treasury Department and the IRS have determined that the section 30D definitions should be limited to electrochemical energy storage batteries that that are used in electric vehicles, and do not need to encompass concepts that are pertinent to other forms of energy storage that are included in the definitions in section 45X(c)(5) (for example, thermal batteries). Accordingly, the final regulations do not adopt this comment.

6. Battery Component

Proposed §§ 1.30D–3(c)(5) and 1.30D–6(a)(6) defined ''battery component'' as a component that forms part of a battery and that is manufactured or assembled from one or more components or constituent materials that are combined through industrial, chemical, and physical assembly steps. Battery components include, but are not limited to, a cathode electrode, anode electrode, solid metal electrode, separator, liquid electrolyte, solid state electrolyte, battery cell, and battery module. Constituent materials are not considered a type of battery component, although constituent materials could be manufactured or assembled into battery components. Some battery components could be made entirely of inputs that do not contain constituent materials. Battery components include any piece of the assembled battery cell that contributes to electrochemical energy storage.

The Treasury Department and the IRS received a number of comments regarding the definition of ''battery component.'' Several commenters were supportive of the definition. The proposed definition of ''battery component'' included a non-exhaustive list of specific components, and many commenters proposed additions to the list. One commenter suggested that the list specifically include cathode and anode foil. Other commenters requested clarity with respect to lead tabs (for battery cells), metal components (for battery modules), and cap assemblies (for the manufacture of canister battery cells). Other items suggested for inclusion were separator coatings, binders, electrolyte solvents and electrolyte salts, current collectors, cell contacting layers, voltage sense harnessing, and battery management systems. Another commenter noted that the inclusion of ''but not be limited to'' language creates uncertainty for automakers and instead asked for a full list of components. In response, the final regulations add a new definition of ''battery materials'' (described in section III.A.7 of this Summary of Comments and Explanation of Revisions) to § 1.30D–2(b). In addition, the final regulations clarify that battery materials without applicable critical minerals are not battery components, as they are not manufactured or assembled. The final regulations do not provide a complete list of battery components because electric vehicle battery components may vary depending on the battery chemistry, especially as battery technology continues to evolve. The illustrative list of battery components in the final regulation allows for future innovation.

Several commenters raised concerns regarding the limitation of battery components to items that contribute to electrochemical energy storage. A commenter supported the limitation as important to both the workability of and intent behind the Battery Components Requirement. On the other hand, another commenter requested that the final regulations expand the definition of ''battery component'' to include additional enabling technologies, such as thermal management, cooling, and housing and enclosure components. The commenter, mentioned previously, that requested clarity with respect to lead tabs and metal components stated that ambiguity with respect to the phrase ''electrochemical storage components'' made it difficult to determine whether these items were battery components. Similarly, commenters suggested that, under the language of section 30D, battery components should include thermal barriers. As noted previously, the proposed definition of ''battery,'' which informs the definition of ''battery component,'' is consistent with the statute because battery modules and cells are the sources ''from which the electric motor of such vehicle draws electricity.'' Section 30D(e)(1)(A) and (2)(A). In addition, this definition is consistent with the purpose of section 30D to provide incentives to move toward more secure and resilient electric vehicle battery inputs. Inputs that do not directly contribute to the electrochemical processes necessary for energy storage (for example, thermal management systems, battery management systems, housing/enclosure components) are generally lower-value and specific to the end use of the battery, rather than the process of storing energy. The same reasoning applies to battery components. As noted by the Joint Committee on Taxation, the battery components requirement in section 30D(e)(2)(A) is ''intended to incentivize the manufacturing or assembly of high-value battery components, such as battery cells, in North America.'' [4] Accordingly, because the proposed definition is consistent with the statutory text and purpose, the final regulations do not adopt these comments.

Finally, multiple commenters raised questions and provided recommendations relating to separators, many of which relate to the determination under the Battery Components Requirement (discussed in section III.B.2 of this Summary of Comments and Explanation of Revisions). One commenter requested clarification as to the incremental value of a coated separator, and recommended that the incremental value be determined by subtracting the value of an uncoated separator (a lithium-ion battery separator) from the value of the coated separator (a ceramic coated separator). Another commenter, noting that ''substantially all'' in the definition of ''North American Battery Component'' was vague, requested that the final regulations state that a separator coated in North America is a North American Battery Component (regardless of where the pre-coated separator was manufactured). This commenter stated that up to 60 percent of the value added by the separator comes from the coating process. In contrast, another commenter requested that the final regulations clarify that coating a separator is not manufacturing or assembly, to ensure that a separator coated in North America is not considered a North American Battery Component if the pre-coated separator was manufactured outside of North America. A different commenter advocated against the inclusion of base film and coating materials used to make such separator in the definition of ''battery component'' for purposes of the Battery Components Requirement and the FEOC Restriction. In addition, one commenter requested that the bare film and binders incorporated into a ceramic-coated separator be classified as battery sub-components and noted that these items should qualify under either the Critical Minerals Requirement or the Battery Components Requirement if manufactured in North America or a country with which the United States has a free trade agreement in effect. This commenter also made suggestions with respect to various other government

[4] Joint Committee on Taxation, Joint Committee on Taxation, *General Explanation of Tax Legislation Enacted in the 117 Congress* (JCS 1–23), December 2023, at 252, n.1070.

rules that may apply to coated separators, which are outside the scope of these final regulations.

In response to these comments, the Treasury Department and the IRS note that a coated separator is a battery component. In general, the base film and coating are battery materials, not battery components, because they are processed rather than manufactured or assembled. If those battery materials contain applicable critical minerals, those battery materials are constituent materials. The final regulations clarify this in the definition of ''battery component'' and the new definition of ''battery materials.''

Finally, several commenters discussed the relationship between the Battery Components Requirement and the FEOC Restriction. One commenter encouraged the Treasury Department and the IRS to use the same definition of ''battery component'' for purposes of the Battery Components Requirement and the FEOC Restriction. In contrast, another commenter suggested that the final regulations adopt a broader definition of ''battery component'' for purposes of the FEOC Restriction that includes components otherwise included in the definition of ''constituent material'' for purposes of the Critical Minerals Requirements. As noted in the Explanation of Provisions to the December Proposed Regulations, the Treasury Department and the IRS intend that terms relevant to both the Critical Minerals and Battery Components Requirement and the FEOC Restriction be interpreted consistently. Consistent with that, the final regulations include one general definition of ''battery component'' for purposes of section 30D, and do not adopt the comment suggesting a broader definition for purposes of the FEOC Restriction.

The final regulations, in § 1.30D–2(b), adopt a definition of ''battery component'' that clarifies the treatment of separators and incorporates the new definition of ''battery materials.'' The definition is modified to improve clarity regarding the relationship between battery components, constituent materials, and battery materials.

7. Battery Materials

To further clarify the line between battery components and constituent materials, the final regulations add a definition of ''battery materials'' to § 1.30D–2(b). The final regulations define ''battery materials'' as direct and indirect inputs to battery components that are produced through processing, rather than manufacturing or assembly. Battery materials are not considered a type of battery component, although battery materials may be manufactured or assembled into battery components. The three categories of battery materials are applicable critical minerals, constituent materials, and battery materials without applicable critical minerals. Examples of battery materials that may or may not contain applicable critical minerals include a separator base film (if not manufactured or assembled) and separator coating. Examples of battery materials without applicable critical minerals include conductive additives, copper foils prior to graphite deposition, and electrolyte solvents.

8. Clean Vehicle Battery

The final regulations add a definition of ''clean vehicle battery'' to § 1.30D–2(b). Consistent with section 30D(d)(1)(F) and 30D(e), the final regulations define ''clean vehicle battery,'' with respect to a new clean vehicle, means the battery from which the electric motor of the vehicle draws electricity to propel such vehicle.

9. Compliant-Battery Ledger

Proposed § 1.30D–6(a)(7) defined ''compliant-battery ledger,'' for a qualified manufacturer for a calendar year, as a ledger that tracks the number of available FEOC-compliant batteries for such calendar year. Proposed § 1.30D–6(d) set forth rules applicable to compliant-battery ledgers. The Treasury Department and the IRS received several comments about the rules for establishing, updating, and reconciling the compliant-battery ledger. These comments are included as part of the discussion of proposed § 1.30D–6(d) in section III.D.3 of this Summary of Comments and Explanation of Revisions.

The final regulations adopt the proposed definition and move it to § 1.30D–2(b).

10. Constituent Materials

Proposed §§ 1.30D–3(c)(6) and 1.30D–6(a)(8) defined ''constituent materials'' as materials that contain applicable critical minerals and are employed directly in the manufacturing of battery components. Constituent materials could include, but are not limited to, powders of cathode active materials, powders of anode active materials, foils, metals for solid electrodes, binders, electrolyte salts, and electrolyte additives, as required for a battery cell. As explained in the Explanation of Provisions to the April Proposed Regulations, the definition of ''constituent materials'' describes the materials that distinguish the steps of extraction, processing, and recycling of critical minerals from the subsequent steps of manufacturing and assembly of battery components. Constituent materials are the final products relevant for calculating the value of the applicable critical minerals in the battery.

The Treasury Department and the IRS received multiple comments with respect to the definition of ''constituent materials.'' Several commenters expressed support for the proposed definition. However, other commenters criticized the definition as not supported by the statute; as at odds with section 45X, which includes ''electrode active materials'' as qualifying battery components; and as an inappropriate reclassification of items that should be battery components, and thus subject to the Battery Components Requirement. One commenter suggested that constituent materials be included within the definition of ''battery component'' or otherwise phased in to allow for additional time to relocate production facilities to North America. Another commenter indicated that the definition of ''constituent materials'' could be exploited to exclude critical minerals.

In response to these comments, the Treasury Department and the IRS note that although section 30D does not define ''battery component,'' it consistently refers to components as ''manufactured or assembled,'' and it consistently refers to ''applicable critical minerals'' as ''extracted, processed, or recycled.'' To avoid a gap in the supply chain between applicable critical minerals and battery components, the proposed regulations introduced the concept of constituent materials to make clear that materials downstream of applicable critical minerals, but still processed rather than manufactured or assembled, belong in the analysis of a battery's applicable critical minerals. Section 30D looks to a material's production steps to determine its status as an applicable critical mineral or a battery component. The constituent materials concept does not alter how the statute works; rather, it clarifies how the statute applies to certain materials.

One commenter suggested modifying the definition of ''constituent materials'' to include domestic alternatives that serve the same purpose as constituent materials but do not contain applicable critical minerals. The final regulations do not adopt this comment because the commenter's proposal would be at odds with the Critical Minerals Requirement and the FEOC Restriction (as applicable to applicable critical minerals).

Other commenters raised questions with respect to whether specific materials are constituent materials. One commenter asked for clarification as to whether foils, such as a copper foil that does not contain any applicable critical minerals, are constituent materials. Another commenter asked for clarity with respect to polyvinylidene fluoride (PVDF). Noting that PVDF made from fluorine (in the form of an applicable critical mineral) would be a constituent material, the commenter asked for clarification about the classification of PVDF that is not made from an applicable critical mineral, such as PVDF sourced from phosphate rock. The final regulations clarify that battery materials may not contain applicable critical minerals. Further, the Treasury Department and the IRS note that the materials referenced by these commenters (foils and PVDF) would both be considered battery materials without applicable critical minerals.

One commenter sought clarification of whether lithium hexafluorophosphate is considered an electrolyte salt for purposes of the definition of constituent materials. If an applicable critical mineral in a form specified in section 45X(c)(6) is used to produce lithium hexafluorophosphate, and this material is integrated into a battery component, the material would be considered a constituent material.

A separate commenter requested that the final regulations clarify that carboxymethylcellulose (CMC), made from wood pulp or linter pulp, is not a constituent material. The commenter notes that CMC does not contain applicable critical minerals. The Treasury Department and the IRS note that, while CMC is used in the manufacture of a battery component as a binder or coating for the production of anode electrodes by deposition of anode active material onto copper foil, CMC itself does not contain an applicable critical mineral, and therefore would not be considered a constituent material.

Finally, one commenter requested clarification with respect to powders of cathode active materials (CAM), which is listed as a constituent material. The commenter noted that the list does not expressly include precursor materials used for making CAM or other intermediate materials incorporating the critical minerals that are used to produce the CAM. The commenter specifically recommended adding these items to the list and including references to the relevant applicable critical minerals by revising the definition to include powders of precursor cathode active materials and any other intermediate products incorporating critical minerals such as manganese, nickel, or cobalt, powders of cathode active materials. The final regulations provide, in the definition of ''applicable critical mineral,'' that determinations under the Critical Minerals Requirement and the FEOC Restriction with respect to an applicable critical mineral take into account each step of extraction, processing, or recycling through the step in which such mineral is processed or recycled into a constituent material. Thus, the final regulations clarify that these precursor or other intermediate materials are relevant for both the Critical Minerals Requirement and the FEOC Restriction.

The final regulations adopt the definition of ''constituent materials'' in proposed §§ 1.30D–3(a)(8) and 1.30D–6(c)(6), consolidate it into a single provision, and move it to § 1.30D–2(b). In addition, the final regulations clarify that battery materials without applicable critical minerals are not constituent materials.

12. Country With Which the United States Has a Free Trade Agreement in Effect

Proposed § 1.30D–3(c)(7) defined the term ''country with which the United States has a free trade agreement in effect'' and listed the countries with which the United States has free trade agreements in effect. As noted in the Explanation of Provisions to the April Proposed Regulations, the term free trade agreement is not defined in the IRA or in the Code. Proposed § 1.30D–3(c)(7)(i) set forth criteria for the identification of a country with which the United States has a free trade agreement in effect, including whether an agreement between the United States and another country, as to the critical minerals contained in electric vehicle batteries or more generally, and in the context of the overall commercial and economic relationship between that country and the United States: (A) reduces or eliminates trade barriers on a preferential basis, (B) commits the parties to refrain from imposing new trade barriers, (C) establishes high-standard disciplines in key areas affecting trade (such as core labor and environmental protections), and/or (D) reduces or eliminates restrictions on exports or commits the parties to refrain from imposing such restrictions on exports.

Proposed § 1.30D–3(c)(7)(ii) identified twenty countries with which the United States has comprehensive free trade agreements (that is, agreements covering substantially all trade in goods and services between the parties, including trade in critical minerals). In addition, the Treasury Department and the IRS proposed to include additional countries identified by the Secretary, after consideration of the listed criteria, and identified Japan as an additional country. On March 28, 2023, the United States and Japan concluded a Critical Minerals Agreement (CMA), which contained robust obligations to help ensure free trade in critical minerals.[5]

Proposed § 1.30D–3(c)(7)(iii) provided that the list of identified countries in paragraph (c)(7)(ii) may be revised and updated through appropriate guidance published in the **Federal Register** or in the *Internal Revenue Bulletin* (see § 601.601 of the Statement of Procedural Rules (26 CFR part 601)).

The final regulations adopt this definition and move it to § 1.30D–2(b). At this time, the Treasury Department and the IRS have not identified any additions to the list of identified countries. The final regulations continue to include Japan on the list of countries with which the United States has free trade agreements in effect. After consulting with the United States Trade Representative in applying the relevant factors for identifying free trade agreements, the Treasury Department and the IRS have concluded that Japan is a country with which the United States has a free trade agreement in effect. The Treasury Department and the IRS specifically sought comments on the proposed criteria for identifying countries with which the United States has free trade agreements in effect, other potential approaches for identifying those countries, and the list of countries set forth in proposed § 1.30D–3(c)(7)(ii).

The Treasury Department and the IRS received several comments with respect to this definition. One comment requested guidance identifying at what stage a trade agreement is considered in effect, noting the signature date of an agreement is frequently different from the trade agreement's implementation date. The commenter requested that the completion date be considered the date that a trade agreement is in effect. As an initial matter, international agreements to which the United States is a party, including those referred to in the § 1.30D–2(b) definition of ''country with which the United States has a free trade agreement in effect,'' ordinarily identify the date on which they enter into force

[5] Agreement Between the Government of the United States of America and the Government of Japan on Strengthening Critical Minerals Supply Chains, concluded March 28, 2023, *https://ustr.gov/sites/default/files/2023-03/US%20Japan%20Critical%20Minerals%20Agreement%202023%2003%2028.pdf.*

and therefore are ''in effect,'' as that term is used in section 30D. Consistent with the approach described in the proposed rules and adopted in the final rules, the Treasury Department and the IRS will also ''make any necessary amendments to the list . . . including adding any additional countries as any new qualifying international agreements enter into force and the Secretary determines that the [applicable] factors have been met.'' The Treasury Department and the IRS have determined that the assessment of whether an agreement is in effect is something that the Secretary will evaluate in the context of individual agreements that may be considered in determining whether to add individual countries to the list of countries with which the United States has free trade agreements in effect.

One commenter requested defining ''country'' to include geographical areas that are of an international nature and do not belong to any one country, such as international waters. The ordinary meaning of ''country'' does not include areas beyond national jurisdiction. Therefore, the final regulations do not adopt this comment.

Several comments suggested that the proposed definition of ''free trade agreement'' expands the regulatory regime and undercuts Congressional intent. Relatedly, a comment specifically criticized the inclusion of Japan on the list on the basis of the CMA. Other commenters supported the inclusion of Japan on the basis of the CMA. Another commenter suggested that the proposed regulations impermissibly expand the Secretary's authority to define ''free trade agreement,'' and that the regulatory definition departs from its accepted meaning. Several commenters suggested defining free trade agreements to include arrangements, including plurilateral agreements, in which the United States and a foreign economy agree to at least some strategic and/or economic partnerships, including government procurement, even if the agreement was not labeled a free trade agreement.

As noted earlier in this discussion and in the Explanation of Provisions to the April Proposed Regulations, the term ''free trade agreement'' is not defined in the IRA or in the Code, and the definition in the proposed regulations is consistent with the statute and its purpose, as reflected in the term's ordinary meaning, use, and context in section 30D and in the broader IRA. As also noted in the Explanation of Provisions to the April Proposed Regulations, the purpose of the IRA's amendments to section 30D is to expand the incentives for taxpayers to purchase new clean vehicles and for vehicle manufacturers to increase their reliance on supply chains in the United States and in countries with which the United States has reliable and trusted economic relationships, which is essential for our national security, our economic security, and our technological leadership. The proposed definition of ''country with which the United States has a free trade agreement in effect'' is consistent with these statutory purposes. In particular, the criteria identified in the proposed definition that must be met for an instrument to be determined to be a free trade agreement include whether an agreement between the United States and another country includes commitments related to reducing or eliminating trade barriers on a preferential basis, refraining from imposing new trade barriers, establishing high-standard disciplines in trade-related areas, and reducing or eliminating restrictions on exports or committing the parties to refrain from imposing such restrictions, all in the context of the overall commercial and economic relationship between the country in question and the United States. Based on the criteria above, Japan was identified as a country with which the United States has a free trade agreement in effect. In particular, the United States-Japan CMA was identified as a free trade agreement under these criteria because it includes robust obligations, such as a commitment to refrain from imposing duties on exports of critical minerals that are currently essential to the electric vehicle battery supply chain, and a commitment for the United States and Japan to confer on best practices regarding review of investments in the critical minerals sector for purposes of assisting a determination of the effect of such investments on national security. The CMA also includes detailed terms related to the relationships of labor and environmental laws to trade in critical minerals and cooperation on non-market policies and practices of non-parties affecting trade in critical minerals. The CMA was concluded in the context of an earlier trade agreement the United States concluded with Japan in 2019, a related 2019 agreement on digital trade, and the U.S.-Japan Partnership on Trade announced in November 2021.

Several commenters addressed issues relating to labor standards, environmental standards, economic and national security, transparency, and enforceability. One commenter requested that the United States Geological Survey be consulted as to the environmental standards and compliance and enforcement histories of specified non-domestic sources. Another commenter encouraged the Treasury Department and the IRS to collaborate with the Department of State to leverage the Minerals Security Partnership (MSP) to secure supply chains needed to scale domestic battery production while establishing higher labor standards, greater transparency, improved environmental practices, and greater value-added benefits for communities located in countries with significant mineral endowments. The Treasury Department and the IRS appreciate these concerns and note that they are appropriately reflected in the criteria identified in the proposed regulations, specifically as high-standard disciplines in key areas affecting trade. The Treasury Department and the IRS will consult with appropriate agencies across the Federal government in applying the listed criteria in the future.

Relatedly, several commenters raised concerns about whether countries with which the United States does not have free trade agreements in effect could launder applicable critical minerals through procurement chains involving countries with which the United States has free trade agreements in effect. The Treasury Department and the IRS have determined that the upfront review process in § 1.30D–3(d) of the final regulations (described in section III.B.3 of this Summary of Comments and Explanation of Revisions), which involves due diligence and requires documentation of critical mineral supply chains, will promote accurate tracing of the full critical mineral supply chain.

Another commenter suggested including a broad set of critical minerals in any future critical minerals agreement. The commenter noted that limiting future critical mineral agreements to a limited subset of applicable critical minerals has the potential to limit innovation. In response to this comment, the Treasury Department and the IRS note that the determination under the Critical Minerals Requirement with respect to ''any country with which the United States has a free trade agreement in effect,'' would not be limited in the case of critical minerals agreements by the scope of minerals covered by such critical minerals agreement. Once the Secretary determines that a country qualifies as a country with which the United States has a free trade agreement

in effect, any applicable critical minerals within the meaning of section 45X(c)(6) extracted or processed in that country are eligible. Finally, several commenters requested that additional countries be added to the list, including Argentina, the Philippines, members of the European Union, and the United Kingdom. At this time, the Treasury Department and the IRS have not identified agreements in effect with the suggested countries within the meaning of section 30D. The Treasury Department and the IRS will continue to work with the United States Trade Representative and across the Federal government to apply the listed criteria to determine if it is appropriate to list additional countries.

13. Extraction

Proposed §§ 1.30D–3(c)(8) and 1.30D–6(a)(9) defined ''extraction'' as the activities performed to extract or harvest minerals or natural resources from the ground or a body of water, including, but not limited to, by operating equipment to extract minerals or natural resources from mines and wells, or to extract or harvest minerals or natural resources from the waste or residue of prior extraction. Under the proposed definition, extraction concludes when activities are performed to convert raw mined or harvested products or raw well effluent to substances that can be readily transported or stored for direct use in applicable critical mineral processing. Extraction includes the beneficiation or other physical processes that allow the extracted materials, including ores, clays, and brines, to become transportable. Extraction also includes the physical processes involved in refining, but not the chemical and thermal processes involved in refining.

Several commenters requested clarity on the line between extraction and processing. Section III.A.22 of the Summary of Comments and Explanation of Revisions addresses these comments.

One commenter suggested that the definition of ''extraction'' be expanded to include critical minerals not physically taken from the ground, citing innovations in producing graphite from biomass that no longer require physical ground extraction. The proposed definition of ''extraction'' includes the extraction of minerals or natural resources from the waste or residue of prior extraction. Therefore, it is unnecessary to modify the definition of ''extraction'' in the manner the commenter suggests. However, the final regulations clarify that extraction also includes crude oil extraction to the extent processes applied to that crude oil yield an applicable critical mineral as a byproduct. The final regulations also clarify that extraction does not include activities that begin with a recyclable commodity (as such activities themselves constitute recycling).

The final regulations adopt the definition of ''extraction'' in the proposed regulations, consolidate it into a single provision with the clarification described previously, and move it to § 1.30D–2(b).

14. Final Assembly

Proposed § 1.30D–2(b) provided that, consistent with section 30D(d)(5), ''final assembly'' means the process by which a manufacturer produces a new clean vehicle at, or through the use of, a plant, factory, or other place from which the vehicle is delivered to a dealer or importer with all component parts necessary for the mechanical operation of the vehicle included with the vehicle, whether or not the component parts are permanently installed in or on the vehicle. To establish where final assembly of a new clean vehicle occurred, the proposed regulations provided that a taxpayer could rely on the following information: (1) the vehicle's plant of manufacture as reported in the VIN pursuant to 49 CFR 565; or (2) the final assembly point reported on the label affixed to the vehicle as described in 49 CFR 583.5(a)(3). The final regulations adopt the proposed definition of ''final assembly'' without change.

The proposed regulations provided two different methods for determining whether a vehicle meets the North American final assembly requirement, either via the VIN or the vehicle label, to ensure that this information was available and accessible for taxpayers. For nearly all vehicles, both methods will provide the same final assembly location. The vehicle's plant of manufacture as reported in the VIN means the plant where the manufacturer affixes the VIN. *See* 49 CFR 565.12. The plant of manufacture is reported in the VIN pursuant to 49 CFR 565.15(d)(2). The DOE, Alternative Fuels Data Center (AFDC), and the Department of Transportation, National Highway Traffic Safety Administration (NHSTA), each provide a VIN decoder to the public, which can be used to identify a vehicle's plant of manufacture. AFDC, VIN Decoder, *https://afdc.energy.gov/laws/electric-vehicles-for-tax-credit;* NHTSA, VIN Decoder, *https://www.nhtsa.gov/vin-decoder.* Labeling requirements in 49 CFR 583.5 require the final assembly point to be reported on the label affixed to a passenger motor vehicle as defined in 49 U.S.C. 32304(11) (which limits such vehicles to those with GVWR of 8,500 pounds or less). Final assembly point means the plant, factory, or other place, which is a building or series of buildings in close proximity, where a new passenger motor vehicle is produced or assembled from passenger motor vehicle equipment and from which such vehicle is delivered to a dealer or importer in such a condition that all component parts necessary to the mechanical operation of such automobile are included with such vehicle, whether or not such component parts are permanently installed in or on such vehicle. For multi-stage vehicles, the labeling requirements provide that the final assembly point is the location where the first stage vehicle is assembled. 49 CFR 583.4(b)(5). Multi-stage vehicles are vehicles manufactured in two or more stages by which an incomplete vehicle becomes a completed vehicle and may involve multiple manufacturers. *See* 49 CFR 567.3 for definitions of ''incomplete vehicle'' and ''completed vehicle.''

A commenter stated that the proposed rule would allow taxpayers to use the vehicle's plant of manufacture reported on the VIN, rather than the final assembly point, for multi-stage vehicles. However, existing vehicle labeling requirements in 49 CFR part 583 apply to both single-stage and multi-stage vehicles with GVWR of 8,500 pounds or less. Therefore, such requirements provide a final assembly point for both types of vehicles. The proposed regulations provided flexibility to taxpayers in determining whether the section 30D credit final assembly requirement is met by allowing taxpayers to look to either the plant of manufacture identified in the VIN or the vehicle label final assembly point. In the limited situations in which the VIN and vehicle label may provide different final assembly locations, the proposed regulations allowed taxpayers to choose the standard that is more favorable to them. Moreover, the VIN and vehicle labels will diverge only in certain limited situations with respect to a multi-stage vehicle, and most multi-stage vehicles have a GVWR of more than 8,500 pounds, and are, therefore, not subject to the part 583 vehicle labeling requirements. Furthermore, it is important to leverage existing standards that provide accessible information to taxpayers, and such information is more accessible if taxpayers have multiple ways to obtain it. Accordingly, the final regulations do not adopt this comment.

Another commenter requested that the final regulations define ''final assembly'' more broadly, to include

assembly of body panels, painting, chassis assembly, trim installation, and other assembly and fabrication processes that are currently found in established final assembly plants, to maximize the incentive for production in the United States. Section 30D(d)(5) and the proposed definition of ''final assembly'' look to the plant, factory, or other place at which all component parts necessary for the mechanical operation of the vehicle are included with the vehicle. Consistent with the commenter's suggestion, this is generally the location where the chassis of the vehicle is assembled, because at that point the vehicle may be mechanically operable. In addition, the two reliance standards described in the proposed regulations, the vehicle's plant of manufacture as reported in the VIN, and the final assembly point reported on the vehicle label, generally also look to the location where the chassis of the vehicle is assembled. The other processes suggested by the commenter (body panel assembly, painting, and trim installation) do not affect mechanical operation of the vehicle and therefore are inconsistent with the definition of ''final assembly'' for purposes of 30D. Moreover, the VIN and labeling standards also would not consider such processes in determining the vehicle's plant of manufacture or final assembly point. To provide accessible information to taxpayers and to create an administrable rule, especially because the final assembly rule was immediately effective upon passage of the IRA,[6] the Treasury Department and the IRS determined it was necessary to leverage existing reporting of final assembly rather than create an alternative definition that relies on information that is not currently available to the public. The Treasury Department and the IRS consulted with the Department of Transportation in developing the proposed and final regulations regarding final assembly. Because the proposed definition of ''final assembly'' is consistent with the statutory definition and provides an administrable rule, the final regulations do not adopt this comment with respect to processes other than chassis assembly.

Another commenter stated that entities already in the process of constructing production facilities should not be held at a disadvantage given the economic opportunity of creating additional domestic jobs. The North American final assembly requirement in section 30D(d)(1)(G) is prescribed by statute, and the IRA provided an immediately applicable effective date for this provision (August 17, 2022). Accordingly, the final regulations do not adopt this comment.

15. Foreign Entity of Concern

Proposed § 1.30D–6(a)(10), consistent with section 30D(d)(7), defined ''foreign entity of concern'' to have the same meaning as in section 40207(a)(5) of the Infrastructure Investment and Jobs Act and guidance promulgated thereunder by the DOE. The final regulations adopt the proposed definition and move it to § 1.30D–2(b).

The definition of ''foreign entity of concern'' under section 40207(a)(5) of the Infrastructure Investment and Jobs Act is under the jurisdiction of the DOE. On December 1, 2023, contemporaneous with the issuance of the December Proposed Regulations, the DOE issued proposed interpretative guidance relating to the definition. 88 FR 84082 (published December 4, 2023). A number of commenters to the December Proposed Regulations made requests or suggestions with respect to the definition. These comments are outside of the scope of these regulations, and are not further addressed in this Summary of Comments and Explanation of Revisions.

Similarly, several commenters requested more detailed thresholds and processes for determining the involvement of FEOC entities based on entity ownership, control of, and/or acting jurisdiction. The determination of whether an entity is owned by, controlled by, or subject to the jurisdiction of a FEOC is within the jurisdiction of the DOE and its interpretive guidance. Accordingly, the comments are outside of the scope of these final regulations. One commenter also requested that the final regulations address the potential for arbitrage by artificially increasing the value of a critical mineral or battery component not based in or under the control of a FEOC. Because the FEOC Restriction is not based on value of materials, the final regulations do not adopt this comment.

16. FEOC-Compliant

Proposed § 1.30D–6(a)(11), adopted and moved to § 1.30D–2(b) of the final regulations, defined ''FEOC-compliant'' to mean in compliance with the applicable excluded entity requirement under section 30D(d)(7). The definition provided specific rules with respect to a clean vehicle battery, a battery component (other than a battery cell), a battery cell, and an applicable critical mineral. A number of commenters raised questions with respect to the due diligence required to determine if an item is FEOC-compliant or commented on the FEOC Restriction. These comments are addressed in section III.D of this Summary of Comments and Explanation of Revisions.

17. Manufacturer

Proposed § 1.30D–2(k) provided, consistent with section 30D(d)(3), that ''manufacturer'' means any manufacturer within the meaning of the regulations prescribed by the EPA for purposes of the administration of title II of the Clean Air Act (CAA) (42 U.S.C. 7521 *et seq.*) and as defined in 42 U.S.C. 7550(1).

Under 42 U.S.C. 7550(1) and 40 CFR 1068.30 under the CAA regulations, multiple parties may be a manufacturer with respect to a vehicle. To address this situation, the proposed definition also provided that, if multiple manufacturers are involved in the production of a vehicle, the requirements provided in section 30D(d)(3), which must be met for a vehicle to qualify for the section 30D, 45W and 25E credits, must be met by the manufacturer who satisfies the reporting requirements of the greenhouse gas emissions standards (CAA emissions reporting requirements) set by the EPA under the CAA for the subject vehicle. The purpose of the proposed multiple manufacturer rule was to provide a clear rule for OEMs and other parties that may be considered a manufacturer under the CAA regulations.

One commenter suggested that the final regulations modify the definition of ''manufacturer'' to include upstream members of the critical mineral supply chain, including cell manufacturers, cathode manufacturers, and anode manufacturers, in addition to the OEMs. Because the proposed regulations define a manufacturer by referring to the CAA regulations, if an upstream manufacturer is covered by the CAA regulations, that party will be a manufacturer under section 30D. However, if the upstream manufacturer is not covered by the CAA regulations, the statute would not include such manufacturers in the definition of ''manufacturer.'' Accordingly, the final regulations do not adopt this comment.

Another commenter requested that the multiple manufacturer rule be modified to include upfitters as manufacturers. Upfitters purchase new internal combustion engine (ICE) motor vehicles from manufacturers and then modify them into clean vehicles prior to the vehicle being placed in service by

[6] The final assembly requirement amendments made to section 30D in the IRA were applicable to vehicles sold after the date of enactment of the IRA. Public Law 117–169 § 13401(k)(2).

the ultimate purchaser. Because the ICE vehicle manufacturer is subject to the CAA emissions reporting requirements, neither the upfitter nor the ICE vehicle manufacturer would be able to meet the requirements of section 30D(d)(1)(C) and (3) under the multiple manufacturer rule in the proposed regulations. As a result, the vehicles modified by the upfitter would be ineligible for the section 25E, 30D, and 45W credits.

The Treasury Department and the IRS have concluded that including upfitters in the definition of ''manufacturer'' is consistent with the statutory language of section 30D and the CAA regulations, as well as Congressional intent to incentivize the development and purchase of non-ICE vehicles. Accordingly, the final regulations modify the multiple manufacturer rule to allow a manufacturer that modifies a new vehicle into either a new clean vehicle or a qualified commercial clean vehicle to enter into an agreement under section 30D(d)(3) if such modification occurs prior to the new motor vehicle being placed in service.

The same commenter requested that the final regulations allow this rule to apply retroactively for purposes of the section 45W credit for upfitters that modify new vehicles into qualified commercial clean vehicles. Section III.A.23 of this Summary of Comments and Explanation of Revisions concerning the definition of qualified manufacturer addresses this comment.

One commenter suggested that final regulations provide robust oversight of OEMs, including mandatory reporting of certain economic impacts including the collective bargaining status of final assembly plants, and repurposing the EPA's Clean School Bus Program's OEM Job Quality and Workforce Development questionnaire. This comment is beyond the scope of the final regulations and is not adopted.

The final regulations adopt the proposed definition of ''manufacturer'' with the modification regarding upfitters. In addition, the final regulations move the definition to § 1.30D–2(b).

18. Manufacturer's Suggested Retail Price (MSRP)

Proposed § 1.30D–2(c) provided that for purposes of the MSRP limitation in section 30D(f)(11)(A), ''manufacturer's suggested retail price'' means the sum of: (A) the retail price of the automobile suggested by the manufacturer as described in 15 U.S.C. 1232(f)(1); and (B) the retail delivered price suggested by the manufacturer for each accessory or item of optional equipment, physically attached to such automobile at the time of its delivery to the dealer, which is not included within the price of such automobile as stated pursuant to 15 U.S.C. 1232(f)(1), as described in 15 U.S.C. 1232(f)(2). This price information is reported on the label that is affixed to the windshield or side window of the vehicle, as described in 15 U.S.C. 1232.17.

One commenter stated that the determination of MSRP by manufacturers is not well-regulated, and that the final regulations should restrict manufacturers from setting an artificially low MSRP. The commenter suggested that the MSRP should be the actual out the door price paid, and should be limited so that the average cash price paid by consumers does not exceed the MSRP set by manufacturers. Another commenter suggested that the vehicle's base price (exclusive of accessories) be used to determine whether a vehicle's price is under the limitation to be eligible for the section 30D credit.

Section 30D(f)(11) restricts vehicle eligibility for the section 30D credit on the basis of MSRP, not on the basis of actual price paid. In addition, the Treasury Department and the IRS have determined that the MSRP should include not just the base MSRP described in 15 U.S.C. 1232(f)(1), but also the portion of the MSRP described in 15 U.S.C. 1232(f)(2) (each accessory or item of optional equipment, physically attached to the automobile at the time of its delivery to the dealer) because looking solely at base MSRP could encourage manufacturers to artificially lower the base MSRP and increase the amount of the MSRP allocated to accessories or items of optional equipment in an attempt to circumvent the MSRP limitations. Accordingly, the final regulations do not adopt the comments.

The final regulations adopt the proposed definition and move it to § 1.30D–2(b).

19. New Clean Vehicle

Proposed § 1.30D–2(m) defined ''new clean vehicle'' as a vehicle that meets the requirements described in section 30D(d). Under the proposed regulations, a new clean vehicle would not include any vehicle for which the qualified manufacturer: (1) fails to provide a periodic written report for such vehicle prior to the vehicle being placed in service, reporting the VIN of such vehicle and certifying compliance with the requirements of section 30D(d); (2) provides incorrect information with respect to the periodic written report for such vehicle; (3) fails to update its periodic written report in the event of a material change with respect to such vehicle; or (4) fails to meet the requirements of proposed § 1.30D–6(d) for new clean vehicles placed in service after December 31, 2024. For purposes of section 30D(d)(6), the term ''new clean vehicle'' includes any new qualified fuel cell motor vehicle (as defined in section 30B(b)(3)) that meets the requirements under section 30D(d)(1)(G) and (H).

Several commenters suggested that the Treasury Department and the IRS not allow leased vehicles to bypass the stringent domestic-sourcing requirements under section 30D by making the section 45W credit available for such vehicles. Another commenter asked whether the Modified AGI limitation would apply to the lessor or lessee if a clean vehicle is leased to individuals and, if used for business purposes, would fall within section 45W. Section 30D and section 45W each include a no double benefit rule. *See* section 30D(f)(2) and section 45W(d)(3). This demonstrates that under the statutory framework, certain vehicles may qualify for both the section 30D credit and the section 45W credit, and that in such instances, the taxpayer must choose which credit to claim. Further, as described in IRS Fact Sheet FS–2023–22, Topic G, Q5–7, a taxpayer that leases clean vehicles to its customers as its business may be eligible to claim the section 45W credit if the taxpayer is the owner of such vehicles for Federal income tax purposes. The owner of the vehicle is determined based on whether the lease is respected as a lease or is recharacterized as a sale for Federal income tax purposes. The Modified AGI limitation, if applicable, applies to the owner of the vehicle who places it in service for use or lease, and not to the lessee. Accordingly, the final regulations do not adopt these comments.

One commenter expressed concern that vehicles used in a courtesy transportation program would be ineligible for the section 30D credit upon a later sale due to the original use rule of section 30D(d)(1)(A). Because the original use rule is statutory, the final regulations do not adopt this comment. However, the owner of the vehicle that is used in a courtesy transportation program may itself be able to claim a section 30D credit.

Section 30D(d)(1)(F) requires the vehicle to be propelled to a significant extent by an electric motor that draws electricity from a battery that has a capacity of not less than 7 kilowatt hours, and is capable of being recharged from an external source of electricity.

One commenter requested that the final regulations define ''significant extent'' in the context of section 30D(d)(1)(F), but did not propose a definition. Given the purpose of this requirement to distinguish ICE vehicles from battery electric vehicles and plug-in hybrid electric vehicles, and the possibility for technical change in this area, it would be impracticable to precisely define the term. For these reasons, the final regulations do not adopt this comment.

Finally, one commenter suggested making the VINs of eligible vehicles available in an accessible, dealer-facing database, which would allow dealers to use a common source to readily identify which vehicles are eligible for the section 30D credit, reduce confusion, and improve deployment. This comment is outside of the scope of these final regulations. However, the Treasury Department and the IRS, together with the DOE, have provided public-facing information regarding vehicle eligibility via the IRS website and *https://fueleconomy.gov* and will continue to develop such information in a way that is accessible to dealers and taxpayers.

The final regulations adopt the proposed definition of ''new clean vehicle'' with clarifying language that new clean vehicles include battery electric vehicles, plug-in hybrid electric vehicles, fuel cell motor vehicles, and plug-in hybrid fuel cell motor vehicles.

20. New Qualified Fuel Cell Motor Vehicle

To provide additional clarity to taxpayers, the final regulations add a definition of a ''new qualified fuel cell motor vehicle'' to § 1.30D–2(b) that is consistent with section 30D(d)(6). Specifically, the final regulations define ''new qualified fuel cell motor vehicle'' to be any new qualified fuel cell motor vehicle (as defined in section 30B(b)(3)) that meets the requirements under section 30D(d)(1)(G) (that is, the final assembly in North America requirement) and (H) (that is, the seller report requirement), and that does not have a clean vehicle battery. This definition includes otherwise qualifying vehicles that have only a ''start-stop'' battery, because such a battery is not a clean vehicle battery.

21. Non-Traceable Battery Materials/ Impracticable-to-Trace Battery Materials

Proposed § 1.30D–6(a)(13)(i) defined ''non-traceable battery materials'' to mean specifically identified low-value battery materials that may originate from multiple sources and are often commingled during refining, processing, or other production processes by suppliers to such a degree that the qualified manufacturer cannot, due to current industry practice, feasibly determine and attest to the origin of such battery materials. Proposed § 1.30D–6(a)(13)(ii), which was reserved, would have provided the specific list of identified non-traceable battery materials. In the Explanation of Provisions to the December Proposed Regulations, the Treasury Department and the IRS, after extensive consultation with the DOE, stated that they would consider whether the following applicable critical minerals (and associated constituent materials) may be designated as identified non-traceable battery materials: applicable critical minerals contained in electrolyte salts, electrode binders, and electrolyte additives.

The Treasury Department and the IRS received a number of comments with respect to the definition of ''non-traceable battery materials'' as well as the related FEOC Restriction transition rule for non-traceable battery materials. Section III.D of this Summary of Comments and Explanation of Revisions discusses these comments.

Consistent with the expectation and requirement that OEMs will develop thorough tracing processes in the future, even while such processes do not now exist, the final regulations retain the list but change the name to ''impracticable-to-trace battery materials.'' The final regulations adopt the proposed definition and move it to § 1.30D–2(b). Specifically, the final regulations define ''identified impracticable-to-trace battery materials'' as applicable critical minerals in the following circumstances: graphite contained in anode materials (both synthetic and natural) and applicable critical minerals contained in electrolyte salts, electrode binders, and electrolyte additives.

22. Processing

Proposed §§ 1.30D–3(c)(13) and 1.30D–6(a)(14) defined ''processing'' as the non-physical processes involved in the refining of non-recycled substances or materials, including the treating, baking, and coating processes used to convert such substances and materials into constituent materials. The proposed regulations further provided that processing begins when chemical or thermal processes, or the combination of them, are used on extracted minerals or natural resources or manmade minerals or resources to create a new product that, through subsequent steps in the applicable critical minerals supply chain, will be processed into a final constituent material. Under the proposed regulations, processing included the chemical or thermal processes involved in refining, but did not include the physical processes involved in refining.

One commenter requested that the final regulations include high temperature heat treatment among the listed non-physical processes involved in refining that constitute processing to ensure that graphitization is included as processing. High temperature heat treatment is a thermal process, so it is already included in the definition of processing. Therefore, the commenter's requested modification is unnecessary.

Another commenter specifically requested that the final regulations address a fact pattern in which lithium carbonate is procured from an ally of the United States that is not a country with which the United States has a free trade agreement in effect, but is processed into both lithium hydroxide and cathode active material in the United States or a country with which the United States has a free trade agreement in effect. Lithium carbonate is a form of an applicable critical mineral specified in 45X(c)(6); therefore, it is subject to the Critical Minerals Requirement. Lithium carbonate that is procured from a region that is not in the United States or a country with which the United States has a free trade agreement in effect but is processed in the United States may be counted in the numerator of the qualifying critical mineral content calculation to the extent of the value added in the United States.

A number of commenters requested clarification on the line between extraction and processing. One commenter requested that the final regulations clarify that minor treatments necessary to render raw materials transportable are not processing (as chemical or thermal refining), but are instead extraction (as beneficiation). Another commenter noted that evolving technologies, such as glycine leaching technology, simplify value chains and may not uniquely fit into the proposed definitions of ''extraction'' or ''processing.'' One commenter recommended narrowing the definition of ''processing'' to exclude processes performed during battery manufacturing. Another commenter requested that the final regulations provide additional examples of different procurement chains that illustrate where the extraction and processing steps begin and end. Finally, another commenter proposed alternative definitions of ''extraction'' and ''processing'' that conform with the commenter's view of industry practice, rather than distinguish between physical and non-physical processes. That same commenter requested that the

final regulations clarify that smelting nickel is extraction rather than processing, again consistent with the commenter's view of industry practice. The Treasury Department and the IRS note that smelting nickel is a thermal process and is therefore already included in the proposed definition of ''processing.'' Further, the proposed regulations expressly list, in the definitions of ''extraction'' and ''processing,'' production steps that are generally high value add, and it is likely not possible to generate an exhaustive list given the variety of production steps that may apply to the various applicable critical minerals. Moreover, the proposed regulations are more administrable than a rule based on industry standards, which may change in the future. Accordingly, the final regulations do not adopt these comments.

The final regulations adopt the definition of ''processing'' in proposed §§ 1.30D–3(c)(13) and 1.30D–6(a)(14), consolidate it into a single provision, and move it to § 1.30D–2(b).

23. Qualified Manufacturer

Proposed § 1.30D–3(c)(15), applicable to the Critical Minerals and Battery Components Requirements, defined a ''qualified manufacturer'' as a manufacturer described in section 30D(d)(3). Proposed § 1.30D–2(l), applicable as a general definition for section 30D purposes, similarly defined a ''qualified manufacturer'' as a manufacturer that meets the requirements described in section 30D(d)(3). In addition, proposed § 1.30D–2(l) provided that the term ''qualified manufacturer'' does not include any manufacturer whose qualified manufacturer status has been terminated by the IRS for fraud, intentional disregard, or gross negligence with respect to any requirements of section 30D, including with respect to the periodic written reports described in section 30D(d)(3) and proposed § 1.30D–2(m), and any attestations, documentation, or certifications described in proposed §§ 1.30D–3(e) and 1.30D–6(d), at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

As in discussed in section III.A.17 of this Summary of Comments and Explanation of Revisions concerning the definition of ''manufacturer,'' a commenter requested that the proposed multiple manufacturer rule be modified to include upfitters as manufacturers. The same commenter requested that the final regulations allow upfitters to rely on any final regulations as of January 1, 2023, register as qualified manufacturers after the final regulations are published, and include in such upfitters' first periodic written report to the IRS information regarding all vehicles that the upfitter asserts are eligible for the section 45W credit. This comment is outside the scope of the final regulations because (i) it pertains to the section 45W credit, and (ii) the qualified manufacturer registration process is addressed in Revenue Procedure 2023–33 and other sub-regulatory guidance. Accordingly, the final regulations do not adopt this comment.

However, in considering the comment regarding upfitters, the Treasury Department and the IRS have determined that it is necessary to clarify when qualified manufacturer status is determined. Accordingly, the final regulations clarify that, for purposes of determining whether the qualified manufacturer requirement of section 30D(d)(1)(C) is met, a new clean vehicle is made by a qualified manufacturer if it is made by a manufacturer that is a qualified manufacturer at the time a written report is submitted to the IRS under a qualified manufacturer agreement, as described in section 30D(d)(3). This rule is consistent with section 30D, as well as its underlying purpose of incentivizing clean vehicle deployment. Further, under this rule, a vehicle made by a manufacturer that was not a qualified manufacturer at the time of production may still qualify as a new clean vehicle, provided the manufacturer becomes a qualified manufacturer and submits a written report to the IRS prior to the time the vehicle is sold. In addition, The Treasury Department and the IRS lack authority to provide retroactive relief with respect to vehicles that were sold prior to the time the qualified manufacturer submitted a periodic written report to the IRS under the qualified manufacturer agreement. Finally, the qualified manufacturer requirements of sections 30D(d)(1)(C) and 30D(d)(3), and therefore these final regulations, also apply for purposes of sections 25E and 45W. *See* sections 25E(c)(1)(D)(i) and 45W(c)(1). Therefore, a vehicle made by a manufacturer that was not a qualified manufacturer at the time of production—including a vehicle produced prior to enactment of the IRA, when there were no qualified manufacturer rules with respect to section 30D—may qualify as a previously-owned clean vehicle, provided the manufacturer becomes a qualified manufacturer and submits a written report to the IRS prior to the time the vehicle is sold. Consistent with this rule and with the statute, the final regulations provide that the IRS may terminate qualified manufacturer status for fraud, intentional disregard, or gross negligence with respect to any requirement of section 25E or section 45W or any regulations thereunder.

The final regulations adopt the proposed definition of ''qualified manufacturer'' with the modification described previously, and move it § 1.30D–2(b).

24. Recycling

Proposed §§ 1.30D–6(a)(15) and 1.30D–3(c)(19) defined ''recycling'' as the series of activities during which recyclable materials containing applicable critical minerals are transformed into specification-grade commodities and consumed in lieu of virgin materials to create new constituent materials; such activities result in new constituent materials contained in the battery from which the electric motor of a new clean vehicle draws electricity. Under the proposed regulations, all physical, chemical, and thermal treatments or modifications that convert recycled feedstocks to specification grade constituent materials are included in recycling. The Explanation of Provisions to the April Proposed Regulations noted that this definition aligns with the current methods of direct, hydrometallurgical, or pyrometallurgical recycling that are utilized commercially for reuse of materials for battery applications.

In addition, proposed § 1.30D–6(c)(4)(ii)(D), provided that, for purposes of the FEOC Restriction, an applicable critical mineral and associated constituent material that is recycled is subject to the FEOC-compliance determination if the recyclable material (1) contains an applicable critical mineral, (2) contains material that was transformed from an applicable critical mineral, or (3) is used to produce an applicable critical mineral at any point during the recycling process. Under the proposed regulations, the determination of whether an applicable critical mineral or associated constituent material that is incorporated into a battery via recycling is FEOC-compliant took into account only activities that occurred during the recycling process.

One commenter noted that the definition of ''recycling'' is vague and does not clearly define which recycling steps (for example, shredding, separating, producing black mass, and critical mineral refinement processing) can and cannot occur within a FEOC. The commenter requested that the final regulations clarify that all recycling

activities must occur in a non-FEOC facility for the recycled material to qualify as FEOC-compliant in a new clean vehicle battery. Under the proposed regulations, the determination of whether an applicable critical mineral or associated constituent material that is incorporated into a battery via recycling is FEOC-compliant already takes into account all recycling activities. Accordingly, the suggested clarification is unnecessary.

Another commenter recommended that the Treasury Department and the IRS work with the DOE and other agencies to develop safeguards to prevent batteries from being recycled before the end of their useful lives by entities seeking to convert non-FEOC-compliant batteries into FEOC-compliant batteries through recycling. Critical minerals and associated constituent materials are subject to both the Critical Minerals Requirement and the FEOC Restriction. The Critical Minerals Requirement generally looks to the value of the recycled materials. Due to this requirement, as well as market forces, it will generally be uneconomical to recycle batteries before the end of their useful lives for purposes of the FEOC Restriction. Accordingly, the final regulations do not adopt this comment.

The final regulations consolidate the definition of ''recycling'' in proposed §§ 1.30D–3(c)(19), 1.30D–6(a)(15), and 1.30D–6(c)(4)(ii)(D) into a single provision, and move it to § 1.30D–2(b). Specifically, the final regulations define ''recycling'' as the series of activities during which recyclable materials containing applicable critical minerals are transformed into specification-grade commodities and consumed in lieu of virgin materials to create new constituent materials; such activities result in new constituent materials contained in the clean vehicle battery. Under the final regulations, all physical, chemical, and thermal treatments or modifications that convert recycled feedstocks to specification-grade constituent materials are included in recycling. Further, recycled applicable critical minerals and associated constituent materials are only subject to the requirements under §§ 1.30D–3 and 1.30D–6 if the recyclable material contains an applicable critical mineral, contains material that was transformed from an applicable critical mineral, or if the recyclable material is used to produce an applicable critical mineral at any point during the recycling process. The requirements under §§ 1.30D–3 and 1.30D–6 only take into account activities that occurred during the recycling process.

The final regulations also add an example that illustrates which activities are taken into account with respect to recycling for purposes of the Critical Minerals Requirement and the FEOC Restriction.

25. Section 30D Regulations

Proposed § 1.30D–2(f) defined ''section 30D regulations'' to mean §§ 1.30D–1 through 1.30D–4. The final regulations modify the definition to mean §§ 1.30D–1 through 1.30D–6, and move it to § 1.30D–2(b).

26. Seller Report

Proposed § 1.30D–2(j) defined ''seller report'' as the report described in section 30D(d)(1)(H) and provided by the seller of a vehicle to the taxpayer and the IRS in the manner provided in, and containing the information described in, guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The proposed regulations further provided that the seller report must be provided to the IRS electronically. In addition, the proposed regulations provided that the term ''seller report'' does not include a report rejected by the IRS due to the information contained therein not matching IRS records. The final regulations adopt the proposed definition and move it to § 1.30D–2(b).

One commenter requested that the IRS issue a form, with related instructions, for making seller reports to taxpayer/purchasers as required by § 30(D)(d)(1)(H). The Treasury Department and the IRS have issued such a form, Form 15400, *Clean Vehicle Seller Report.*

27. Value

Proposed § 1.30D–3 defined ''value,'' with respect to property, as the arm's-length price that was paid or would be paid for the property by an unrelated purchaser determined in accordance with the principles of section 482 of the Code and regulations thereunder. The final regulations adopt the proposed definition and move it to § 1.30D–2(b).

One commenter recommended that the Treasury Department and the IRS consider how the term ''value'' might be defined in a manner that accommodates and incentivizes further technological innovation, increased performance and efficiency, and minimization of environmental impacts. The commenter, however, did not propose a specific modification to the definition. The final regulations, consistent with the proposed regulations, define ''value'' in accordance with longstanding tax law principles.

28. Vehicle Classifications

Proposed § 1.30D–2(g) provided that the vehicle classification of a new clean vehicle is to be determined consistent with the EPA's fuel economy labeling rules and definitions provided in 40 CFR 600.315–08 for vans, sport utility vehicles, pickup trucks, and other vehicles. Specifically, ''van'' means a vehicle classified as a van or minivan under 40 CFR 600.315–08(a)(2)(iii) and (iv), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a)(3)(ii); ''sport utility vehicle'' means a vehicle classified as a small sport utility vehicle or standard sport utility vehicle under 40 CFR 600.315–08(a)(2)(v) and (vi), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a)(3)(ii); ''pickup truck'' means a vehicle classified as a small pickup truck or standard pickup truck under 40 CFR 600.315–08(a)(2)(i) and (ii), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a)(3)(ii); and ''other vehicle'' means any vehicle classified in one of the classes of passenger automobiles listed in 40 CFR 600.315–08(a)(1), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a)(3)(ii).

One commenter commended the Treasury Department's and the IRS's decision to align the section 30D vehicle classification definitions with existing EPA regulations, which incorporate certain classification flexibility. For added clarity, the commenter recommended that the final regulations adopt by reference less specific pin cites in the EPA fuel economy labeling regulations to better reflect EPA's general classification authority. In particular, the commenter suggested that the final regulations define a sport utility vehicle by citing 40 CFR 600.315–08(a)(1), which states that the EPA Administrator may classify passenger automobiles by car line into one of the classes based on interior volume index or seating capacity except for those that the Administrator determines are most appropriately placed in a different classification. Additionally, the commenter suggested that the final regulations define pickup truck by citing 40 CFR 600.315–08(a)(2) or 40 CFR 600.315–08 generally rather than 40 CFR 600.315–08(a)(3)(ii). After consultation with the EPA, the Treasury Department and the IRS agree that a more general cross-reference to EPA's classification authority is warranted, given the authority not only in 40 CFR 600.315–08(a)(3)(ii) but also in 40 CFR 600.315–08(a)(1) and (2). The final

regulations adopt the comment and modify the definitions accordingly.

Another commenter requested that the MSRP limitation under section 30D(f)(11)(B) be expanded to apply to all crossover vehicles similar to the regime described in 40 CFR 600.315–08, which would further incentivize automakers to onshore electric vehicle supply chains by making additional vehicles eligible for the section 30D credit. The Treasury Department and the IRS note that crossover vehicles are included in the vehicle classifications subject to the appropriate MSRP limitation. Under the EPA fuel economy labeling regulations, crossover vehicles may be categorized as either a sport utility vehicle or other vehicle. The Treasury Department and the IRS adopted the EPA fuel economy labeling definitions in part because they are reported on the vehicle label and are accessible on *https://fueleconomy.gov*, making the classification accessible to both consumers and the IRS. In addition, the EPA fuel economy labeling definitions provide some discretion, which EPA may exercise to align its classifications with consumer expectations regarding vehicle type. Because the proposed regulations already adopt the regime suggested by commenters and because the MSRP limitation is prescribed by statute, the final regulations do not adopt this comment.

A different commenter requested that low-speed vehicles be included in the ''other vehicles'' classification under proposed § 1.30D–2(g)(5), noting that they are commercial, street-legal vehicles. However, as the commenter notes, a new clean vehicle must be treated as a motor vehicle for purpose of title II of the Clean Air Act as described in section 30D(d)(1)(D). Under section 216 of the title II of the Clean Air Act, a motor vehicle is defined as ''any self-propelled vehicle designed for transporting persons or property on a street or highway.'' 42 U.S.C. 7550(2). EPA regulations at 40 CFR 85.1703(e)(1) further define a motor vehicle under title II of the Clean Air Act to exclude vehicles with maximum speeds of 25 miles per hour, which excludes low-speed vehicles. Because section 30D requires new clean vehicles to meet Clean Air Act standards, which exclude low-speed vehicles, the final regulations do not adopt this comment.

Some commenters praised the proposed implementation of the fuel economy labeling regime, whereas others claimed there is a potential for misclassifying vehicles given the lessened emphasis on weight and other physical characteristics as major classification factors under EPA standards as compared to gas-powered vehicles. In particular, a commenter stated the proposed vehicle classification regime is arbitrary and unreliable, due to the EPA's subjective authority granted without explicit authorization found in title I of the IRA. The commenter requested that the final regulations use objective vehicle classification standards, such as those found in 40 CFR 600.002, rather than subjective EPA determinations. An additional commenter stated that light trucks and SUVs in particular may be misclassified as passenger cars if physical characteristics are overlooked for emissions.

The Treasury Department and the IRS previously considered adopting the vehicle classification definitions used by the CAFE standards in 40 CFR 600.002, as described in Notice 2023–1. After consultation with the DOE and the EPA, as provided for in section 30D(f)(11)(C), the Treasury Department and the IRS determined that the fuel economy labeling standards in 40 CFR 600.315–08 better reflect consumer expectations and marketing practices regarding vehicle classifications. In addition, the vehicle classification, as determined under the fuel economy labeling standards, is shown on the vehicle label and is otherwise accessible on *https://fueleconomy.gov,* making the classification accessible to both consumers and the IRS. In contrast, a particular vehicle's classification under the CAFE standard is not publicly available information under current practices. For these reasons, the final regulations do not adopt the comments.

The final regulations adopt the proposed definition, with more general cross-references to EPA's classification authority, and move it to § 1.30D–2(b).

B. Critical Minerals and Battery Components Requirements

Section 30D(e) provides requirements for critical minerals and battery components with respect to clean vehicle batteries. The Critical Minerals and Battery Components Requirements apply to applicable critical minerals and battery components, respectively, contained in a battery. The April Proposed Regulations set forth rules for the Critical Minerals and Battery Components Requirements in proposed § 1.30D–3. The final regulations reorganize the rules of the Critical Minerals and Battery Components Requirements.

First, the proposed regulations included, in proposed § 1.30D–3(c), definitions applicable for purposes of the Critical Minerals and Battery Components Requirements. As noted previously in section III.A of this Summary of Comments and Explanation of Revisions, the final regulations move many of these definitions to § 1.30D–2(b), as general definitions for purposes of section 30D and the section 30D regulations. The final regulations retain the definitions applicable to the calculations of the Critical Minerals Requirement in § 1.30D–3(c)(1), and the definitions applicable to and the Battery Components Requirement in § 1.30D–3(c)(2). Second, the final regulations include rules for the calculation of qualifying critical mineral content for purposes of the Critical Minerals Requirement in § 1.30D–3(a), and for the calculation of qualifying battery component content for purposes of the Battery Components Requirement in § 1.30D–3(b). Third, the final regulations finalize, as § 1.30D–3(d),[7] the rules for upfront review of the Critical Minerals and Battery Components Requirements. Fourth, the final regulations add a new rule for new qualified fuel cell motor vehicles as § 1.30D–3(e). Finally, in response requests from commenters, the final regulations add examples that illustrate the calculations under the Critical Minerals and Battery Components Requirements as § 1.30D–3(f).

1. Critical Minerals Requirement

Proposed § 1.30D–3(a)(1) provided that that Critical Minerals Requirement was met if the qualifying critical mineral content of the clean vehicle battery of the vehicle is equal to or exceeds the applicable critical minerals percentage provided in section 30D(e)(1)(B) and proposed § 1.30D–3(a)(2). Proposed § 1.30D–3(c)(18) defined ''qualifying critical mineral content'' as the percentage of the value of the applicable critical minerals contained in the clean vehicle battery that were extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or were recycled in North America.

The April Proposed Regulations provided a three-step process (50% Value Added Test) for determining the qualifying critical mineral content of a clean vehicle battery.

First, qualified manufacturer would determine the procurement chain or chains for each applicable critical

[7] The April Proposed Regulations reserved proposed § 1.30D–3(d) for excluded entities. The December Proposed Regulations modified proposed § 1.30D–3(d) to include a cross reference to the rules for excluded entities in proposed § 1.30D–6. These final regulations finalize those rules in § 1.30D–6; § 1.30D–3(d) is deleted as unnecessary.

mineral. Proposed § 1.30D–3(c)(14) defined a ''procurement chain'' as a common sequence of extraction, processing, or recycling activities that occur in a common set of locations, concluding in the production of constituent materials. In addition, proposed § 1.30D–3(c)(14) clarified that sources of a single applicable critical mineral may have multiple procurement chains if, for example, one source of the applicable critical mineral undergoes the same extraction, processing, or recycling process in different locations. Each applicable critical mineral procurement chain would be evaluated separately pursuant to proposed § 1.30D–3(a)(3)(ii).

Second, qualified manufacturers would evaluate each applicable critical mineral procurement chain in the clean vehicle battery to determine whether critical minerals procured from the chain have been (1) extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or (2) recycled in North America. Applicable critical minerals that satisfy this requirement are considered qualifying critical minerals. Proposed § 1.30D–3(c)(17) defined ''qualifying critical mineral'' as an applicable critical mineral that is extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or that is recycled in North America. Proposed § 1.30D–3(c)(17) used a 50 percent threshold to determine whether an applicable critical mineral is a ''qualifying critical mineral.'' Thus, under the proposed regulations, an applicable critical mineral was treated as extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, if: (1) 50 percent or more of the value added to the applicable critical mineral by extraction is derived from extraction that occurred in the United States or in any country with which the United States has a free trade agreement in effect; or (2) 50 percent or more of the value added to the applicable critical mineral by processing is derived from processing that occurred in the United States or in any country with which the United States has a free trade agreement in effect. An applicable critical mineral would be treated as recycled in North America if 50 percent or more of the value added to the applicable critical mineral by recycling is derived from recycling that occurred in North America. Proposed § 1.30D–3(c)(25) defined ''value added,'' with respect to recycling, extraction, or processing of an applicable critical mineral, as the increase in the value of the applicable critical mineral attributable to the relevant activity.

Third, qualified manufacturers would calculate qualifying critical mineral content. Under proposed § 1.30D–3(a)(3)(i), qualifying critical mineral content would be calculated as the percentage that results from dividing the total value of qualifying critical minerals by the total value of critical minerals. Proposed § 1.30D–3(c)(23) defined ''total value of qualifying critical minerals'' as the sum of the values of all the qualifying critical minerals contained in a battery described in proposed § 1.30D–3(a)(1). Proposed § 1.30D–3(c)(22) defined ''total value of critical minerals'' as the sum of the values of all applicable critical minerals contained in a battery described in proposed § 1.30D–3(a)(1).

Proposed § 1.30D–3(a)(3)(iii) required qualified manufacturers to select a date for determining the values associated with the total value of qualifying critical minerals (determined separately for each procurement chain) and the total value of critical minerals. Such date needs to be after the final processing or recycling step for the applicable critical minerals relevant to the certification described in section 30D(e)(1)(A) of the Code and should be uniformly applied for all applicable critical minerals contained in the battery.

Proposed § 1.30D–3(a)(3)(iv) provided that a qualified manufacturer may determine qualifying critical mineral content based on the value of the applicable critical minerals actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying critical mineral content for batteries in a group of vehicles, a qualified manufacturer could average the qualifying critical mineral content calculation over a limited period of time (for example, a year, quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof, with final assembly (as defined in section 30D(d)(5) of the Code and proposed § 1.30D–2(b)) within North America.

The Treasury Department and the IRS received numerous comments with respect to the Critical Minerals Requirement. To the extent comments relate to general definitions, such as ''constituent material,'' ''extraction,'' or ''processing,'' they are addressed in section III.A of this Summary of Comments and Explanation of Revisions.

Many commenters expressed criticism or concerns relating to the Critical Minerals Requirement. Several criticized the requirement as too strict. For example, one commenter stated that classifying the supply chains of the United States' allies as non-qualifying would damage the development of a North American supply chain. Section 30D(e)(1) requires an analysis of the location of supply chain activities (that is, extraction, processing, and recycling). Accordingly, the final regulations do not adopt these comments.

Similarly, one commenter requested that the Critical Minerals Requirement be restricted to nickel, cobalt, lithium, manganese, and graphite, as minerals. Because section 30D(e)(1)(A) defines ''applicable critical minerals'' by reference to section 45X(c)(6), which includes a broader list of minerals than the five noted by the commenter, the final regulations do not adopt this comment.

Many comments addressed the 50% Value Added Test. Multiple comments were supportive of the tests, while others recommended that the final regulations adopt a different rule. One commenter suggested that, for lithium and nickel, the final regulations replace the 50% Value Added Test with rules that specify which combinations of extraction and processing are necessary for qualification as qualifying critical mineral content. Two commenters recommended that the 50% Value Added Test be replaced with a determination based on change in tariff classifications. Several comments asserted that the 50% Value Added Test was not strict enough. One commenter stated that the 50% Value Added Test impermissibly stretches the statute by substantially diluting the applicable percentage requirement of section 30D(e)(1)(B). Similarly, another commenter states that the 50% Value Added Test improperly dilutes section 30D(e)(1)(B), and that it improperly bifurcates the Critical Minerals Requirement into separate tests for extraction and processing. Several commenters proposed that the 50% Value Added Test be increased to a higher percentage. Another commenter requested that the 50% Value Added Test be eliminated entirely after 2024. A different commenter requested that guidance describing a more stringent test under the Critical Minerals Requirement be provided as soon as possible, in order to provide clarity to taxpayers, OEMs, and battery suppliers. However, another commenter suggested that the IRS and the Treasury Department refrain from drafting a replacement to the 50% Value Add Test until supply chains are more mature.

An applicable critical mineral may undergo multiple steps of each of extraction, processing, or recycling that occur in multiple locations, and section 30D(e)(1)(A) does not specify how to determine whether an applicable critical mineral was extracted, processed, or recycled in a statutorily-required location. To account for this, the 50% Value Added Test was developed to determine whether an applicable critical mineral procurement chain was sufficiently produced in a statutory-required location to count toward meeting the Critical Minerals Requirement. The 50% Value Added Test allows qualified manufacturers to make an objective determination of when an applicable critical mineral was produced in a manner that would qualify under section 30D(e)(1)(A). While some commenters have criticized the 50 percent threshold as too low, this percentage, as noted in the Explanation of Provisions to the April Proposed Regulations, was intended as a transition rule while ensuring that a significant portion of the extraction, processing, or recycling activities was performed in a statutorily required location. The percentage was designed with the purposes of section 30D(e)(1) in mind and to allow qualified manufacturers time to transition supply chains in anticipation of a more stringent rule.

The final regulations adopt the Traced Qualifying Value Test, described more fully after the discussion of comments in this section of the Summary of Comments and Explanation of Revisions. This test is more precise than the 50% Value Added Test, as it requires an OEM to fully trace any value added in each procurement chain that it applies toward the Critical Minerals Requirement. It is also generally more stringent, because the OEM may treat as qualifying only a percentage of value of an applicable critical mineral, and not the full value. The Traced Qualifying Value Test credits the share of value added by extraction or processing in the United States or a country with which the United States has a free trade agreement in effect, or recycling in North America, in determining whether the Critical Minerals Requirement is met. By looking to the highest value-added percentage of the three specified activities (extraction, processing, or recycling) for each applicable critical mineral procurement chain, the Traced Qualifying Value Test appropriately implements the statutory language requiring only one of the three specified activities with respect to an applicable critical mineral to occur in a qualifying place in order to have the value of an applicable critical mineral count toward satisfying the Critical Minerals Requirement.

In response to comments suggesting alternative approaches to determining whether the Critical Minerals Requirement is satisfied, the Treasury Department and the IRS have determined that specifying combinations of extraction and processing steps would not be administrable given the potential number of permutations. Moreover, specifying combinations only for certain minerals would be at odds with the rules of section 30D(e)(1), which apply to all critical minerals. Similarly, the Treasury Department and the IRS have determined that determining qualifying mineral content based on a change in tariff classification would not be administrable or provide certainty to OEMs because changes in tariff classification may not provide the clear standards required for purposes of tax credit eligibility determinations.

The final regulations adopt the Traced Qualifying Value Test, which is described further below after the discussion of comments in this section of the Summary of Comments and Explanation of Revisions, for taxable years ending after May 6, 2024. In response to commenters who supported the 50% Value Added Test or who supported a longer transition period, the final regulations permit use of the 50% Value Added Test as an optional transition rule for vehicles for which a qualified manufacturer provides a periodic written report prior to January 1, 2027, and require the 50% Value Added Test for vehicles for which a qualified manufacturer provides a periodic written report prior to May 6, 2024.

Several commenters to the April Proposed Regulations raised questions about how the FEOC Restriction applied to applicable critical minerals. These questions were answered in the December Proposed Regulations, which are finalized herein.

Several commenters raised questions relating to the calculation under the 50% Value Added Test. These questions may be relevant under these final regulations for either the 50% Value Added Test (as it is retained as a transition rule) or for the Traced Qualifying Value Test, and so are addressed herein. For example, one commenter requested clarification on whether lithium carbonate or lithium ore corresponding to lithium carbonate should be used to calculate the total value of qualifying critical minerals. The final regulations clarify, in the definition of ''applicable critical mineral'' in § 1.30D–2(b), that the Critical Minerals Requirement and FEOC Restriction determinations with respect to an applicable critical mineral take into account each step of extraction, processing, or recycling through the step in which such mineral is processed or recycled into an associated constituent material, even if the mineral is not in a form listed in section 45X(c)(6) at every step of production. Thus, both the lithium carbonate and lithium ore should be taken into account. Several commenters raised specific questions about specific components of the calculation. Another commenter requested that the final regulations clarify that, under step three of the 50% Value Added Test calculation, the total value of qualifying critical minerals and total value of critical minerals means the value of the corresponding constituent materials. Because a constituent material may be composed of an applicable critical mineral that has multiple procurement chains, or of multiple critical minerals, their values may not necessarily correspond to the value of the associated constituent material. Accordingly, the final regulations do not adopt this comment. Another commenter asked whether a weighted average is used for purposes of the 50% Value Added Test if an applicable critical mineral has two or more procurement chains. The same commenter asked if the 50% Value Added Test can be satisfied by adding percentages across extraction and processing. Under both the proposed and final regulations, the 50% Value Added Test does not use a weighted average, and the percentages must be examined separately for each of extraction, processing, or recycling. Relatedly, two commenters noted that the proposed regulations did not provide a methodology for distributing the value-add across procurement chains. The proposed regulations required a separate analysis of each procurement chain and did not allow for analysis across procurement chains. Because allowing analysis across procurement chains would be at odds with the supply-chain tracing requirements of section 30D(e)(1), the final regulations do not adopt these comments.

One commenter asked for clarification on how to determine value added in cases in which multiple applicable critical minerals are processed together, and recommended that the final regulations provide that value added be allocated to each applicable critical

mineral based on weight. The proposed regulations defined ''value added'' with respect to recycling, extracting, or processing of an applicable critical mineral as the increase in the value of the applicable critical mineral attributable to the relevant activity; the proposed regulations did not provide a specific rule for a case in which multiple applicable critical minerals are processed together. In response to this comment, the final regulations clarify that, in the case in which multiple applicable critical mineral procurement chains are part of the same processing or recycling activity, value added should be allocated to each procurement chain based on relative mass.

The proposed regulations allowed qualified manufacturers to average qualifying critical mineral content over a limited period of time (for example, a year, quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof. The Treasury Department and the IRS received a number of comments on this rule. Several commenters were supportive of the proposed rule or sought a broader averaging rule. One commenter asked that the final regulations expressly allow for an 18-month averaging period. One commenter requested that the final regulations consider also allowing qualified manufacturers to average critical mineral content over batteries produced at a particular facility. Similarly, another commenter requested that the final regulations allow automakers to calculate, on a companywide basis, their volume or percentage of qualifying critical minerals and allocate such minerals to specific batteries or vehicles on a unit-by-unit or VIN-by-VIN basis. On the other hand, several commenters raised concerns that the averaging rule could allow for manipulation. One commenter suggested limitations on the averaging rule, and requested that the final regulations require automakers to offer a clear explanation of how they perform the calculation, and demonstrate to the IRS that the calculation will neither exclude any vehicles with a battery that the automaker brings to market, nor double count any vehicles. The commenter also suggested that the IRS limit an automaker's ability to switch between groupings of vehicles (for purpose of calculating the average) to minimize the opportunity to manipulate the calculation. The commenter further recommended that automakers be allowed to choose a test period (preferably as late as possible in the year) over which to calculate average values to take advantage of growing qualifying supply chains, but with sufficient time to ensure the automaker can determine vehicle eligibility for the tax credit before the beginning of a calendar year. Another commenter noted that averaging qualifying critical mineral content by alternative periods of time by model line, plant, class, or combination thereof with final assembly in North America may prove an administrative burden and result in an increased risk of manipulation, citing how anode and cathode critical minerals could move through the procurement supply chain to manipulate value calculations. A separate commenter expressed concern that the averaging rules could allow OEMs to source critical minerals from outside the United States and countries with which the United States has free trade agreements in effect, yet still satisfy the Critical Minerals Requirement. The Treasury Department and the IRS have determined that the proposed rules reflect a reasonable balancing of these considerations by allowing averaging, but limiting it to groups of vehicles that may share the same procurement chains (that is, vehicles from the same model line, plant, class, or some combination of thereof). In addition, the upfront review process, finalized as § 1.30D–3(d), provides a mechanism for review and verification of OEM calculations, which will prevent manipulation. Finally, the time periods of a year, quarter, or month are exemplary and do not prevent averaging over a different time period. However, the averaging period should be consistent with any rules and procedures established by the upfront review process. Accordingly, the final regulations do not adopt these comments.

Several commenters raised concerns with respect to the volatility of mineral pricing. One such commenter requested that qualified manufacturers be given the option to elect to average the most common critical mineral's value with the historical values of that material based on previous annual contracts. Others requested a historical lookback period of between eighteen months to five years. Another commenter requested that the Treasury Department and the IRS allow for multiple methods of calculation to address market fluctuations. Specifically, the commenter recommended that to address market fluctuations, the previous year's average mineral price could be used, or a five-year average. The commenter further noted that this would take into account the very large difference in the value of the different materials, but mitigate against market volatility. A commenter suggested the Treasury Department and the IRS provide the option to use widely-recognized and trusted market indices to serve as an acceptable estimation of the price of a particular step in the procurement chain for which actual prices for certain procurement chains or portions of the procurement chain cannot be determined by the manufacturer. The commenter noted that contracts with suppliers usually indicate what the ''controllable piece'' is, essentially what cost of that supplier's value-add is within the overall cost of the supplied product. However, contracts typically do not provide a set cost for inputs, as those inputs are price flexible based on the mineral markets, meaning that using an established mineral market index for cost estimation would more closely reflect the real-world prices paid for that material. The commenter indicated that these indices may include those commonly cited in U.S. Geological Survey reports. Finally, commenters proposed adopting a safe harbor provision due to the price volatility of critical minerals, which would enable producers of critical minerals to relocate sourcing operations to the United States or countries with which the United States has free trade agreements in effect. The Treasury Department and the IRS acknowledge these commenters' concerns relating to mineral valuation and volatility. The averaging rules of the proposed and final regulations are intended, in part, to address these concerns by allowing qualified manufacturers to determine qualifying critical mineral content based on an average value (rather than the value at a specific time that may be unusually high or low) and by allowing qualified manufacturer flexibility in determining the averaging period. Similarly, the proposed and final regulations allow qualified manufacturers to choose a date, after the final processing or recycling step, for the determination of value, which also provides flexibility. Accordingly, the final regulations do not adopt these comments.

Several commenters commented on sourcing and OEM due diligence. One commenter suggested that the final regulations require qualified manufacturers to engage in detailed tracing, and provide related documentation to the IRS. That commenter suggested that the processes of the EU Battery Regulation could provide a model. Another commenter encouraged the Treasury Department

and the IRS to work closely with the DOE, Environmental Protection Agency, and Department of Transportation to explore how a digital battery identifier could help facilitate material sourcing transparency and improve the efficiency of battery repurposing and recycling. Several commenters suggested adopting standards based on Organisation for Economic Co-operation and Development (OECD) standards. A commenter requested clarification on what due diligence is required with respect to battery supply chains, particularly in instances in which intermediate materials may not be sold on an open market. The upfront review process of § 1.30D–3(d) is intended to provide clear rules and a clear process for automakers to provide information regarding due diligence with respect to the Critical Minerals and Battery Components Requirements to the IRS. The Treasury Department and the IRS are considering future sub-regulatory guidance with respect to the upfront review process.

Finally, one commenter raised concerns that unexpected events could affect the supply of either applicable critical minerals or battery components, and suggested that the Treasury Department and the IRS allow for a temporary waiver request process in such cases, allowing the affected minerals or components to be excluded from the calculation under the Critical Minerals or Battery Components Requirements. The commenter set out a detailed scheme for the waiver process. Another commenter similarly requested a waiver process in cases in which certain production steps are affected by either market volatility or unexpected events. The Treasury Department and the IRS determined that the averaging rules under the Critical Minerals and Battery Components Requirements allow for flexibility in the case of both price fluctuations and unexpected events. In addition, allowing OEMs or their suppliers a waiver with respect to certain production steps could be subject to manipulation. Accordingly, these comments are not adopted.

As under the proposed regulations, the final regulations, under § 1.30D–3(a)(1), provide that the Critical Minerals Requirement is met if the qualifying critical mineral content of the clean vehicle battery of the vehicle is equal to or exceeds the applicable critical minerals percentage provided in section 30D(e)(1)(B) and § 1.30D–3(a)(2). The proposed regulations included the 50% Value Added Test for determination of the qualifying critical mineral content. In the Explanation of Provisions to the April Proposed Regulations, the Treasury Department and the IRS anticipated that the 50% Value Added Test would serve as a transition rule, which would provide manufacturers time to develop the necessary capability to certify compliance with the Critical Minerals Requirement throughout their supply chains, and the final regulations would move to a more stringent test. Certain commenters criticized the April NPRM rules as inconsistent with the statute, while others have been supportive. Several commenters asked for additional clarity as to how to make the calculations and for specific examples. Others asked that the calculation in the proposed rule be made permanent. Other than as described above, commenters generally did not identify alternative proposals for the Critical Minerals requirement. Consistent with this, and taking into account the comments received, the final regulations adopt the following rules for determining qualifying critical mineral content.

For vehicles for which a qualified manufacturer provides a periodic written report on or after May 6, 2024, § 1.30D–3(a)(3), as finalized, provides a three-step process (Traced Qualifying Value Test) for the calculation under the Critical Minerals Requirement.

First, the qualified manufacturer determines each procurement chain, as defined in § 1.30D–3(c)(1)(i), consistent with the April Proposed Regulations.

Second, the qualified manufacturer must determine the ''traced qualifying value'' of all applicable critical minerals'' and the ''total traced qualifying value.'' These definitions are introduced in the final regulations. ''Traced qualifying value'' is defined, in § 1.30D–3(c)(1)(vii) as, with respect to an applicable critical mineral that is extracted and processed into a constituent material, the value of the applicable critical mineral multiplied by the greater of (A) the value added to the applicable critical mineral by extraction that occurred in the United States or in any country with which the United States has a free trade agreement in effect, divided by the total value added from extraction of the applicable critical mineral; or (B) the value added to the applicable critical mineral by processing that occurred in the United States or in any country with which the United States has a free trade agreement in effect, divided by the total value added from processing of the applicable critical mineral. ''Traced qualifying value'' is defined as, with respect to an applicable critical mineral that is recycled into an associated constituent material, the value of the applicable critical mineral multiplied by the percentage obtained by dividing the value added to the applicable critical mineral by recycling that occurred in North America by the total value added from recycling of the applicable critical mineral. ''Valued added'' is defined in § 1.30D–3(c)(1)(viii), consistent with the April Proposed Regulations. Section 1.30D–3(a)(3)(ii) provides that the traced qualifying value of an applicable critical mineral, including the percentage or percentages necessary to determine the traced qualifying value, must be determined separately for each procurement chain. ''Total traced qualifying value,'' in § 1.30D–3(c)(1)(iv), is defined as the sum of the traced qualifying values of all applicable critical minerals contained in the clean vehicle battery.

Third, the qualified manufacturer determines the qualifying critical mineral content. Section 1.30D–3(a)(3)(i) provides that qualifying critical mineral content is determined by dividing the total traced qualifying value (calculated in step 2) by the total value of critical minerals. The final regulations, consistent with the proposed regulations, provide in § 1.30D–3(c)(1)(v) that the ''total value of critical minerals'' means the sum of the values of all applicable critical minerals contained in a clean vehicle battery.

Section 1.30D–3(a)(3)(iii) requires qualified manufacturers to select a date for determining the values associated with the total traced qualifying value (determined separately for each procurement chain) and the total value of critical minerals. Such date would need to be after the final processing or recycling step for the applicable critical minerals relevant to the certification described in section 30D(e)(1)(A) of the Code. This date would need to be uniformly applied for all applicable critical minerals contained in the battery.

Section 1.30D–3(a)(3)(iv) provides that a qualified manufacturer may determine qualifying critical mineral content based on the value of the applicable critical minerals actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying critical mineral content for batteries in a group of vehicles, a qualified manufacturer could average the qualifying critical mineral content calculation over a limited period of time (for example, a year, calendar quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof, with final assembly within North America.

As noted above, the Traced Qualifying Value Test is more precise than the 50% Value Added Test, as it requires an OEM to fully trace any value added in each procurement chain that it applies toward the Critical Minerals Requirement. It is also generally more stringent, because the OEM may treat as qualifying only a percentage of value of an applicable critical mineral, and not the full value. The Treasury Department and the IRS also considered adapting the 50% Value Added Test to require a higher threshold percentage than 50%, but such an approach results in a ''cliff effect'' whereby the value of applicable critical minerals just below the threshold percentages is not applied toward the Critical Minerals Requirement while the full value of applicable critical minerals just above the threshold percentage is treated as qualifying, which could lead to counter-intuitive results and increased potential for gaming. By contrast, the Traced Qualifying Value Test incentivizes each incremental increase in value-added activities in the United States and free trade agreement partner countries or in North America, as applicable. For these reasons, the Treasury Department and the IRS have determined that this test is the most effective of the potential alternatives considered in furthering the statutory purpose of transitioning to secure clean vehicle battery supply chains in the United States and allied countries.

In order to allow for a transition to the Traced Qualifying Value Test, the final regulations provide that, for vehicles for which a qualified manufacturer provides a periodic written report on or after May 6, 2024 and prior to January 1, 2027, a qualified manufacturer may calculate qualifying critical mineral content under the 50% Value Added Test. Finally, the regulations finalize the 50% Value Added Test for vehicles for which a qualified manufacturer provides a periodic written report prior to May 6, 2024.

2. Battery Components Requirement

The final regulations adopt the Battery Components Requirement of the April Proposed Regulations without change. Section § 1.30D–3(c)(2)(iii) defines ''qualifying battery component content'' as the percentage of the value of the battery components contained in the clean vehicle battery that were manufactured or assembled in North America. As finalized in § 1.30D–3(b)(1), the Battery Components Requirement is met if the qualifying battery component content of a clean vehicle battery is equal to or exceeds the applicable battery components percentage provided in section 30D(e)(2)(B) and § 1.30D–3(a)(2).

The final regulations provide a four-step process for determining the percentage of the value of the battery components in a battery that contribute toward meeting the Battery Components Requirement.

First, qualified manufacturers determine whether each battery component in a battery was a ''North American battery component,'' that is, a battery component substantially all of the manufacturing or assembly of which occurs in North America, without regard to the location of the manufacturing or assembly activities of any components that make up the particular battery component (as defined in § 1.30D–3(c)(2)(ii).

Second, qualified manufacturers determine the ''total incremental value of North American battery components,'' that is, the sum of the incremental values of each North American battery component contained in clean vehicle battery (as defined in § 1.30D–3(c)(2)(v)). ''Incremental value'' is defined as, with respect to the battery component, the value of that battery component minus the value of the manufactured or assembled battery components, if any, that are contained in that battery component (as defined in § 1.30D–3(c)(2)(i)).

Third, qualified manufacturers determine the ''total incremental value of battery components,'' that is, the sum of the incremental values of each battery component contained in a clean vehicle battery (as defined in § 1.30D–3(c)(2)(iv)).

Fourth, qualified manufacturers determine the qualifying battery component content, by dividing the total incremental value of North American battery components (determined in step 2) by the total incremental value of battery components (determined in step 3), as provided in § 1.30D–3(b)(3)(i).

Section 1.30D–3(b)(3)(ii) requires qualified manufacturers to select a date for determining the values associated with the total incremental value of North American battery components and the total incremental value of battery components. Such date needs to be after the last manufacturing or assembly step for the battery components relevant to the certification described in section 30D(e)(2)(A). This date must be uniformly applied for all battery components contained in the battery.

Section 1.30D–3(b)(3)(iii) provides that a qualified manufacturer may determine qualifying battery component content based on the incremental values of the battery components actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying battery component content for batteries in a group of vehicles, a qualified manufacturer could average the qualifying battery component content calculation over a limited period of time (for example, a year, a calendar quarter, or a month) with respect to vehicles from the same model line, plant, class, or some combination of thereof, with final assembly (as defined in section 30D(d)(5) of the Code and § 1.30D–2(b) of the final regulations) within North America.

Finally, the final regulations, in § 1.30D–3(c)(2)(iv), clarify that the battery module is the end point for the purpose of calculating the value of battery components. This clarification was noted in the Explanation of Provisions to the April Proposed Regulations. In addition, the final regulations clarify that, in the case of a cell-to-pack battery design with no modules, the battery cell is the end point for the purpose of calculating the value of battery components.

The Treasury Department and the IRS received a number of comments with respect to the Battery Components Requirement. Comments with respect to generally applicable definitions, such as ''assembly,'' ''battery,'' ''battery component,'' or ''manufacturing,'' are discussed in section III.A of this Summary of Comments and Explanation of Revisions. This section discusses comments with respect to the calculation required to determine compliance with the Battery Components Requirement.

One commenter criticized the Battery Components Requirement and noted that it may reduce efficiency, cost effectiveness, and innovation with respect to battery components. In response to this, the Treasury Department and the IRS note that the Battery Components Requirement is mandated by the statute. Similarly, another commenter recommended that battery components manufactured or assembled in Japan be considered as qualifying. However, this is prohibited by the statute because battery components must be manufactured or assembled in North America to meet the Battery Components Requirement.

A commenter asked for a more detailed components list along with calculation examples that include the components in the list. As discussed in section III.A.6 of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS decline to amend the list of

battery components. However, the final regulations add a new definition for the term ''battery materials,'' and clarify that battery materials are not battery components. In addition, the Treasury Department and the IRS have included in the Summary of Comments and Explanation of Revisions to the final regulations an example calculation under the Battery Components Requirement that references specific components.

Proposed § 1.30D–3(b)(3)(iii) provided flexible rules that allow a qualified manufacturer to average the qualifying battery component content calculation over a limited period of time (for example, a year, quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof. One commenter raised a concern that these rules were too flexible and could create gaming opportunities. The commenter suggested that the final regulations clearly describe which vehicle characteristics may be averaged together and directly state that any combination of characteristics not identified in the final regulations may not be averaged together. Because the category of vehicle characteristics is open-ended, may vary by manufacturer, and is subject to change in the future, it is not practicable to specify certain vehicle characteristics that are necessary for grouping. In addition, a specified list of vehicle characteristics may not correspond to the vehicle procurement chains of particular manufacturers. For these reasons, the Treasury Department and the IRS appreciate the concerns raised by this comment, but have concluded that the flexibility of the proposed rule is necessary in order to provide an administrable rule to qualified manufacturers. In addition, the upfront review process described in proposed § 1.30D–3(e), discussed in section III.B.3 of this Summary of Comments and Explanation of Revisions, will also help prevent gaming of the Battery Components Requirement calculations. This commenter also suggested that the Treasury Department and the IRS maintain the right to update which characteristics may be averaged together in the future, should changes be necessary. In response to this, the Treasury Department and the IRS will continue to study this issue as the Treasury Department and the IRS gain experience with the upfront review process.

Finally, two commenters suggested that the final regulations consider allowing for a waiver of the Critical Minerals and Battery Components Requirements in certain cases. The statute does not provide for a waiver program; thus, the final regulations do not adopt these comments. Commenter proposals for a waiver process are discussed in more detail in section III.B.1 of this Summary of Comments and Explanation of Revisions.

3. Upfront Review

Proposed § 1.30D–3(e) provided for an upfront review to assess a qualified manufacturer's conformance with the Critical Minerals and Battery Components Requirements. Specifically, proposed § 1.30D–3(e) provided that for new clean vehicles placed in service after December 31, 2024, the qualified manufacturer must provide attestations, certifications, and documentation demonstrating compliance with the requirements of section 30D(e), at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The IRS, with analytical assistance from the DOE, will review the attestations, certifications, and documentation. This rule is finalized as § 1.30D–3(d).

One commenter stated that, if final regulations require qualified manufacturer submissions, the Treasury Department and the IRS should develop a system to protect confidential business secrets. In response to this, the Treasury Department and the IRS note that they intend to continue to engage with OEMs and other stakeholders to develop the rules under the upfront review process.

4. Rule for New Qualified Fuel Cell Motor Vehicles

The final regulations provide in § 1.30D–3(e) that the requirements of section 30D(e) and § 1.30D–3 (Critical Minerals and Battery Components Requirements) are deemed to be satisfied with respect to new qualified fuel cell motor vehicles. Thus, the amount of the credit with respect to these vehicles, under section 30D(b), is $7,500. However, a qualified fuel cell motor vehicle (as defined in section 30B(b)(3)) with a clean vehicle battery, such as a plug-in hybrid fuel cell electric vehicle, would be subject to the Critical Minerals and Battery Components Requirements because it draws electricity from the clean vehicle battery.

Because new qualified fuel cell motor vehicles do not have a clean vehicle battery, these vehicles do not have applicable critical minerals or battery components contained in such battery that would be subject to the Critical Minerals and Battery Components Requirements. The IRA's enactment of section 30D(d)(6), which provides that new qualified fuel cell motor vehicles are new clean vehicles if such vehicles meet the North American final assembly and seller reporting requirements (*see* section 30D(d)(1)(G) and (H)), indicates that Congress intended for these vehicles to be eligible for the section 30D credit. Therefore, the better reading of section 30D as a whole is that new qualified fuel cell motor vehicles are eligible for the full section 30D credit amount of $7,500.

C. Special Rules

Proposed § 1.30D–4 provided special rules with respect to the section 30D credit. Among those rules, proposed § 1.30D–4(b)(5)(i) provided that, except as provided in proposed § 1.30D–4(b)(5)(ii), in the case of a new clean vehicle that is placed in service by a corporation or other taxpayer that is not an individual for whom AGI is computed under section 62, the Modified AGI limitation does not apply. One commenter expressed concern about individuals circumventing the Modified AGI limitation by having a non-grantor trust place in service an otherwise qualifying vehicle, suggesting that an anti-abuse rule would prevent such occurrences. In response to this comment, the final regulations provide that the Modified AGI limitation applies to individuals, estates, and non-grantor trusts. For estates and non-grantor trusts, Modified AGI is AGI as determined under section 67(e) of the Code. The final regulations also provide that the $150,000 threshold amount applies to estates and non-grantor trusts for purposes of the Modified AGI limitation, and that an estate or non-grantor trust will be treated as having Modified AGI above the threshold amount for any year in which it is not in existence. The Treasury Department and the IRS will also continue to monitor this issue. In further response to this comment, the final regulations also clarify the applicability of this credit to grantor trusts, and provide that, to the extent that the grantor or another person is treated as owning all or part of a trust under sections 671 through 679 of the Code, the section 30D credit is allocated to such grantor or other person in accordance with § 1.671–3(a)(1). In addition, the Modified AGI limitation applies based on the Modified AGI of the grantor or other deemed owner, not the Modified AGI of the trust or any other beneficiary.

The final regulations also clarify that with regard to partnerships and S corporations, the Modified AGI limitation applies on a partner or shareholder level. Finally, consistent with the preceding, the final regulations provide that the Modified AGI

limitation does not apply to corporations and taxpayers other than individuals, estates, trusts, and partners or shareholders of passthrough entities.

D. FEOC Restriction

Section 30D(d)(7), the excluded entities provision or FEOC Restriction, excludes from the definition of ''new clean vehicle'' any vehicle placed in service after December 31, 2024, with respect to which any of the applicable critical minerals contained in the battery of such vehicle (as described in section 30D(e)(1)(A)) were extracted, processed, or recycled by a FEOC (as defined in section 40207(a)(5) of the Infrastructure Investment and Jobs Act), or any vehicle placed in service after December 31, 2023, with respect to which any of the components contained in the battery of such vehicle (as described in section 30D(e)(2)(A)) were manufactured or assembled by a FEOC (as so defined).

Several commenters either criticized the FEOC Restriction or requested that these applicability dates be delayed in order to give the industry time to reconfigure their supply chains. Similarly, commenters noted that the FEOC Restriction may be problematic for land-based sourcing of nickel, cobalt, and manganese in particular. As the FEOC Restriction and its applicability dates are statutory, the final regulations do not adopt these comments.

Proposed § 1.30D–6(a) provided definitions for terms relevant to the FEOC Restriction and proposed § 1.30D–6. The final regulation moves these definitions to § 1.30D–2(b), and include a new § 1.30D–6(a) that is a general statement of the FEOC Restriction rules. Otherwise, the final regulations adopt the structure and framework of proposed § 1.30D–6, with the modifications described herein.

1. Due Diligence and Transition Rule for Non-Traceable Battery Materials

Proposed § 1.30D–6(b) provided due diligence requirements for qualified manufacturers to determine compliance with the FEOC Restriction. Proposed § 1.30D–6(b)(2) provided a temporary exception to the due diligence requirements for identified non-traceable battery materials.

i. Due Diligence

Proposed § 1.30D–6(b)(1) provided that the qualified manufacturer must conduct due diligence with respect to all battery components and applicable critical minerals (and associated constituent materials) that are relevant to determining whether such components or minerals are FEOC-compliant. This due diligence must comply with standards of tracing for battery materials available in the industry at the time of the attestation or certification that enable the qualified manufacturer to know with reasonable certainty the provenance of applicable critical minerals, constituent materials, and battery components. As noted in the Explanation of Provisions to the December Proposed Regulations, such tracing standards may include international battery passport certifications and enhanced battery material and component tracking and labeling. Proposed § 1.30D–6(b)(1) specified that reasonable reliance on a supplier attestation or certification will be considered due diligence if the qualified manufacturer does not know or have reason to know after due diligence that such supplier attestation or certification is incorrect.

The due diligence must be conducted by the qualified manufacturer prior to its determination of any information to establish a compliant-battery ledger described in proposed § 1.30D–6(d), and on an ongoing basis. A battery is not considered FEOC-compliant unless the qualified manufacturer has conducted such due diligence with respect to all such components and applicable critical minerals of the battery and provided required attestations or certifications described in section III.D. of this Summary of Comments and Explanation of Revisions.

The Treasury Department and the IRS received a number of comments relating to the due diligence requirement.

As noted previously, proposed § 1.30D–6(b)(1) provided that due diligence must comply with standards of tracing for battery materials available in the industry at the time of the attestation or certification. The proposed regulations did not specify a tracing system. Several commenters requested that the final regulations create an industry standard for due diligence to avoid confusion and provide a standardized system. One such commenter suggested that the Catena-X battery passport, used in Europe, as a model while another commenter recommended against adopting such rules because the commenter considered them to be burdensome and largely untested. Another commenter suggested defining ''due diligence'' according to certain OECD standards. That same commenter suggested requiring use of digital battery identifiers (that is, battery passports). Another commenter suggested that until mineral supply chain tracing becomes standardized, voluntary standards using multi-stakeholder governance with independent, publicly available, third-party auditing (such as the Initiative for Responsible Mining Assurance's standard), can assist. Finally, one commenter expressed a desire to better understand expectations for supply chain tracing and offered to assist the Treasury Department and qualified manufacturers in implementing effective traceability mechanisms.

The Treasury Department and the IRS appreciate the number of comments about due diligence. However, the broad range of perspectives offered by the commenters counsels against mandating a universal standard at this time. The Treasury Department and the IRS will continue to monitor industry standards, battery passports, and other methodologies for tracing, and will consider this issue for future guidance.

The Treasury Department and the IRS also received comments with respect to the due diligence requirements and upstream suppliers of the OEMs. One commenter requested that the final regulations require battery manufacturers and suppliers of battery components and applicable critical minerals to cooperate and provide information to qualified manufacturers. Alternatively, the commenter requested that battery manufacturers be required to directly submit information to the IRS and provide qualified manufacturers with certification that any items are FEOC-compliant. Section 30D does not provide authority to require submissions by upstream suppliers, either to the qualified manufacturer or to the IRS. Section 30D(d)(3) authorizes information reporting to the Secretary regarding new clean vehicles only by qualified manufacturers. Qualified manufacturers may seek to incorporate reporting and assurances by their battery suppliers as part of their supply contracts, but such an arrangement would be outside the scope of these regulations. Accordingly, the final regulations do not adopt this comment.

Two commenters raised issues with respect to battery supplier reliance on further upstream suppliers. Proposed § 1.30D–6(b)(1) specified that reasonable reliance on a supplier attestation or certification will be considered due diligence if the qualified manufacturer does not know or have reason to know after due diligence that such supplier attestation or certification is incorrect. The two commenters requested that the reasonable reliance rule be extended to third-party manufacturers or suppliers who conduct due diligence under proposed § 1.30D–6(c)(5). The Treasury Department and the IRS agree with these commenters. Accordingly, the final regulations also specify that that

reasonable reliance on a supplier attestation or certification will also be considered due diligence if the third-party manufacturer or supplier (described in § 1.30D–6(c)(5)) does not know or have reason to know after due diligence that such supplier attestation or certification is incorrect.

One commenter stated that additional clarification is needed to identify the elements of reasonable reliance and due diligence beyond the attestation of the supplier. For instance, suppliers may, in certain circumstances, be reluctant to share certain sourcing information as proprietary and competitive in nature. The commenter asked whether a supplier statement based on undisclosed information could be reasonably relied upon. In addition, the commenter sought more information about implications of a qualified manufacturer's reasonable reliance on supplier attestations that prove later to be inaccurate, such as whether the qualified manufacturer's reasonable reliance would act as a shield against a penalty. Another commenter suggested that Treasury should consider establishing a process for certifying that suppliers are not FEOCs. The commenter posited that such a process could mirror existing U.S. government certification, accreditation, or registration processes, such as International Traffic in Arms Regulations (ITAR) registration or National Institute of Standards and Technologies (NIST) certification.

The Treasury Department and the IRS appreciate the commenters' desire for certainty regarding the procedures for establishing reasonable reliance and due diligence. As described in proposed § 1.30D–6(f), the IRS will consider a range of remedial options in the event of inaccurate attestations, certification, or documentation, and the IRS will exercise discretion in pursuing any of the specified options on the basis of the unique facts and circumstances of the inaccuracy, including reasonable reliance on supplier information. In addition, parties to supply contracts may include a provision for such attestations as part of their contracts.

ii. Transition Rule for Impracticable-to Trace-Battery Materials

Proposed § 1.30D–6(b)(2) provided that for any new clean vehicles for which the qualified manufacturer provides a periodic written report before January 1, 2027, the due diligence requirement may be satisfied by excluding identified non-traceable battery materials (and associated constituent materials). In addition, proposed § 1.30D–6(c)(2) provided that identified non-traceable battery materials (and associated constituent materials) may be excluded from the determination of whether a battery cell is FEOC-compliant. To use these transition rules, qualified manufacturers must submit a report during the up-front review process (described in section III.B.3 of this Summary of Comments and Explanation of Revisions) demonstrating how the qualified manufacturer will comply with the excluded entity restrictions once the transition rule is no longer in effect and once all materials must be fully traced through the entire electric vehicle battery supply chain.

Proposed § 1.30D–6(a)(13)(i) defined ''non-traceable battery materials'' to mean specifically identified low-value battery materials that may originate from multiple sources and are often commingled during refining, processing, or other production processes by suppliers to such a degree that the qualified manufacturer cannot, due to current industry practice, feasibly determine and attest to the origin of such battery materials. For this purpose, low-value battery materials are those that have low value compared to the total value of the battery. Proposed § 1.30D–6(a)(13)(ii) was reserved to contain the specific list of identified non-traceable battery materials. While proposed § 1.30D–6(a)(13)(ii) was reserved, the Explanation of Provisions to the December Proposed Regulations identified as exemplar materials, for potential inclusion on the list, applicable critical minerals contained in electrolyte salts, electrode binders, and electrolyte additives.

As noted in section III.A. of this Summary of Comments and Explanation of Revisions, consistent with the expectation and requirement that OEMs will develop tracing processes in the future, the final regulations retain the list but change the name to ''impracticable-to-trace battery materials,'' in order to better describe the rationale underlying the list.

The Treasury Department and the IRS received many comments with respect to the list of identified nontraceable battery materials as well as the proposed transition rules.

Several commenters requested changes to the meaning of ''low value.'' [8] One commenter requested that low value be determined by reference to the battery as a whole, and not just the total value of applicable critical minerals. Similarly, another commenter requested that ''low value'' be defined with respect to a specified percentage relative to the value of the battery. Several commenters requested that ''low value'' be defined as less than 5 percent or 10 percent of the value of the battery. However, another commenter proposed that ''low value'' be defined as less than 5 percent of the total value of the critical minerals in the batteries. Finally, one commenter objected to a definition based on value, noting that, apart from certain cathode materials, the economic value of every other component in lithium ion batteries is low relative to the total value of the battery. The final regulations do not adopt these comments, as the determination of low-value is not an operative rule with respect to the impracticable-to-trace battery materials list. Instead, the Explanation of Provisions to the December Proposed Regulations only noted the low-value of certain materials, relative to the value of the clean vehicle battery, for the purpose of identifying materials that qualified manufacturers could not feasibly trace. However, the as noted in this Summary of Comments and Explanation of Revisions, the term ''low-value'' is not defined as a specific percentage. Instead, a low-value battery material is one for which qualified manufacturers have not historically conducted due diligence or tracing, due to its relatively low value in relation to either the battery or the applicable critical minerals in the battery.

Several commenters supported the development of a specific list of nontraceable battery materials as this would provide the greatest clarity and certainty for the supply chain. Several commenters also requested a full enumerated list of materials. Many commenters requested certainty as soon as possible. Several commenters requested that the non-traceable battery materials rule be made permanent. On the other hand, several commenters supported the transition rule for non-traceable battery materials, agreed with the temporary nature of the rule, and were in favor of this approach over other alternatives, such as a de minimis rule or set of criteria for exclusion. Many commenters agreed with the exemplar materials identified in the Explanation of Provisions to the December Proposed Regulations (that is, applicable critical minerals contained in electrolyte salts, electrode binders, and

[8] The Explanation of Provisions to the December Proposed Regulations noted that, where battery materials make up only a very small percentage of the value of the battery as a whole, many industry participants had little reason to trace the source of these materials prior to the passage of the IRA. On the other hand, that Explanation of Provisions identified exemplar materials that accounted for less than two percent of the value of applicable critical minerals in the battery.

electrolyte additives). A few commenters suggested clarification regarding other materials. One commenter requested that the final rule exclude low value anode materials from the tracing requirements. Some commenters requested that applicable critical minerals contained in foils be added to the list. Other commenters recommended that low-value materials, comprising less than five or ten percent of the value of all critical minerals in a battery, be excluded from sourcing requirements under any final rule and specifically lists cobalt, zinc, tungsten, yttrium, titanium, graphite, and fluorspar as potential low-value materials. Finally, one commenter requested that constituent materials be added to the list. That commenter gave the specific example of the electrolyte, and noted that the battery manufacturer may have difficulty conducting due diligence with respect to electrolytes, due to the tiers of upstream suppliers as well as the need to request confidential commercial information.

Other commenters noted that certain minerals or materials should not be included in the definition of non-traceable battery materials. One commenter noted that consultation with industry is needed to develop a list, because many materials either can be traceable or will be traceable before 2027. Several commenters took issue with the exemplar materials identified in the Explanation of Provisions to the April Proposed Regulations. Some commenters disputed the idea that applicable critical minerals contained in electrolyte salts and electrode binders are non-traceable. One commenter noted that special electrolyte salts and additives (SESAs) are never commingled during transport or usage and may be traced to the source through a certification of origin. Other commenters specifically enumerated minerals that they asserted were traceable, including magnesium, magnesium sulfate, manganese sulphate monohydrate and related manganese materials and manganese oxides; fluorspar, fluorspar-based hydrofluoric acid, fluorine compounds, polyvinylidene fluoride (PVDF) and PVDF binder technology; rare earth elements; lithium and Lithium hexafluorophosphate (LiPF6); cobalt; and nickel. Finally, one commenter suggested that the list of non-traceable battery materials only include non-essential battery materials that have ready substitutes. The commenter contrasted those materials with essential battery materials (such as fluorinated salts and fluorinated binders) that are essential to making an EV battery and have no meaningful substitutes. The commenter recommended that such essential battery materials not be added to the nontraceable battery materials list.

Several comments raised questions relating to the justifications for the identified non-traceable battery materials list. One commenter, while generally supportive of the proposed rules, stated that all materials are in fact able to be traced.

Finally, several commenters suggested that the final regulations adopt a different approach for a transition rule. One commenter requested that the final regulations provide a detailed list of low-value and non-traceable battery materials that form part of constituent materials, so that battery manufacturers do not have to trace materials to specific upstream suppliers. Another commenter proposed establishing a dynamic list of non-traceable battery materials rather than a static list. Several commenters also suggested that the final regulations provide a list of criteria for manufacturers to apply to determine what materials are excludible. Similarly, several commenters recommended that the final regulations adopt a de minimis threshold, with some suggesting a five percent threshold and others a ten percent threshold. One commenter requested that the Treasury Department and the IRS remove the non-traceable battery materials transition rule and replace it with an exemption from due diligence for battery materials produced by DOE Office of Manufacturing Energy and Supply Chains battery grant awardees. Finally, one commenter requested a three- to four-year grace period for certain applicable critical minerals, such as graphite and powders of cathode active materials.

Balancing all of the varying and opposing considerations reflected in these comments, the final regulations do not adopt a de minimis percentage threshold. The statute does not provide guidance for determining a numerical de minimis percentage. Instead, the statute compels qualified manufacturers to conduct due diligence in order to determine that vehicles satisfy the FEOC Restriction. The final transition rule requires due diligence in light of existing tracing capabilities and the practicalities of mineral and battery component supply chains, such as the presence of commingling. Instead of adopting a numerical de minimis percentage, the final regulations retain the proposed list and the related transition rules from the proposed regulations, but generally include only the exemplar materials identified in the Explanation of Provisions to the April Proposed Regulations.

In addition, however, graphite contained in anode materials is added to the list of impracticable-to-trace battery materials. Several commenters raised issues relating to graphite. Many commenters that supported the transition rule also generally supported including graphite on the list. One commenter noted that graphite accounts for only 3 to 4 percent of EV battery value, and that it is especially difficult to trace because battery cell manufacturers frequently mix synthetic and natural graphite together. Another commenter requested clarification of whether the FEOC analysis for synthetic graphite (1) begins with the petroleum coke from which synthetic graphite is derived or, instead, (2) goes all the way upstream to the oil extraction. This commenter noted that, in the latter case, tracing would not be possible. However, a different commenter stated that the ''battery coke'' used by the EV industry to make synthetic graphite is not produced from a nontraceable supply chain, and that such battery coke (unlike commodity cokes) is not commingled prior to shipment to an end user. Taking these comments under consideration, the Treasury Department and the IRS have determined that, due to the commingling of natural and synthetic graphite, as well as the difficulty of tracing synthetic graphite fully upstream, graphite contained in anode materials is an impracticable-to-trace material. Consequently, the final regulations include graphite contained in anode materials on the list of identified impracticable-to-trace battery materials.

The final regulations add a definition of ''impracticable-to-trace battery materials'' to § 1.30D–2(b), and specify identified impracticable-to-trace battery materials as applicable critical minerals in the following circumstances: graphite contained in anode materials and applicable critical minerals contained in electrolyte salts, electrode binders, and electrolyte additives. Section 1.30D–6(b)(2) provides that for any new clean vehicles for which the qualified manufacturer provides a periodic written report before January 1, 2027, the due diligence requirement may be satisfied by excluding identified impracticable-to-trace battery materials (and associated constituent materials). Section § 1.30D–6(c)(3)(iii) provides that identified impracticable-to-trace battery materials (and associated constituent materials) may be excluded from the determination of whether a battery cell is FEOC-compliant.

In addition, the proposed regulations provided that, to use these transition rules, qualified manufacturers must submit a report during the up-front review process demonstrating how the qualified manufacturer will comply with the FEOC Restriction once the transition rules end. The final regulations keep this requirement and further clarify that this report must include information about efforts made to date to secure a FEOC-compliant battery supply once the transition rule is no longer in effect. Additional requirements related to this report will be described in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The Treasury Department and the IRS anticipate that such requirements will include robust documentation of efforts made to date to secure FEOC-compliant battery supply, such as potential suppliers engaged, offtake agreements, and contracts entered into with domestic or compliant suppliers. Finally, the Treasury Department and the IRS note that the inclusion of materials on the impracticable-to-trace battery materials list does not relieve any person from compliance obligations with respect to any other laws or requirements of other federal agencies or international organizations, including U.S. sanctions law administered by the Treasury Department's Office of Foreign Assets Control (OFAC) (31 CFR Chapter V).

2. FEOC Compliance

Proposed § 1.30D–6(c) provided the rules for determining whether battery components, battery cells, and applicable critical minerals (and associated constituent materials) are FEOC-compliant. These rules generally required the physical tracking of applicable critical minerals, battery cells, and battery components. However, proposed § 1.30D–6(c)(3)(ii)(A) provided that the determination that a battery cell is a FEOC-compliant battery cell may be made through an allocation of the available mass of applicable critical minerals and associated constituent materials to specific battery cells manufactured or assembled in a battery cell production facility, without the physical tracking of the mass of applicable critical minerals (and associated constituent materials) to specific battery cells. This allocation-based determination was an exception to the general rule, which required specific tracking. Proposed § 1.30D–6(c)(3)(ii)(F) provided that the allocation-based exception would be a temporary rule for any new clean vehicle for which the qualified manufacturer provides a periodic written report before January 1, 2027.

In the Explanation of Provisions to the December Proposed Regulations the Treasury Department and the IRS requested comments on whether industry practices are likely to develop that allow for physical tracking before December 31, 2032, and, if not, whether the allocation-based determination should be included as a permanent compliance approach rather than as a temporary transition rule.

In response, several commenters expressed appreciation for the allocation-based determination. Commenters also requested that the rule be made permanent, due to the inability to quickly modify supply chains and the impracticability or impossibility of physically tracing applicable critical minerals. One commenter appreciated the inclusion of the transition rule in allowing allocation-based determinations for critical minerals and constituent materials, as well as the transition rule regarding non-traceable materials. One commenter noted that the time frame for the temporary allocation-based approach (ending December 31, 2026) is very short and was not sure it would be sufficient for manufacturers to alter their supply chains, as needed. The commenter further recommended that the proposed transition rule for allocation-based accounting be made permanent for the duration of the section 30D tax credit. In response to these comments, these final regulations make the allocation-based determination a permanent rule. Informed by the consensus view from the comments and consultation with the DOE, the Treasury Department and the IRS recognize that it may be difficult to de-commingle supply chains by 2027. In addition, it would be difficult and impracticable to track individual masses of applicable critical minerals through the supply chain in order to determine which masses are FEOC-compliant and which are not. Moreover, allocation-based accounting is consistent with the purposes of the statute, because it encourages OEMs and their suppliers to ensure secure supply chains; under an allocation-based accounting rule, the number of new clean vehicles that OEMs are able to produce is limited by the supply of the lowest-quantity FEOC-compliant critical mineral.

In addition, several commenters requested changes to the calculation-based methodology under the allocation-based accounting rule. Two commenters requested that the allocation be of total aggregated mass of FEOC-compliant applicable critical minerals, rather than limiting the FEOC-compliant battery cells to the critical mineral that has the lowest percentage of FEOC-compliant supply. The Treasury Department and the IRS disagree with these comments. Under the total aggregated mass approach suggested by the commenters, a qualified manufacturer with 0 percent FEOC-compliant mass of a specific applicable critical mineral would still have FEOC-compliant batteries based on the total mass of FEOC-compliant applicable critical minerals. This result would be inconsistent with the purposes of section 30D(d)(7). Accordingly, the final regulations do not adopt these comments.

Two commenters recommended that the final regulations adopt a mass balance approach with respect to allocated accounting. A full mass balance approach would require full physical tracing across long procurement chains for arrays of materials into the battery materials production. Given concerns with the ability of manufacturers to implement a robust tracking process in the near term to this level of specificity, the final regulations do not adopt this approach.

Proposed § 1.30D–6(c)(3)(iii) provided that for new clean vehicles for which the qualified manufacturer provides a periodic written report before January 1, 2027, the determination of whether a battery cell is FEOC-compliant under proposed § 1.30D–6(c)(3) may be satisfied by excluding non-traceable battery materials, and their associated constituent materials. As described in section III.D.1.ii. of this Summary of Comments and Explanation of Revisions, this rule is finalized with respect to identified impracticable-to-trace battery materials.

3. Compliant-Battery Ledger

Proposed § 1.30D–6(d)(1) provided that for new clean vehicles placed in service after December 31, 2024, the qualified manufacturer must determine and provide information to the IRS to establish a compliant-battery ledger for each calendar year, as described in proposed § 1.30D–6(d)(2)(i) and (ii). One compliant-battery ledger may be established for all vehicles for a calendar year, or there may be separate ledgers for specific models or classes of vehicles.

The Treasury Department and the IRS received several comments with respect to the compliant-battery ledger.

Several commenters noted that the upfront review process is both novel and complicated, and will require continued conversation between OEMs and the Treasury Department and the IRS. One such commenter commended

the Treasury Department and the IRS's willingness to engage with manufacturers to support compliance and also asked for sufficient advance notice to qualified manufacturers regarding the upfront review process. Another noted that the process of establishing the mechanisms of the compliant-battery ledger will be an iterative process. In response to this, the Treasury Department and the IRS note that they intend to continue to engage with OEMs and other stakeholders to develop the rules under the upfront review process.

One commenter requested further clarification on the administrative procedures and necessary documentation requirements on areas such as FEOC-compliant certification and compliant-battery ledger. In response, the Treasury Department and the IRS generally note that initial guidance with respect to the upfront review process was issued in Revenue Procedure 2023–38.

Section 5.08 of Revenue Procedure 2023–38 requires qualified manufacturers to report any decrease to the ledger within 30-days of discovery. One commenter requested that this 30-day time period be extended. Although the comment is outside the scope of these final regulations, the Treasury Department and the IRS note that they will continue to study how best to administer the rules for establishing and updating compliant-battery ledgers.

One commenter raised a concern that the compliant-battery ledger may allow for noncompliance because batteries need not be tracked to specific vehicles. Proposed § 1.30D–6(c)(1) requires the physical tracking of batteries to specific new clean vehicles via serial number or other identification system. Therefore, the commenter's concern is already addressed.

Finally, two commenters requested additional mechanisms for the upfront review process. First, one commenter requested that the Treasury Department and the IRS create a safe harbor system through which sourcing plans and licensing agreements of a proposed transaction are submitted for review and clearance. This commenter suggested that the Treasury Department's Committee on Foreign Investment in the United States process could provide a model. Second, several commenters noted that OEMs may have difficulty verifying information due to confidentiality obligations as well as the lack of harmonization among suppliers, and proposed that the Treasury Department and the IRS create an online portal to allow OEMs and suppliers to match information. The Treasury Department and the IRS intend that the upfront review process will be an iterative process in which attestations, certifications, and documentation regarding the section 30D sourcing requirements are submitted for review to the IRS, with analytical assistance from the DOE. This process allows for additional information to be requested of and supplied by qualified manufacturers. In addition, qualified manufacturers may rely on determinations provided by third-party manufacturers or suppliers, provided the requirements in § 1.30D–6(c)(5) are met.

4. Rule for New Qualified Fuel Cell Motor Vehicles

The final regulations add § 1.30D–6(g) to clarify that the FEOC Restriction does not apply to new qualified fuel cell motor vehicles. However, a qualified fuel cell motor vehicle (as defined in section 30B(b)(3)) with a clean vehicle battery, such as a plug-in hybrid fuel cell electric vehicle, would be subject to the FEOC Restriction.

Because new qualified fuel cell motor vehicles do not contain clean vehicle batteries, these vehicles do not have applicable critical minerals or battery components contained in such battery that would subject the vehicles to the FEOC Restriction. Thus, the rule regarding new qualified fuel cell vehicles flows naturally from the statute.

IV. Section 6213(g)(2)

The IRA added three new definitions to the exclusive list of ''mathematical or clerical errors'' in section 6213(g)(2). These new definitions are set out in sections 6213(g)(2)(T), (U), and (V). Section 6213(g)(2)(T) provides that the term ''mathematical or clerical error'' means an omission of a correct VIN required under section 30D(f)(9) (relating to the credit for new clean vehicles) to be included on a return; section 6213(g)(2)(U) provides that the term ''mathematical or clerical error'' means an omission of a correct VIN required under section 25E(d) (relating to the credit for previously-owned clean vehicles) to be included on a return; and section 6213(g)(2)(V) provides that the term ''mathematical or clerical error'' means an omission of a correct VIN required under section 45W(e) (relating to the credit for qualified commercial clean vehicles) to be included on a return.

The flush language added in 1998 to the end of section 6213(g)(2) regarding whether a taxpayer is treated as having omitted a correct taxpayer identification number does not provide the clarification that is necessary to determine the meaning of ''an omission of a correct vehicle identification number'' under sections 6213(g)(2)(T) through (V). Accordingly, proposed § 301.6213–2 provided rules for determining whether the IRS is authorized to use math error authority to make a summary assessment if there has been an ''omission of a correct vehicle identification number'' on a taxpayer's return on which the taxpayer is claiming or electing to transfer the credits under sections 30D, 25E and 45W.

A comment recommended that the proposed regulation be modified to clarify how it applies to taxpayers who rely on a seller report containing mistakenly entered VINs, or taxpayers who rely on manufacturers' incorrect determinations that a vehicle is eligible for the section 25E or 30D credit if the vehicle is in fact ineligible for either credit.

Vehicle sellers can prevent the situation described by the commenter by submitting the seller report described in §§ 1.25E–1(b)(19) and § 1.30D–2(b)(48), which must be submitted electronically by the seller to the IRS at the time of sale. The reported VIN's eligibility is checked against qualified manufacturer reporting to the IRS at the time of submission of the seller report. The taxpayer then receives a copy of the seller report only after VIN eligibility is verified through the seller reporting process in real time. Accordingly, the seller report should not contain an incorrect VIN or VIN for a vehicle that was ineligible for a clean vehicle credit. Vehicle sellers are advised to ensure they accurately enter the VIN of the clean vehicle the taxpayer is purchasing when submitting the seller report and to be cautious in finalizing transactions in any case in which a VIN's eligibility has not been confirmed by the IRS through an electronically submitted seller report. Taxpayers should also ensure that the VIN listed on their seller report matches the VIN of the clean vehicle actually purchased. In addition, the taxpayer can rely on the information and certifications contained in the qualified manufacturer written reports for the sections 25E and 30D credits pursuant to §§ 1.25E–2(h) and 1.30D–4(h).

V. Applicability Dates

The final rules modify the applicability dates of the proposed rules for uniformity and administrability across the various rules included in the April, October, and December Proposed Regulations. Consistent with the authority in section 7805(b)(1), the applicability dates generally are

modified to apply to taxable years ending after the latest publication date of the proposed regulations to which the section relates. Accordingly, the section 25E final regulations generally apply to taxable years ending after October 10, 2023, and the section 30D final regulations generally apply to taxable years ending after December 4, 2023.

The regulatory applicability dates also align with certain statutory applicability dates. For example, the rules regarding transfer of the section 25E and 30D credits in §§ 1.25E–3 and 1.30D–5 apply to clean vehicles placed in service after December 31, 2023, in taxable years ending after December 31, 2023, to reflect the statutory applicability date of vehicles acquired (section 25E) or placed in service (section 30D) after December 31, 2023. Similarly, the rules related to the FEOC Restriction in § 1.30D–6 reflect the statutory applicability date of vehicles placed in service after December 31, 2023.

Special Analyses

I. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) generally requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit.

Any collection burden associated with rules described in these final regulations is previously accounted for in OMB Control Number 1545–2137. These final regulations do not alter previously accounted for information collection requirements and do not create new collection requirements. OMB Control Number 1545–2137 covers Form 8936 and Form 8936–A regarding electric vehicle credits, including the new requirement in section 30D(f)(9) to include on the taxpayer's return for the taxable year the VIN of the vehicle for which the section 30D credit is claimed. Revenue Procedure 2022–42 describes the procedural requirements for qualified manufacturers to make periodic written reports to the Secretary to provide information related to each vehicle manufactured by such manufacturer that is eligible for the section 30D credit as required in section 30D(d)(3), including the critical mineral and battery component certification requirements in sections 30D(e)(1)(A) and (e)(2)(A). In addition, Revenue Procedure 2022–42 provides the procedures for sellers of new clean vehicles to report information required by section 30D(d)(1)(H) for vehicles to be eligible for the section 30D credit. The collections of information contained in Revenue Procedure 2022–42 are described in that document and were submitted to the Office of Management and Budget in accordance with the Paperwork Reduction Act under control number 1545–2137.

The requirement to determine the final assembly location as defined in § 1.30D–2(b) by relying on (1) the vehicle's plant of manufacture as reported in the VIN pursuant to 49 CFR 565 or (2) the final assembly point reported on the label affixed to the vehicle as described in 49 CFR 583.5(a)(3) is accounted for by the Department of Transportation in OMB Control Numbers 2127–0510 and 2127–0573.

For purposes of the PRA, the reporting burden associated with the collection of information in §§ 1.25E–3 and 1.30D–5 regarding credit transfer elections will be reflected in the PRA Submissions associated with Revenue Procedure 2023–33. The OMB control number for Revenue Procedure 2023–33 is 1545–2311.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

III. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present a final regulatory flexibility analysis (FRFA) of the proposed rule.

In connection with the April and December Proposed Regulations, the Secretary certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities.

April Proposed Regulations: The regulations proposed in April affect two types of business entities: (1) qualified manufacturers that must trace and report on their critical minerals and battery components in order to certify that their new clean vehicles qualify for the section 30D credit, and (2) businesses that may earn the section 30D credit when purchasing and placing in service a new clean vehicle.

While the tracking and reporting of critical minerals and battery components is likely to involve significant administrative costs, according to public filings, all qualified manufacturers had total revenues above $1 billion in 2022. There are a total of 13 qualified manufacturers that have indicated that they manufacture vehicles currently eligible for the section 30D credit.

Qualified manufacturers also have to certify that their vehicles qualify under the Critical Minerals and Battery Components Requirements. The regulations provide definitions and general rules for the section 30D credit, including rules for qualified manufacturers to comply with the Critical Minerals and Battery Components Requirements. The Treasury Department and the IRS intend that the rules provide clarity for qualified manufacturers for consistent application of critical minerals and battery components calculations and for taxpayers purchasing new clean vehicles that qualify for the section 30D credit. The Treasury Department and the IRS have determined that qualified manufacturers do not meet the applicable definition of small entity.

Business purchasers of clean vehicles who take the section 30D credit must satisfy reporting requirements that are largely the same as those faced by individuals accessing the section 30D credit to purchase clean vehicles. Taxpayers will continue to file Form 8936, Clean Vehicle Credit, to claim the section 30D credit. As was the case for the section 30D credit prior to amendments made by the IRA, taxpayers can rely on qualified manufacturers to determine if the vehicle being purchased qualifies for the section 30D credit and the credit amount. The estimated burden for individual and business taxpayers filing this form is approved under OMB control number 1545–0074 and 1545–0123. To make it easier for a taxpayer to determine the potential section 30D credit available for a specific vehicle, the regulations provide business entities with tools and definitions to ascertain

whether any vehicles purchased would be eligible for the credit. The VIN reporting required by section 30D(f)(9) and described in the proposed regulations was included in prior section 30D reporting.

December Proposed Regulations: The regulations proposed in December affect qualified manufacturers that must determine their compliance with the FEOC Restriction in order to certify that their new clean vehicles placed in service after December 31, 2023, qualify for the section 30D credit.

While the tracking and reporting of compliance with the FEOC Restriction is likely to involve significant administrative costs, according to public filings, every qualified manufacturer had total revenues above $1 billion in 2022. There are a total of 13 qualified manufacturers that have indicated that they manufacture vehicles currently eligible for the section 30D credit. Qualified manufacturers also have to certify that their vehicles comply with the FEOC Restriction and contain batteries that are FEOC-compliant. The regulations provide definitions and general rules for this purposes. Accordingly, the Treasury Department and the IRS intend that the rules provide clarity for qualified manufacturers for consistent application of the FEOC Restriction. The Treasury Department and the IRS have determined that qualified manufacturers do not meet the applicable definition of small entity.

For these reasons, it is hereby certified that §§ 1.30D–1, 1.30D–3, 1.30D–4(a)–(e) and 1.30D–6, and the accompanying definitions in § 1.30D–2 that were proposed in the April and December Proposed Regulations, do not have a significant economic impact on a substantial number of small entities.

In connection with the October Proposed Regulations, the Treasury Department and the IRS presented an IRFA to invite comments on both the number of entities affected and the economic impact on small entities. No comments were received specific to these areas of inquiry. In the absence of comments in response to the October Proposed Regulations, this FRFA is presented with the final rule.

In addition, pursuant to section 7805(f) of the Code, the April, October, and December proposed regulations preceding this final rule were submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

A. Need for and Objectives of the Rule

The final regulations provide the eligibility rules and key definitions regarding the section 25E and section 30D credits to allow taxpayers to know whether their purchase of a previously-owned clean vehicle or new clean vehicle is eligible for the section 25E and section 30D credits, respectively. In addition, the final regulations provide rules regarding the recapture authority under sections 25E(e) and 30D(f)(5), so that taxpayers and the IRS have clear rules regarding when a clean vehicle may cease being eligible for the section 25E and section 30D credits. Further, the final regulations provide rules regarding the omission of a correct VIN for purposes of math error authority as described in section 6213(g)(2). Clear rules regarding the exercise of math error authority will provide for efficient and fair tax administration.

The final regulations provide guidance for purposes of taxpayers electing to transfer vehicle credits under sections 25E(f) and 30D(g) to eligible entities, and for eligible entities participating in the advance payment program with respect to those transferred credits. The final regulations provide rules regarding the process for taxpayers to elect to transfer the credits and for eligible entities to register and receive advance payments from the IRS, and rules regarding the Federal income tax treatment of the credit transfer election, including recapture and excessive payments. The final rules regarding the credit transfer election ensure certainty regarding the consequences of the transfer election, decrease the risk of fraud, and expedite the process by which an eligible entity may receive an advance payment under section 25E(f) or 30D(g).

The final rules are expected to encourage taxpayers to increase the placing in service of new and previously-owned clean vehicles. Thus, the Treasury Department and the IRS intend and expect that the final rules will deliver benefits across the economy and environment that will beneficially impact various industries, including clean vehicle manufacturers and dealers.

B. Issues Raised by Public Comments in Response to the IRFA

As previously noted, there were no comments filed that specifically addressed the impact of the proposed rules and policies on small entities or the number of potentially impacted entities presented in the IRFA. Additionally, no comments were filed by the Chief Counsel of Advocacy of the Small Business Administration.

C. Affected Small Entities

The Small Business Administration estimates in its 2023 Small Business Profile that 99.9 percent of United States businesses meet its definition of a small business. The applicability of these final regulations does not depend on the size of the business, as defined by the Small Business Administration. As described more fully in the Summary of Comments and Explanation of Revisions to this final regulation and in this FRFA, these rules may affect a variety of different businesses across several different industries, but will primarily affect dealers of new and previously-owned clean vehicles that would like to be eligible entities to receive a transferred credit from the buyers of a clean vehicle. The Treasury Department and the IRS currently estimate the number of dealers of new clean vehicles to be approximately 16,000, and the number of dealers of previously-owned clean vehicles to be approximately 36,000.

Of the estimated 16,000 dealers of new clean vehicles, we estimate that 10,000 will have receipts in excess of $25 million; 3,000 will have receipts between $10-$25 million; 1,000 will have receipts between $5–10 million, and 2,000 will have receipts under $5 million. Of the estimated 36,000 dealers of previously-owned clean vehicles, we estimate that 500 will have receipts in excess of $25 million; 1,500 will have receipts between $10-$25 million; 2,000 will have receipts between $5–10 million, and 32,000 will have receipts under $5 million.

The Treasury Department and the IRS expect to receive more information on the impact on small businesses through comments on this final rule.

D. Impact of the Rules

The recordkeeping and reporting requirements would increase for taxpayers who elect to transfer the section 25E or 30D credit to an eligible entity. In addition, the recordkeeping and reporting requirements would increase for dealers who seek to qualify as eligible entities and participate in the advance payment program. Although the Treasury Department and the IRS do not have sufficient data to precisely determine the likely extent of the increased costs of compliance, the estimated burden of complying with the recordkeeping and reporting requirements are described in section II of the Special Analyses regarding the PRA. The Treasury Department and the IRS estimate that, based on the total of

52,000 dealers of new (16,000) and previously-owned (36,000) clean vehicles, it will take approximately one hour to register as entities eligible to receive advance payments of credits under sections 25E and 30D, for a total of 52,000 hours total. The Treasury Department and the IRS further estimate that there are approximately 950,000 taxpayers who will purchase new clean vehicles and 28,750 taxpayers who will purchase previously-owned clean vehicles who will elect to transfer their respective credits to the eligible entity, for a total of 978,750 elections annually. The Treasury Department and the IRS estimate each election will take approximately 15 minutes to complete, for a total burden of approximately 244,688 hours per year.

E. Steps Taken To Minimize Impacts on Small Entities and Alternatives Considered

The Treasury Department and the IRS considered various alternatives in promulgating these final regulations. Significant alternatives considered include: (1) the sale price definition in § 1.25E–1(b)(16); (2) the first transfer rule described in § 1.25E–1(b)(14)(ii); (3) the recapture rules provided in §§ 1.25E–2(c) and 1.30D–4(e), and (4) the dealer registration requirements provided in §§ 1.25E–3(c) and 1.30D–5(c).

Regarding the sale price definition in § 1.25E–1(b)(16), the Treasury Department and the IRS considered the appropriate scope of the definition and how the definition of sale price should be consistent with or diverge from the definition of manufacturer's suggested retail price for purposes of section 30D(f)(11). The definition of ''manufacturer's suggested retail price'' in § 1.30D–2(b) refers to a statutory definition in 15 U.S.C. 1232 that is used for purposes of vehicle labeling on the vehicle window sticker. That definition includes optional accessories or items included by the manufacturer at the time of delivery to the dealer but excludes delivery charges to the dealer. For previously-owned clean vehicles, however, there are not similar vehicle labeling standards that provide a standard for defining sale price. In addition, in a previously-owned clean vehicle sale, the dealer and buyer may negotiate to characterize a portion of the sale price as a separately stated fee or charge (other than those required by law) to avoid the section 25E sale price cap of $25,000. To prevent this type of recharacterization, § 1.25E–1(b)(16) defines sale price to mean the total sale price agreed upon by the buyer and the dealer, including any delivery charges. This definition specifically excludes separately-stated taxes and fees required by State or local law because such taxes and fees are not subject to negotiation or recharacterization by the dealer and buyer.

The Treasury Department and the IRS considered various alternatives to the first transfer rule described in § 1.25E–1(b)(14)(ii). This rule is necessary to determine whether a sale of a previously-owned clean vehicle is a qualified sale pursuant to section 25E(c)(2). One of the requirements to be a qualified sale is that the sale be the first transfer to a qualified buyer since the enactment of section 25E other than to the person with whom the original use of the vehicle commenced. However, some of the characteristics of being a qualified buyer are unknowable to the dealer and the buyer in a subsequent sale, including that a qualified buyer be an individual, not be a dependent, and not have claimed the section 25E credit in the prior three years. As a result, if a previously-owned clean vehicle is transferred more than once after the date of enactment of section 25E, there is no way for the parties after the first transfer to know if the first transfer was to a qualified buyer. Because the IRS may have access to some information necessary to determine whether a first transfer was to a qualified buyer, the Treasury Department and the IRS considered alternatives to the first transfer rule such as a look-up tool regarding prior claims of the section 25E credit for a particular vehicle or information regarding prior vehicle purchasers. However, disclosure of this information raises significant confidentiality issues. Accordingly, the Treasury Department and the IRS have provided the first transfer rule to provide certainty to buyers and dealers as to which transfer of a previously-owned clean vehicle is the first transfer and will qualify for the section 25E credit by relying on the vehicle history report.

The Treasury Department and the IRS considered alternatives to the recapture rules provided in §§ 1.25E–2(c) and 1.30D–4(e). Given the increased availability and benefits of the section 30D credit and the new section 25E credit arising because the credit can be transferred to an eligible entity and is not limited by the taxpayer's tax liability, the Treasury Department and the IRS determined it was necessary to provide rules regarding when the value of the clean vehicle credits can be recaptured. The Treasury Department and the IRS also considered the appropriate length of time within which a return or resale of a vehicle would make the taxpayer ineligible for the credit. Longer and shorter periods of time were considered. Based on industry standard return policies, including money-back guarantees, the Treasury Department and the IRS determined that it was appropriate to deny the benefit of the credit if the vehicle was returned within 30 days. In addition, the Treasury Department and the IRS determined it was reasonable to assume an intent to resell the vehicle, making the purchase of the vehicle ineligible, if the vehicle was resold within 30 days.

Finally, with respect to the dealer registration requirements provided in §§ 1.25E–3(c) and 1.30D–5(c), the Treasury Department and the IRS considered various processes by which a seller could become an eligible entity and participate in the advance payment program. The Treasury Department and the IRS considered a process that did not require submission of a significant amount of information prior to the dealer becoming an eligible entity, but such an approach could require more back-end compliance. To ensure efficient tax administration and reduce fraud, the Treasury Department and the IRS determined that an up-front, electronic registration process was necessary for the IRS to effectively review and validate eligible entity status. In addition, the Treasury Department and the IRS determined that dealers must submit identity information and attestations regarding their participation in the advance payment program to ensure program integrity. Finally, the Treasury Department and the IRS determined that dealer tax compliance was necessary to ensure that advance payments are being paid only to compliant dealers.

F. Duplicative, Overlapping, or Conflicting Federal Rules

The final rule does not duplicate, overlap, or conflict with any relevant Federal rules. As discussed in the Summary of Comments and the Explanation of Revisions, the final rules merely provide requirements, procedures, and definitions related to the credit transfer election for sections 25E and 30D. The Treasury Department and the IRS invite input from interested members of the public about identifying and avoiding overlapping, duplicative, or conflicting requirements.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that

includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $198 million. This final rule does not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency (to the extent practicable and permitted by law) from promulgating any regulation that has federalism implications, unless the agency meets the consultation and funding requirements of section 6 of the Executive order, if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

VI. Regulatory Planning and Review

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule as defined by 5 U.S.C. 804(2).

Statement of Availability of IRS Documents

The IRS Revenue Procedures, Notices, and other guidance cited in this preamble is published in the *Internal Revenue Bulletin* and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC, 20402, or by visiting the IRS website at *https://www.irs.gov*.

Drafting Information

The principal authors of the regulations are Rika Valdman, Maggie Stehn, Nicole Stenchever, Mark C. Frantz, Jr., James Williford, and Iris Chung of the Office of Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in the development of the final regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Penalties, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, the Treasury Department and the IRS amend 26 CFR parts 1 and 301 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order for §§ 1.25E–1 through 1.25E–3, and 1.30D–1 through 1.30D–6 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.25E–1 also issued under 26 U.S.C. 25E.

Section 1.25E–2 also issued under 26 U.S.C. 25E.

Section 1.25E–3 also issued under 26 U.S.C. 25E, 26 U.S.C. 30D(g)(1) and (g)(10), and 26 U.S.C. 6011.

* * * * *

Section 1.30D–1 also issued under 26 U.S.C. 30D.

Section 1.30D–2 also issued under 26 U.S.C. 30D.

Section 1.30D–3 also issued under 26 U.S.C. 30D.

Section 1.30D–4 also issued under 26 U.S.C. 30D and 26 U.S.C. 45W(d)(3).

Section 1.30D–5 also issued under 26 U.S.C. 30D and 26 U.S.C. 6011.

Section 1.30D–6 also issued under 26 U.S.C. 30D.

* * * * *

■ **Par 2.** Sections 1.25E–0 through 1.25E–3 are added to read as follows:

Sec.

* * * * *

* * * * *

§ 1.25E–0 Table of contents.

This section lists the captions contained in §§ 1.25E–1 through 1.25E–3.

§ 1.25E–1 Credit for previously-owned clean vehicles.

(a) *In general.* Section 25E(a) of the Internal Revenue Code (Code) allows as a credit against the tax imposed by chapter 1 of the Code (chapter 1) for the taxable year of a taxpayer an amount equal to the lesser of $4,000, or the amount equal to 30 percent of the sale price of a previously-owned clean vehicle, if that previously-owned clean vehicle is placed in service during the taxable year by a taxpayer that acquired the previously-owned clean vehicle in a qualified sale in which that taxpayer is a qualified buyer. This section provides definitions and generally applicable rules that apply for purposes of determining the credit under section 25E and the section 25E regulations (section 25E credit). Section 1.25E–2 provides special rules under section 25E(e) and other special rules with respect to the section 25E credit. Section 1.25E–3 provides rules under section 25E(f).

(b) *Definitions.* The definitions in this paragraph (b) apply for purposes of section 25E and the section 25E regulations.

(1) *Advance payment program. Advance payment program* means advance payment program as defined in § 1.25E–3(b)(1).

(2) *Credit transfer election. Credit transfer election* means credit transfer election as defined in § 1.25E–3(b)(2).

(3) *Dealer. Dealer* has the meaning provided in section 25E(c)(2)(A) by reference to section 30D(g)(8) of the Code, except that the term does not include persons licensed solely by a territory of the United States, and includes a dealer licensed by any jurisdiction described in section 30D(g)(8) (other than one licensed solely by a territory of the United States) that makes sales at sites outside of the jurisdiction in which it is licensed.

(4) *Dealer tax compliance. Dealer tax compliance* means dealer tax compliance as defined in § 1.25E–3(b)(3).

(5) *Electing taxpayer. Electing taxpayer* means electing taxpayer as defined in § 1.25E–3(b)(4).

(6) *Eligible entity. Eligible entity* means eligible entity as defined in § 1.25E–3(b)(5).

(7) *Excessive payment. Excessive payment* means excessive payment as defined in § 1.25E–3(g)(2)(iii).

(8) *Incentive*—(i) *For purposes of sale price.* For purposes of the definition of *sale price* in § 1.25E–1(b)(16), *incentive* means any reduction in price offered to and accepted by a taxpayer from the dealer or manufacturer, other than a reduction in the form of a partial payment or down payment for the purchase of a previously-owned clean vehicle pursuant to section 25E(f) and § 1.25E–3.

(ii) *For purposes of eligible entity requirements.* For purposes of the eligible entity requirements for a credit transfer election pursuant to sections 25E(f) and 30D(g)(2)(B) and (D), *incentive* means any reduction in price offered to the taxpayer by the dealer or manufacturer of the previously-owned clean vehicle, including in combination with other incentives, other than a reduction in the form of a partial payment or down payment for the purchase of a previously-owned clean vehicle pursuant to section 25E(f) and § 1.25E–3.

(9) *Modified adjusted gross income. Modified adjusted gross income* means adjusted gross income (as defined in section 62 of the Code) increased by any amount excluded from gross income under section 911, 931, or 933 of the Code.

(10) *Placed in service.* A previously-owned clean vehicle is considered to be placed in service on the date the taxpayer takes possession of the vehicle.

(11) *Previously-owned clean vehicle. Previously-owned clean vehicle* has the meaning provided in section 25E(c)(1). Vehicles that may qualify as previously-owned clean vehicles include battery electric vehicles, plug-in hybrid electric vehicles, fuel cell motor vehicles, and plug-in hybrid fuel cell motor vehicles.

(12) *Qualified buyer. Qualified buyer* means, with respect to a sale of a motor vehicle, a taxpayer—

(i) Who is an individual;

(ii) Who purchases such vehicle for use and not for resale;

(iii) With respect to whom no deduction is allowable to another taxpayer under section 151 of the Code; and

(iv) Who has not been allowed a credit under section 25E and this section for any sale during the three-year period beginning three years before the date of the sale of such vehicle and ending on the date of the sale of such vehicle.

(13) *Qualified manufacturer. Qualified manufacturer* means qualified manufacturer as defined in § 1.30D–2(b)(42).

(14) *Qualified sale. Qualified sale* means a sale of a motor vehicle—

(i) By a dealer;

(ii) For a sale price that does not exceed $25,000; and

(iii) That is a sale to a qualified buyer (other than the person with whom the original use of such vehicle commenced), and that is the first transfer of the motor vehicle since August 16, 2022 (other than a transfer to a dealer).

(15) *Registered dealer. Registered dealer* means registered dealer as defined in § 1.25E–3(b)(6).

(16) *Sale price.* The *sale price* of a previously-owned clean vehicle means the total price agreed upon by the taxpayer and dealer in a written contract at the time of sale, including any delivery charges and after the

application of any incentives. The sale price of a previously-owned clean vehicle does not include separately stated taxes and fees required by State or local law. The sale price of a previously-owned clean vehicle is determined before the application of any trade-in value.

(17) *Section 25E regulations. Section 25E regulations* means this section and §§ 1.25E–2 and 1.25E–3.

(18) *Seller report. Seller report* means the report described in section 25E(c)(1)(D)(i) by reference to section 30D(d)(1)(H) that the seller of a previously-owned clean vehicle provides to the taxpayer and the IRS in the manner provided in, and containing the information described in, guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The seller report must be transmitted to the IRS electronically. The term *seller report* does not include a report rejected by the IRS due to the information contained therein not matching IRS records.

(19) *Time of sale. Time of sale* means time of sale as defined in § 1.25E–3(b)(7).

(20) *Vehicle history report. Vehicle history report* means a report that provides the ownership history of a motor vehicle. *Vehicle history report* includes a vehicle history report issued by a data provider approved by the National Motor Vehicle Title Information System.

(c) *Limitation based on modified adjusted gross income*—(1) *In general.* Under section 25E(b)(1), no section 25E credit is allowed for any taxable year if—

(i) The lesser of—

(A) The modified adjusted gross income of the taxpayer for such taxable year, or

(B) The modified adjusted gross income of the taxpayer for the preceding taxable year, exceeds

(ii) The threshold amount.

(2) *Threshold amount.* For purposes of section 25E(b)(1) and paragraph (c)(1) of this section, the threshold amount is determined based on the taxpayer's return filing status for the taxable year, as set forth in paragraphs (c)(2)(i) through (iii) of this section. *See* section 25E(b)(2).

(i) In the case of a joint return or a surviving spouse (as defined in section 2(a) of the Code), the threshold amount is $150,000.

(ii) In the case of a head of household (as defined in section 2(b)), the threshold amount is $112,500.

(iii) In the case of a taxpayer not described in paragraph (c)(2)(i) or (ii) of this section, the threshold amount is $75,000.

(3) *Special rule for change in filing status.* If the taxpayer's filing status for the taxable year differs from the taxpayer's filing status in the preceding taxable year, then the taxpayer satisfies the limitation in section 25E(b)(1) and paragraph (c)(1) of this section if the taxpayer's modified adjusted gross income does not exceed the threshold amount in either year based on the applicable filing status for that taxable year.

(d) *Credit may be claimed on only one tax return*—(1) *In general.* The amount of the section 25E credit attributable to a previously-owned clean vehicle may be claimed on only one Federal income tax return, including on a joint return for which one of the spouses is listed on the seller report. In the event a previously-owned clean vehicle is placed in service by multiple taxpayers who do not file a joint return, such as married individuals filing separate returns, no allocation or proration of the section 25E credit is available.

(2) *Seller reporting.* The name and taxpayer identification number of the taxpayer claiming the section 25E credit must be listed on the seller report pursuant to sections 25E(c)(1)(D)(i) and 30D(d)(1)(H). The credit will be allowed only on the Federal income tax return of the taxpayer listed in the seller report.

(e) *Examples.* The following examples illustrate the application of the rules in this section.

(1) *Example 1: First transfer since enactment of section 25E.* On August 1, 2022, a dealer sells a previously-owned vehicle that satisfies the requirements of section 25E(c)(1)(A), (B), and (D). On May 7, 2024, a dealer sells the vehicle to a qualified buyer, X, for a sale price of $24,000. X places the vehicle in service the same day. The May 7, 2024, sale to X is the first transfer of the vehicle since the enactment of section 25E.. The May 7, 2024, sale is a qualified sale pursuant to section 25E(c)(2) and paragraph (b)(14) of this section. As a result, the vehicle also satisfies the requirement of section 25E(c)(1)(C) and is a previously-owned clean vehicle as defined in section 25E(c)(1) and paragraph (b)(11) of this section.

(2) *Example 2: Multiple transfers since enactment of section 25E.* On July 1, 2023, a dealer sells a previously-owned vehicle that satisfies the requirements of section 25E(c)(1)(A), (B), and (D) to an individual, X, for a sale price of $30,000. X places the vehicle in service the same day. This is the first transfer of the vehicle since the enactment of section 25E. On May 7, 2024, a dealer sells the vehicle to an individual, Y, for a sale price of $24,500. The July 1, 2023, sale of the vehicle to X is not a qualified sale because the sale price exceeds the $25,000 limitation described in section 25E(c)(2)(B) and paragraph (b)(14) of this section. The May 7, 2024, sale to Y is not a qualified sale because it is not the first transfer since the enactment of section 25E.

(3) *Example 3: Multiple transfers; commercial purchaser.* The facts are the same as in paragraph (e)(2) of this section (*Example 2*), except that X is a partnership and the July 1, 2023, sale is for a sale price of $24,000. Although the vehicle is a previously-owned clean vehicle as defined in section 25E(c)(1) and paragraph (b)(11) of this section, no section 25E credit is allowed in relation to the sale because X is not a qualified buyer. The May 7, 2024, sale to Y is not a qualified sale because it is not the first transfer since enactment of section 25E.

(4) *Example 4: Multiple transfers; buyer exceeds modified adjusted gross income limitation.* The facts are the same as in paragraph (e)(2) of this section (*Example 2*), except the July 1, 2023, sale is for a sale price of $24,000 and X's modified adjusted gross income exceeds the limitation described in section 25E(b)(2) and paragraph (c) of this section. No section 25E credit is allowed in relation to the July 1, 2023, sale to X because X's modified adjusted gross income exceeds the limitation described in section 25E(b)(2) and paragraph (c) of this section. The May 7, 2024, sale to Y is not a qualified sale because it is not the first transfer since the enactment of section 25E.

(5) *Example 5: Multiple transfers; buyer elects to not take credit.* The facts are the same as in paragraph (e)(2) of this section (*Example 2*), except the July 1, 2023, sale is for a sale price of $24,000 and X elects to not claim the section 25E credit. The May 7, 2024, sale to Y is not a qualified sale because it is not the first transfer since the enactment of section 25E.

(6) *Example 6: Multiple transfers; sale between dealers.* On July 1, 2023, a dealer, D1, sells a previously-owned vehicle that satisfies the requirements of section 25E(c)(1)(A), (B), and (D) to another dealer, D2, for $18,000. D1 and D2 are not individuals. On August 1, 2024, D2 sells the vehicle to an individual, Y, for a sale price of $24,500. Y places the vehicle in service the same day. Y satisfies the modified adjusted gross income limitation in section 25E(b)(2) and paragraph (c) of this section. The July 1, 2023, sale to D2 is ignored because it is a transfer

between dealers. Further, with regard to the July 1, 2023, sale, D2 is not a qualified buyer because D2 is not an individual. The May 7, 2024, sale to Y is a qualified sale because it is the first transfer that is regarded since the enactment of section 25E.

(f) *Reliance on vehicle history report for purposes of determining whether sale is a qualified sale.* A taxpayer may rely on a vehicle history report obtained on the date of sale or as part of the sale transaction to determine whether the requirements of section 25E(c)(2)(C) and paragraph (b)(14) of this section are satisfied, including in the case where there has been a prior sale and return or resale described in § 1.25E–2(c).

(g) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(h) *Applicability date.* This section applies to previously-owned clean vehicles placed in service after December 31, 2022, in taxable years ending after October 10, 2023.

§ 1.25E–2 Special rules.

(a) *In general.* This section provides guidance under section 25E(e) of the Internal Revenue Code (Code), which incorporates rules similar to the rules of section 30D(f) of the Code, other than section 30D(f)(10) or 30D(f)(11). Unless otherwise provided in this section, the rules of section 30D(f) apply to section 25E and the section 25E regulations in the same manner by replacing, if applicable, any reference to section 30D or the section 30D credit with a reference to section 25E or the section 25E credit. This section also provides guidance regarding other special rules with respect to the section 25E credit.

(b) *No double benefit*—(1) *In general.* Under sections 25E(e) and 30D(f)(2), the amount of any deduction or other credit allowable under chapter 1 of the Code (chapter 1) for a vehicle for which a section 25E credit is allowable must be reduced by the amount of the section 25E credit allowed for such vehicle.

(2) *Interaction between section 25E and section 30D credits.* A section 30D credit that has been allowed with respect to a vehicle in a taxable year before the year in which a section 25E credit is allowable for that vehicle does not reduce the amount allowable under section 25E.

(c) *Recapture*—(1) *In general.* This paragraph (c) provides rules regarding the recapture of the section 25E credit.

(i) *Cancelled sale.* If the sale of a previously-owned clean vehicle between the taxpayer and dealer is cancelled before the taxpayer places the vehicle in service, then—

(A) The taxpayer may not claim the section 25E credit with respect to the vehicle;

(B) The sale will be treated as not having occurred (and no transfer of the vehicle is considered to have occurred by reason of the cancelled sale), and the vehicle will, therefore, still be eligible for the section 25E credit upon a subsequent sale meeting the requirements of section 25E and the section 25E regulations;

(C) The seller report must be rescinded by the seller in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter); and

(D) The taxpayer cannot make a credit transfer election under section 25E(f) and § 1.25E–3 with respect to the cancelled sale.

(ii) *Vehicle return.* If a taxpayer returns a previously-owned clean vehicle to the dealer within 30 days of placing such vehicle in service, then—

(A) The taxpayer cannot claim the section 25E credit with respect to the vehicle;

(B) The sale will be treated as having occurred (and a transfer of the vehicle is therefore considered to have occurred by reason of the sale), and the vehicle will not qualify for the section 25E credit upon a subsequent sale;

(C) The seller report must be updated by the seller; and

(D) A credit transfer election made pursuant to section 25E(f) and § 1.25E–3, if applicable, will be treated as nullified and any advance payment made pursuant to section 25E(f) and § 1.25E–3, if applicable, will be collected from the eligible entity as an excessive payment pursuant to § 1.25E–3(g)(2).

(iii) *Resale.* If a taxpayer resells a previously-owned clean vehicle within 30 days of placing the vehicle in service, then the taxpayer is treated as having purchased such vehicle with the intent to resell, and—

(A) The taxpayer cannot claim the section 25E credit with respect to the vehicle;

(B) The sale to the taxpayer will be treated as having occurred (and a transfer of the vehicle is therefore considered to have occurred by reason of the sale), and the vehicle will not qualify for the section 25E credit upon a subsequent sale;

(C) The seller report will not be updated;

(D) A credit transfer election made pursuant to section 25E(f) and § 1.25E–3, if applicable, will remain in effect and any advance payment made pursuant to section 25E(f) and § 1.25E–3 will not be collected from the eligible entity; and

(E) The amount of any transferred credit will be collected from the taxpayer as an increase in tax imposed by chapter 1 of the Code for the taxable year in which the vehicle was placed in service.

(iv) *Other returns and resales.* In the case of a vehicle return not described in paragraph (c)(1)(ii) of this section or a resale not described in paragraph (c)(1)(iii) of this section, the previously-owned clean vehicle will not be eligible for the section 25E credit upon a subsequent sale.

(2) *Recapture rules in the case of a credit transfer election.* For additional recapture rules that apply in the case of a credit transfer election, see § 1.25E–3(g)(1). For excessive payment rules that apply in the case of an advance payment made to an eligible entity, see § 1.25E–3(g)(2).

(3) *Example: Vehicle return.* On May 1, 2024, a dealer, D, sells a vehicle that satisfies the requirements of section 25E(c)(1) to a qualified buyer, X. X returns the vehicle to D within 30 days of placing the vehicle in service, and does not claim the section 25E credit. On July 9, 2024, D sells the vehicle to a qualified buyer, Y, for a sale price of $24,000. The vehicle history report obtained on July 9, 2024, reflects the May 1, 2024, sale and subsequent return of the vehicle. The July 9, 2024, sale of the vehicle is not a qualified sale because it is not the first transfer of the vehicle after the enactment of section 25E. Therefore, no section 25E credit is allowed in relation to that sale. It is irrelevant that X did not claim the section 25E credit with respect to the May 1, 2024, sale.

(d) *Branded title.* A title to a previously-owned clean vehicle indicating that such vehicle has been damaged, or is otherwise a branded title, does not impact the vehicle's eligibility for a section 25E credit.

(e) *Seller registration.* A seller must register with the IRS in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) for purposes of filing seller reports (as defined in § 1.25E–1(b)(18)).

(f) *Requirement to file income tax return.* No section 25E credit is allowed unless the taxpayer claiming such credit files a Federal income tax return for the taxable year in which the previously-owned clean vehicle is placed in service. The taxpayer must attach to such return a completed Form 8936, *Clean Vehicle Credits,* or successor

form, that includes all information required by the form and instructions. The taxpayer must also attach a completed Schedule A (Form 8936), *Clean Vehicle Credit Amount,* or successor form or schedule, that includes all information required by the schedule and instructions, such as the vehicle identification number of the previously-owned clean vehicle.

(g) *Taxpayer reliance on manufacturer certifications and periodic written reports to IRS.* A taxpayer who acquires a previously-owned clean vehicle in a qualified sale and places it in service may rely on the manufacturer's certification concerning the manufacturer's status as a qualified manufacturer. A taxpayer also may rely on the information and certifications contained in the qualified manufacturer's periodic written reports to the IRS for purposes of determining whether a vehicle is a previously-owned clean vehicle. The procedures for such written reports are established in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). To the extent a taxpayer relies on such certifications or information, the previously-owned clean vehicle the taxpayer acquires will be deemed to meet the requirements of section 25E(c)(1)(D) (except the section 30D(d)(1)(H) requirement cross-referenced in section 25E(c)(1)(D)(i), which must be satisfied separately), provided the certifications or information relied upon by the taxpayer support this result. *See* § 1.25E–3(g)(3)(ii) for an example that illustrates the interplay between the rule in this paragraph (g) and the excessive payment rule in § 1.25E–3(g)(2).

(h) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(i) *Applicability date.* This section applies to previously-owned clean vehicles placed in service after December 31, 2022, in taxable years ending after October 10, 2023.

§ 1.25E–3 Transfer of credit.

(a) *In general.* This section provides rules related to the transfer and advance payment of the section 25E credit pursuant to section 25E(f) of the Internal Revenue Code (Code) by cross reference to section 30D(g) of the Code. Under the rules of section 30D(g) and this section, a taxpayer may elect to transfer a section 25E credit to an eligible entity, and the eligible entity may receive an advance payment for such credit, provided certain requirements are met. *See* paragraph (d) of this section for rules applicable to credit transfer elections. *See* paragraph (f) of this section for rules applicable to advance payments of transferred section 25E credits. Section 30D(g)(2) sets forth certain requirements that a dealer must satisfy to be an eligible entity for credit transfer and advance payment purposes. Section 30D(g)(2)(A) requires registration with the IRS. *See* paragraph (c) of this section for rules related to dealer registration. Section 30D(g)(2)(B) through (D) and paragraph (f)(2) of this section impose additional requirements that a registered dealer must satisfy in order to be an eligible entity for credit transfer and advance payment purposes.

(b) *Definitions.* This paragraph (b) provides definitions that apply for purposes of section 25E(f) and this section. *See* § 1.25E–1(b) for definitions that are generally applicable to section 25E and the section 25E regulations.

(1) *Advance payment program. Advance payment program* means the program described in paragraph (f)(1) of this section.

(2) *Credit transfer election. Credit transfer election* has the meaning provided in sections 25E(f) and 30D(g), and paragraph (d) of this section.

(3) *Dealer tax compliance. Dealer tax compliance* means that the dealer has filed all required Federal information and tax returns, including for Federal income and employment tax purposes, and the dealer has paid all Federal tax, penalties, and interest due as of the time of sale. A dealer that has entered into an installment agreement with the IRS for which a dealer is current on its obligations (including required filings) is treated as being in dealer tax compliance.

(4) *Electing taxpayer. Electing taxpayer* means an individual who purchases and places in service a previously-owned clean vehicle and elects to transfer the section 25E credit that would otherwise be allowable to such individual to an eligible entity pursuant to section 25E(f) and paragraph (d) of this section. A taxpayer is an electing taxpayer only if the taxpayer makes certain attestations to the registered dealer, pursuant to procedures provided in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter), including that the taxpayer does not anticipate exceeding the modified adjusted gross income limitation of section 25E(b)(1) and § 1.25E–1(b).

(5) *Eligible entity. Eligible entity* has the meaning provided in section 30D(g)(2) and paragraph (f)(2) of this section.

(6) *Registered dealer. Registered dealer* means a dealer that has completed registration with the IRS as provided in paragraph (c) of this section.

(7) *Time of sale. Time of sale* means the date the previously-owned clean vehicle is placed in service, as defined in § 1.25E–1(b)(10).

(c) *Dealer registration*—(1) *In general.* A dealer must register with the IRS in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) for the dealer to receive credits transferred by an electing taxpayer pursuant to section 25E(f) and paragraph (d) of this section.

(2) *Dealer tax compliance required.* A dealer must be in dealer tax compliance to complete and maintain its registration with the IRS. If the dealer is not in dealer tax compliance for any of the taxable periods during the last five taxable years, then the dealer may complete its initial registration with the IRS, but the dealer will not be eligible for the advance payment program (and, therefore, the dealer will not be eligible to receive transferred section 25E credits) until the compliance issue is resolved. The IRS will notify the dealer in writing that the dealer is not in dealer tax compliance, and the dealer will have the opportunity to address any failure through regular procedures. If the failure is corrected, the IRS will complete the dealer's registration, and, provided all other requirements of section 25E(f) and this section are met, the dealer will then be allowed to receive transferred section 25E credits and participate in the advance payment program. Additional procedural guidance regarding this paragraph is set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(3) *Suspension of registration.* A registered dealer's registration may be suspended pursuant to the procedures described in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). Any decision made by the IRS relating to the suspension of a registered dealer's registration is not subject to administrative appeal to the IRS Independent Office of Appeals unless the IRS and the IRS Independent Office of Appeals agree that such review is available and the IRS provides the time and manner for such review.

(4) *Revocation of registration.* A registered dealer's registration may be revoked pursuant to the procedures described in guidance published in the *Internal Revenue Bulletin* (see § 601.601). Any decision made by the IRS relating to the revocation of a

dealer's registration is not subject to administrative appeal to the IRS Independent Office of Appeals unless the IRS and the IRS Independent Office of Appeals agree that such review is available and the IRS provides the time and manner for such review.

(d) *Credit transfer election by electing taxpayer.* For a previously-owned clean vehicle placed in service after December 31, 2023, an electing taxpayer may elect to apply the rules of section 25E(f) and this section to make a credit transfer election with respect to the vehicle so that the section 25E credit is allowed to the eligible entity specified in the credit transfer election (and not to the electing taxpayer) pursuant to the advance payment program described in paragraph (f) of this section. The electing taxpayer, as part of the credit transfer election, must transfer the entire amount of the credit that would otherwise be allowable to the electing taxpayer under section 25E with respect to the vehicle, and the eligible entity specified in the credit transfer election must pay the electing taxpayer an amount equal to the amount of the credit included in the credit transfer election. A credit transfer election must be made no later than the time of sale, and must be made in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). Once made, a credit transfer election is irrevocable.

(e) *Federal income tax consequences of credit transfer election*—(1) *Tax consequences for electing taxpayer.* In the case of a credit transfer election, the Federal income tax consequences for the electing taxpayer are as follows—

(i) The amount of the section 25E credit that the electing taxpayer elects to transfer to the eligible entity under section 30D(g) (by reason of section 25E(f)) and paragraph (d) of this section may exceed the electing taxpayer's regular tax liability (as defined in section 26(b)(1) of the Code) for the taxable year in which the sale occurs, and the excess, if any, is not subject to recapture on the basis that it exceeded the electing taxpayer's regular tax liability;

(ii) The payment made by an eligible entity to an electing taxpayer under section 30D(g)(2)(C) (by reason of 25E(f)) and paragraph (d) of this section to an electing taxpayer pursuant to a credit transfer election is not includible in the gross income of the electing taxpayer; and

(iii) The payment made by an eligible entity under section 30D(g)(2)(C) (by reason of section 25E(f)) and paragraph (d) of this section is treated as repaid by the electing taxpayer to the eligible entity as partial payment of the sale price of the previously-owned clean vehicle. Thus, the repayment by the electing taxpayer is included in the electing taxpayer's basis in the previously-owned clean vehicle prior to the application of the basis reduction rule of section 30D(f)(1) that applies by reason of section 25E(e) and § 1.25E–2(a).

(2) *Tax consequences for eligible entity.* In the case of a credit transfer election, the Federal income tax consequences for the eligible entity are as follows—

(i) The eligible entity is allowed the section 25E credit with respect to the previously-owned clean vehicle and may receive an advance payment pursuant to section 30D(g)(7) (by reason of section 25E(f)) and paragraph (f) of this section;

(ii) Advance payments received by the eligible entity are not treated as a tax credit in the hands of the eligible entity and may exceed the eligible entity's regular tax liability (as defined in section 26(b)(1)) for the taxable year in which the sale occurs;

(iii) An advance payment received by the eligible entity is not included in the gross income of the eligible entity;

(iv) The payment made by an eligible entity under section 30D(g)(2)(C) (by reason of section 25E(f)) and paragraph (d) of this section to an electing taxpayer is not deductible by the eligible entity;

(v) The payment made by an eligible entity to the electing taxpayer under section 30D(g)(2)(C) (by reason of section 25E(f)) and paragraph (d) of this section is treated as paid by the electing taxpayer to the eligible entity as partial payment of the sale price of the previously-owned clean vehicle. Thus, the repayment by the electing taxpayer is treated as an amount realized by the eligible entity under section 1001 of the Code and the regulations under section 1001; and

(vi) If the eligible entity is a partnership or an S corporation, then—

(A) The IRS will make the advance payment to such partnership or S corporation equal to the amount of the section 25E credit allowed that is transferred to the eligible entity;

(B) Such section 25E credit is reduced to zero and is, for any other purpose of the Code, deemed to have been allowed solely to such entity (and not allocated or otherwise allowed to its partners or shareholders) for such taxable year; and

(C) The amount of the advance payment is not treated as tax exempt income to the partnership or S corporation for purposes of the Code.

(3) *Form of payment from eligible entity to electing taxpayer.* The tax treatment of the payment made by the eligible entity to the electing taxpayer described in paragraphs (e)(1) and (2) of this section is the same regardless of whether the payment is made in cash, in the form of a partial payment or down payment for the purchase of the previously-owned clean vehicle, or as a reduction in sale price (without the payment of cash) of the previously-owned clean vehicle.

(4) *Additional requirements.* In the case of a credit transfer election, the following additional rules apply:

(i) The requirements of section 30D(f)(1) (regarding basis reduction) and 30D(f)(2) (regarding no double benefit), by reason of section 25E(e), apply to the electing taxpayer as if the credit transfer election were not made (so, for example, the electing taxpayer must reduce the electing taxpayer's basis in the vehicle by the amount of the section 25E credit, regardless of the credit transfer election).

(ii) Section 30D(f)(6) (regarding the election not to take the credit), by reason of section 25E(e), will not apply (in other words, by electing to transfer the credit, the electing taxpayer is electing to take the credit).

(iii) Section 30D(f)(9) (regarding the vehicle identification number requirement), by reason of section 25E(e), and section 25E(d) (regarding the vehicle identification number requirement) will be treated as satisfied if the eligible entity provides the vehicle identification number of such vehicle to the IRS in the form and manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The electing taxpayer must also provide the vehicle identification number with their Federal income tax return for the taxable year in which the vehicle is placed in service. *See* section 6213(g)(2)(U) of the Code and § 301.6213–2 of this chapter for rules relating to the omission of a correct vehicle identification number.

(5) *Examples.* The following examples illustrate the rules of paragraph (e) of this section.

(i) *Example 1: Electing taxpayer's regular tax liability less than amount of credit*—(A) *Facts.* T, an individual, purchases a previously-owned clean vehicle from a dealer, D, which is a C corporation. T satisfies the requirements to be an electing taxpayer and elects to transfer the section 25E credit to D. D is a registered dealer and satisfies the requirements to be an eligible entity. The sale price of the vehicle is $24,000. The section 25E credit otherwise allowable to T is $4,000. D makes the payment required to be made to T in the form of a cash payment of $4,000. T

uses the $4,000 as a partial payment for the vehicle. T pays D an additional $20,000 from other funds. T's regular tax liability for the year is less than $4,000.

(B) *Analysis.* Under paragraph (e)(1)(i) of this section, T may transfer the credit to D, even though T's regular tax liability is less than $4,000, and no amount of the credit will be recaptured from T on the basis that the allowable credit exceeded T's regular tax liability. D's $4,000 payment to T is not included in T's gross income, and the sale price of the vehicle is $24,000 (including both the $4,000 payment and the additional $20,000 paid by T from other funds), prior to the application of the basis reduction rule of section 30D(f)(1) (by reason of section 25E(e)). After application of the basis reduction rule, T's basis in the vehicle is $20,000. D is eligible to receive an advance payment of $4,000 for the transferred section 25E credit as provided in section 30D(g)(7) (by reason of section 25E(e)) and paragraph (f) of this section. Under paragraph (e)(2) of this section, D may receive the advance payment regardless of whether D's regular tax liability is less than $4,000. The advance payment is not treated as a credit toward D's tax liability (if any), nor is it included in D's gross income. Further, D's $4,000 payment to T is not deductible, and D's amount realized is $24,000 upon the sale of the vehicle (including both the $4,000 payment from D to T that T uses as a partial payment, and the additional $20,000 paid by T from other funds).

(ii) *Example 2: Non-cash payment by eligible entity to electing taxpayer*—(A) *Facts.* The facts are the same as in paragraph (e)(5)(i)(A) of this section (facts of *Example 1*), except that D makes the payment to T in the form of a reduction in the sale price of the vehicle (rather than as a cash payment).

(B) *Analysis.* Paragraph (e)(3) of this section provides that the application of paragraphs (e)(1) and (2) of this section is not dependent on the form of payment from an eligible entity to an electing taxpayer (for example, a payment in cash or a payment in the form of a reduction in sale price). Thus, the analysis is the same as in paragraph (e)(5)(i)(B) of this section (analysis of *Example 1*).

(iii) *Example 3: Eligible entity is a partnership*—(A) *Facts.* The facts are the same as in paragraph (e)(5)(i)(A) of this section (facts of *Example 1*), except that D is a partnership.

(B) *Analysis.* The analysis as to T is the same as in paragraph (e)(5)(i)(B) of this section (analysis of *Example 1*). Because D is a partnership, paragraph (e)(2)(vi) of this section applies. Thus, the advance payment is made to the partnership, the credit is reduced to zero and is, for any other purpose of the Code, deemed to have been allowed solely to the partnership (and not allocated or otherwise allowed to its partners) for such taxable year. The amount of the advance payment is not treated as tax exempt income to the partnership for purposes of the Code.

(f) *Advance payments received by eligible entities*—(1) *In general.* An eligible entity may receive advance payments from the IRS (corresponding to the amount of the section 25E credit for which a credit transfer election was made by an electing taxpayer to transfer the credit to the eligible entity pursuant to section 30D(g) (by reason of section 25E(f)) and paragraph (d) of this section) before the eligible entity files its Federal income tax return or information return, as appropriate, for the taxable year with respect to which the credit transfer election corresponds. This advance payment program is the exclusive mechanism for an eligible entity to receive the section 25E credit transferred pursuant to section 25E(f) and paragraph (d) of this section. An eligible entity receiving a transferred section 25E credit may not claim the credit on a tax return.

(2) *Requirements for a registered dealer to become an eligible entity.* A registered dealer qualifies as an eligible entity, and may therefore receive an advance payment in connection with a credit transfer election, if it meets the following requirements:

(i) The registered dealer submits all required registration information and is in dealer tax compliance;

(ii) The registered dealer retains information regarding the credit transfer election for three calendar years beginning with the year immediately after the year in which the vehicle is placed in service, as described in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter);

(iii) The registered dealer meets any other requirements set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) or in forms and instructions; and

(iv) The registered dealer meets any other requirements of section 25E(f) by reference to section 30D(g), including those in section 30D(g)(2)(B) through (E).

(g) *Increase in tax*—(1) *Recapture if electing taxpayer exceeds modified adjusted gross income limitation.* If an electing taxpayer has modified adjusted gross income that exceeds the limitation in section 25E(b) and § 1.25E–1(b), then the income tax imposed on such taxpayer under chapter 1 of the Code (chapter 1) for the taxable year in which the vehicle was placed in service is increased by the amount of the payment received by the taxpayer. The electing taxpayer must recapture such amounts on the Federal income tax return described in paragraph (h) of this section.

(2) *Excessive payments*—(i) *In general.* This paragraph provides rules under section 25E(f) by reference to section 30D(g)(7)(B), which provides that rules similar to the rules of section 6417(d)(6) of the Code apply to the advance payment program. In the case of any advance payment to an eligible entity that the IRS determines constitutes an excessive payment, the tax imposed on the eligible entity under chapter 1, regardless of whether such entity would otherwise be subject to tax under chapter 1, for the taxable year in which such determination is made will be increased by the sum of the following amounts—

(A) The amount of the excessive payment; plus

(B) An amount equal to 20 percent of such excessive payment.

(ii) *Reasonable cause.* The amount described in paragraph (g)(2)(i)(B) of this section will not apply to an eligible entity if the eligible entity demonstrates to the satisfaction of the IRS that the excessive payment resulted from reasonable cause. In the case of a previously-owned clean vehicle (with respect to which a credit transfer election was made by the electing taxpayer) that is returned to the eligible entity within 30 days of being placed in service, the eligible entity will be treated as having demonstrated that the excessive payment resulted from reasonable cause.

(iii) *Excessive payment defined.* Excessive payment means an advance payment made—

(A) To a registered dealer that fails to meet the requirements to be an eligible entity provided in paragraph (f)(2) of this section; or

(B) Except as provided in paragraph (g)(2)(iv) of this section, to an eligible entity with respect to a previously-owned clean vehicle to the extent the payment exceeds the amount of the credit that, without application of section 25E(f) and this section, would be otherwise allowable to the electing taxpayer with respect to the vehicle for such tax year.

(iv) *Special rule for cases in which electing taxpayer's modified adjusted gross income exceeds the limitation.* Any excess described in paragraph (g)(2)(iii)(B) of this section that arises due to the electing taxpayer exceeding

the limitation based on modified adjusted gross income in section 25E(b) and § 1.25E–1(b) is not an excessive payment. Instead, the amount of the advance payment is recaptured from the taxpayer under section 25E(e) and paragraph (g)(1) of this section.

(3) *Examples.* The following examples illustrate the excessive payment rules in paragraph (g)(2) of this section.

(i) *Example 1: Registered dealer is not an eligible entity*—(A) *Facts.* In 2024, D, a registered dealer, receives an advance payment of $4,000 with respect to a credit transferred pursuant to section 25E(f) and paragraph (d) of this section for a previously-owned clean vehicle, vehicle V. In 2025, the IRS determines that D was not an eligible entity with respect to vehicle V at the time it received the advance payment in 2024 because D failed to satisfy one of the requirements of section 30D(g)(2) (applicable by reason of section 25E(e)) and paragraph (f)(2) of this section. D is unable to show reasonable cause for the failure.

(B) *Analysis.* Under paragraph (g)(2)(i) of this section, the tax imposed on D is increased by the amount of the excessive payment if the advance payment received by D constitutes an excessive payment. Under paragraph (g)(2)(iii) of this section, the entire amount of the $4,000 advance payment received by D is an excessive payment because D did not meet the requirements to be an eligible entity under section 30D(g)(2) (applicable by reason of section 25E(f) and paragraph (f)(2) of this section). Additionally, because D cannot show reasonable cause for its failure to meet these requirements, the tax imposed under chapter 1 on D is increased by $4,800 in 2025 (the taxable year of the IRS determination). This is comprised of the $4,000 excessive payment plus the $800 penalty, calculated as 20% of the $4,000 excessive payment (20% × $4,000 = $800). This treatment applies regardless of whether D is otherwise subject to tax under chapter 1 (for example, if D is a partnership).

(ii) *Example 2: Incorrect manufacturer certifications*—(A) *Facts.* In 2024, T, a taxpayer, makes an election to transfer a $4,000 credit pursuant to section 25E(f) and paragraph (d) of this section to registered dealer, E, with respect to vehicle V. M, the manufacturer of vehicle V, certified to the IRS that vehicle V has a battery with a capacity of not less than 7 kilowatt hours (kwh). T and vehicle V otherwise meet the eligibility requirements for the section 25E credit. T, in reliance on the manufacturer's certification to the IRS regarding vehicle V's battery capacity, transfers the section 25E credit to E. Subsequent to T's purchase of vehicle V and election to transfer the $4,000 credit to E, M reports to the IRS that vehicle V has a battery capacity of less than 7 kwh.

(B) *Analysis.* Section 1.25E–2(g) provides that T may rely on the information and certifications provided in M's written report to the IRS for purposes of determining whether vehicle V is a previously-owned clean vehicle, as defined in section 25E(c)(1) and § 1.25E–1(b)(11). Because T relied on M's certification to the IRS regarding vehicle V's battery capacity and T and vehicle V otherwise meet the eligibility requirements for the section 25E credit, vehicle V is deemed to meet the requirements of section 30D(d)(1)(F) (as cross-referenced in section 25E(c)(1)(D)(i)). Under paragraph (g)(2)(iii)(B) of this section, an advance payment to an eligible entity with respect to a vehicle is an excessive payment to the extent the payment exceeds the amount of the credit that, without a credit transfer election, would be otherwise allowable to the electing taxpayer with respect to the vehicle for such taxable year. Because the amount of the credit that would be allowable to T for 2024 is $4,000, and T transferred the $4,000 credit to E, there is no excessive payment with respect to E.

(h) *Return requirement.* An electing taxpayer that makes a credit transfer election must file a Federal income tax return for the taxable year in which the credit transfer election is made and indicate such election on the return in accordance with the instructions to the form on which the return is made. The electing taxpayer must attach to such return a completed Form 8936, *Clean Vehicle Credits,* or successor form, that includes all information required by the form and instructions. The electing taxpayer must also attach a completed Schedule A (Form 8936), *Clean Vehicle Credit Amount,* or successor form or schedule, that includes all information required by the schedule and instructions, such as the vehicle identification number of the previously-owned clean vehicle.

(i) *Two credit transfer elections per year.* A taxpayer may make no more than two credit transfer elections per taxable year, consisting of either two elections to transfer section 30D credits, or one section 30D credit and one election to transfer a section 25E credit. In the case of taxpayers who file a joint return, each individual taxpayer may make no more than two credit transfer elections per taxable year.

(j) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions will continue in effect.

(k) *Applicability date.* This section applies to previously-owned vehicles placed in service after December 31, 2023, in taxable years ending after December 31, 2023.

■ **Par 3.** Sections 1.30D–0 through 1.30D–6 are added to read as follows:

§ 1.30D–0 Table of contents.

This section lists the captions contained in §§ 1.30D–1 through 1.30D–6.

§ 1.30D–1 Credit for new clean vehicles.

(a) *In general.* Section 30D(a) of the Internal Revenue Code (Code) allows as a credit against the tax imposed by chapter 1 of the Code (chapter 1) for the taxable year of a taxpayer an amount equal to the sum of the credit amounts determined under section 30D(b) with respect to each new clean vehicle purchased by the taxpayer that the taxpayer places in service during the taxable year. This section provides generally applicable rules that apply for purposes of determining the credit under section 30D and the section 30D regulations (section 30D credit). Section 1.30D–2 provides definitions that apply for purposes of section 30D and the section 30D regulations. Section 1.30D–3 provides rules regarding the critical minerals and battery components requirements of section 30D(e). Section 1.30D–4 provides guidance regarding the limitations and special rules in section 30D(f) as well as other special rules with respect to the section 30D credit. Section 1.30D–5 provides rules for the credit transfer election and advance payment program and for recapture. Section 1.30D–6 provides rules regarding the foreign entities of concern (FEOC) restriction of section 30D(d)(7).

(b) *Application with other credits*—(1) *Business credit treated as part of general business credit.* Section 30D(c)(1) requires that so much of the section 30D credit that would be allowed under section 30D(a) for any taxable year (determined without regard to section 30D(c) and this paragraph (b)) that is attributable to a depreciable vehicle must be treated as a general business credit under section 38 of the Code that is listed in section 38(b)(30) for such taxable year (and not allowed under section 30D(a)). In the case of a depreciable vehicle the use of which is 50 percent or more business use in the taxable year such vehicle is placed in service, the section 30D credit that would be allowed under section 30D(a) for that taxable year (determined without regard to section 30D(c) and this paragraph (b)) that is attributable to such depreciable vehicle must be treated as a general business credit under section 38(b)(30) for such taxable year (and not allowed under section 30D(a)). See paragraph (b)(2) of this section for rules applicable in the case of a depreciable vehicle the use of which is less than 50 percent business use in the taxable year such vehicle is placed in service. See paragraph (b)(3) of this section for rules applicable to a section 30D credit allowed under section 30D(a) pursuant to section 30D(c)(2) or paragraph (b)(2)(ii) or (b)(3) of this section.

(2) *Apportionment of section 30D credit.* Unless the taxpayer has elected to transfer the credit pursuant to section 30D(g) and § 1.30D–5(d), in the case of a depreciable vehicle the business use of which is less than 50 percent of a taxpayer's total use of the vehicle for the taxable year in which the vehicle is placed in service, the taxpayer's section 30D credit for that taxable year with respect to that vehicle must be apportioned as follows:

(i) The portion of the section 30D credit corresponding to the percentage

of the taxpayer's business use of the vehicle is treated as a general business credit under section 30D(c)(1) and paragraph (b)(1) of this section (and not allowed under section 30D(a) or paragraph (b)(3) of this section).

(ii) The portion of the section 30D credit corresponding to the percentage of the taxpayer's personal use of the vehicle is treated as a section 30D credit allowed under section 30D(a) pursuant to section 30D(c)(2) and paragraph (b)(3) of this section.

(3) *Personal credit limited based on tax liability.* Section 26 of the Code limits the aggregate amount of credits allowed to a taxpayer by subpart A of part IV of subchapter A of chapter 1 (subpart A) based on the taxpayer's tax liability. Under section 26(a), the aggregate amount of credits allowed to a taxpayer by subpart A cannot exceed the sum of the taxpayer's regular tax liability (as defined in section 26(b)) for the taxable year reduced by the foreign tax credit allowable under section 27 of the Code, and the alternative minimum tax imposed by section 55(a) of the Code for the taxable year. Section 30D(c)(2) provides that the section 30D credit allowed under section 30D(a) for any taxable year (determined after application of section 30D(c)(1) and paragraphs (b)(1) and (2) of this section) is treated as a credit allowable under subpart A for such taxable year, and the section 30D credit allowed under section 30D(a) is therefore subject to the limitation imposed by section 26.

(c) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(d) *Applicability date.* This section applies to taxable years ending after December 4, 2023.

§ 1.30D–2 Definitions for purposes of section 30D.

(a) *In general.* The definitions in this section apply for purposes of section 30D of the Internal Revenue Code (Code) and the section 30D regulations.

(b) *Definitions*—(1) *Advance payment program. Advance payment program* means advance payment program as defined in § 1.30D–5(b)(1).

(2) *Applicable critical mineral*—(i) *In general. Applicable critical mineral* means an applicable critical mineral as defined in section 45X(c)(6) of the Code. The requirements of §§ 1.30D–3(a) and 1.30D–6 with respect to an applicable critical mineral take into account each step of extraction, processing, or recycling through the step in which such mineral is processed or recycled into a constituent material, even if the mineral is not in a form listed in section 45X(c)(6) at every step of production. However, an applicable critical mineral is disregarded for purposes of the requirements of §§ 1.30D–3(a) and 1.30D–6 if it is fully consumed in the production of the constituent material or battery component and no longer remains in any form in the battery.

(ii) *Example: Form of applicable critical mineral.* Mineral Y is extracted and is intended to be incorporated into the battery of an electric vehicle. Mineral Y is not in a form listed in section 45X(c)(6) at the time of such extraction, but subsequently it is refined into an applicable critical mineral form listed in section 45X(c)(6). Both the extraction and processing are taken into account for purposes of the requirements of §§ 1.30D–3(a) and 1.30D–6.

(3) *Assembly.* Assembly, with respect to battery components, means the process of combining battery components into battery cells and battery modules.

(4) *Associated constituent material.* Associated constituent material, with respect to an applicable critical mineral, means a constituent material that has been processed or recycled from such mineral into the constituent material with which it is associated, even if that processing or recycling transformed such mineral into a form not listed in section 45X(c)(6).

(5) *Battery.* Battery, for purposes of a new clean vehicle, means a collection of one or more battery modules, each of which has two or more electrically configured battery cells in series or parallel, to create voltage or current. The term *battery* does not include items such as thermal management systems or other parts of a battery cell or module that do not directly contribute to the electrochemical storage of energy within the battery, such as battery cell cases, cans, or pouches.

(6) *Battery cell.* Battery cell means a combination of battery components (other than battery cells) capable of electrochemically storing energy from which the electric motor of a new clean vehicle draws electricity.

(7) *Battery cell production facility.* Battery cell production facility means a facility in which battery cells are manufactured or assembled.

(8) *Battery component.* Battery component means a component that forms part of a clean vehicle battery and that is manufactured or assembled from one or more components or battery materials that are combined through industrial, chemical, and physical assembly steps. Battery components may include, but are not limited to, a cathode electrode, anode electrode, solid metal electrode, coated separator, liquid electrolyte, solid state electrolyte, battery cell, and battery module.

(9) *Battery materials.* Battery materials means direct and indirect inputs to battery components that are produced through processing rather than through manufacturing or assembly. Battery materials are not considered a type of battery component, although battery materials may be manufactured or assembled into battery components. The three categories of battery materials are applicable critical minerals, constituent materials, and battery materials without applicable critical minerals. Examples of battery materials that may or may not contain applicable critical minerals include a separator base film (if not manufactured or assembled) and separator coating. Examples of battery materials without applicable critical minerals include conductive additives, copper foils prior to graphite deposition, and electrolyte solvents.

(10) *Clean vehicle battery.* Clean vehicle battery, with respect to a new clean vehicle, means the battery from which the electric motor of the vehicle draws electricity to propel such vehicle.

(11) *Compliant-battery ledger. A compliant-battery ledger,* for a qualified manufacturer for a calendar year, is a ledger established under the rules of § 1.30D–6(d) that tracks the number of available FEOC-compliant batteries for such calendar year.

(12) *Constituent materials.* Constituent materials means battery materials that contain applicable critical minerals. Constituent materials may include, but are not limited to, powders of cathode active materials, powders of anode active materials, foils, metals for solid electrodes, binders, electrolyte salts, and electrolyte additives, as required for a battery cell. Battery materials without applicable critical minerals are not constituent materials.

(13) *Country with which the United States has a free trade agreement in effect*—(i) *In general.* The term *country with which the United States has a free trade agreement in effect* means any of those countries identified in paragraph (b)(13)(ii) of this section or that the Secretary of the Treasury or her delegate (Secretary) may identify in the future. The criteria the Secretary will consider in determining whether to identify a country under this paragraph (b)(13) include whether an agreement between the United States and that country, as to the critical minerals contained in clean vehicle batteries or more generally, and in the context of the overall commercial

and economic relationship between that country and the United States:

(A) Reduces or eliminates trade barriers on a preferential basis;

(B) Commits the parties to refrain from imposing new trade barriers;

(C) Establishes high-standard disciplines in key areas affecting trade (such as core labor and environmental protections); and/or

(D) Reduces or eliminates restrictions on exports or commits the parties to refrain from imposing such restrictions.

(ii) *Free trade agreements in effect.* The countries with which the United States currently has free trade agreements in effect are: Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Japan, Jordan, South Korea, Mexico, Morocco, Nicaragua, Oman, Panama, Peru, and Singapore.

(iii) *Updates.* The list of countries in paragraph (b)(13)(ii) of this section may be revised and updated through guidance published in the **Federal Register** or in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(14) *Credit transfer election.* Credit transfer election means credit transfer election as defined in § 1.30D–5(b)(2).

(15) *Dealer.* Dealer means dealer as defined in § 1.30D–5(b)(3).

(16) *Dealer tax compliance.* Dealer tax compliance means dealer tax compliance as defined in § 1.30D–5(b)(4).

(17) *Depreciable vehicle.* Depreciable vehicle means a vehicle of a character subject to an allowance for depreciation.

(18) *Electing taxpayer.* Electing taxpayer means electing taxpayer as defined in § 1.30D–5(b)(5).

(19) *Eligible entity.* Eligible entity means eligible entity as defined in § 1.30D–5(b)(6).

(20) *Excessive payment.* Excessive payment means excessive payment as defined in § 1.30D–5(g)(2)(iii).

(21) *Extraction.* Extraction means the activities performed to harvest minerals or natural resources from the ground or from a body of water. Extraction includes, but is not limited to, operating equipment to harvest minerals or natural resources from mines and wells and the physical processes involved in refining. Extraction also includes operating equipment to extract minerals or natural resources from the waste or residue of prior extraction, including crude oil extraction to the extent that processes applied to that crude oil yield an applicable critical mineral as a byproduct. Extraction concludes when activities are performed to convert raw mined or harvested products or raw well effluent to substances that can be readily transported or stored for direct use in critical mineral processing. Extraction does not include activities that begin with a recyclable commodity (as such activities are recycling). Extraction does not include the chemical and thermal processes involved in refining.

(22) *FEOC-compliant.* FEOC-compliant means in compliance with the applicable excluded entity requirement under section 30D(d)(7). In particular—

(i) A battery component (other than a battery cell), with respect to a new clean vehicle placed in service after December 31, 2023, is FEOC-compliant if it is not manufactured or assembled by a FEOC;

(ii) An applicable critical mineral, with respect to a new clean vehicle placed in service after December 31, 2024, is FEOC-compliant if it is not extracted, processed, or recycled by a FEOC;

(iii) A battery cell, with respect to a new clean vehicle placed in service after December 31, 2023, and before January 1, 2025, is FEOC-compliant if it is not manufactured or assembled by a FEOC and it contains only FEOC-compliant battery components;

(iv) A battery cell, with respect to a new clean vehicle placed in service after December 31, 2024, is FEOC-compliant if it is not manufactured or assembled by a FEOC and it contains only FEOC-compliant battery components and FEOC-compliant applicable critical minerals; and

(v) A clean vehicle battery, with respect to a new clean vehicle placed in service after December 31, 2023, is FEOC-compliant if it contains only FEOC-compliant battery components (other than battery cells) and FEOC-compliant battery cells (as described in paragraph (b)(22)(iii) or (iv) of this section, as applicable).

(23) *Final assembly.* Final assembly means the process by which a manufacturer produces a new clean vehicle at, or through the use of, a plant, factory, or other place from which the vehicle is delivered to a dealer or importer with all component parts necessary for the mechanical operation of the vehicle included with the vehicle, whether or not the component parts are permanently installed in or on the vehicle. To establish where final assembly of a new clean vehicle occurred for purposes of the requirement in section 30D(d)(1)(G) that final assembly of a new clean vehicle occur within North America, the taxpayer may rely on the following information:

(i) The vehicle's plant of manufacture as reported in the vehicle identification number pursuant to 49 CFR 565; or

(ii) The final assembly point reported on the label affixed to the vehicle as described in 49 CFR 583.5(a)(3).

(24) *Foreign entity of concern.* Foreign entity of concern (FEOC) has the meaning provided in section 40207(a)(5) of the Infrastructure Investment and Jobs Act (42 U.S.C. 18741(a)(5)) and guidance promulgated thereunder by the Department of Energy (DOE).

(25) *Impracticable-to-trace battery materials*—(i) *In general. Impracticable-to-trace battery materials* means specifically identified, low-value battery materials that originate from multiple sources and are commingled during refining, processing, or other production processes by suppliers to such a degree that the qualified manufacturer cannot, due to current industry practice, feasibly determine and attest to the origin of such battery materials. For this purpose, impracticable-to-trace battery materials are those that have low value compared to the total value of the clean vehicle battery.

(ii) *Identified impracticable-to-trace battery materials.* Identified impracticable-to-trace battery materials means applicable critical minerals in the following circumstances: graphite contained in anode materials, and applicable critical minerals contained in electrolyte salts, electrolyte binders, or electrolyte additives.

(26) *Incentive.* Incentive means incentive as defined in § 1.30D–5(b)(7).

(27) *Incremental value. Incremental value* means incremental value as defined in § 1.30D–3(c)(2)(i).

(28) *Manufacturer*—(i) *In general. A manufacturer* means any manufacturer within the meaning of the regulations prescribed by the Administrator of the Environmental Protection Agency (EPA) for purposes of the administration of title II of the Clean Air Act (42 U.S.C. 7521 *et seq.*) and as defined in 42 U.S.C. 7550(1). Except as provided in paragraph (b)(28)(ii) of this section, if multiple manufacturers are involved in the production of a vehicle, the requirements of section 30D(d)(3) must be met by the manufacturer that satisfies the reporting requirements of the greenhouse gas emissions standards set by the EPA under the Clean Air Act (42 U.S.C. 7521 *et seq.*) for the subject vehicle.

(ii) *Modification of a new motor vehicle*—(A) If a manufacturer modifies a new motor vehicle (as defined in 42 U.S.C. 7550(3)) that does not satisfy the requirements of section 30D(d)(1)(F) or (d)(6) so that the new motor vehicle, after modification, does satisfy such

requirements, then such manufacturer may satisfy the requirements of section 30D(d)(3) if the modification occurred prior to the new motor vehicle being placed in service.

(B) If a manufacturer modifies a new motor vehicle (as defined in 42 U.S.C. 7550(3)) that does not satisfy the requirements of 45W(c)(3) so that the new motor vehicle, after modification, does satisfy such requirements, then such manufacturer may satisfy the requirements of 30D(d)(3) if the modification occurred prior to the new motor vehicle being placed in service.

(29) *Manufacturer's suggested retail price*—(i) *In general.* Manufacturer's suggested retail price means the sum of the retail price and the retail delivered price (as defined in paragraphs (b)(29)(ii) and (iii) of this section) as reported on the label that is affixed to the windshield or side window of the vehicle, as described in 15 U.S.C. 1232.

(ii) *Retail price.* Retail price, for purposes of paragraph (b)(29)(i) of this section, means the retail price of the automobile suggested by the manufacturer as described in 15 U.S.C. 1232(f)(1).

(iii) *Retail delivered price.* Retail delivered price, for purposes of paragraph (b)(29)(i) of this section, means the retail delivered price suggested by the manufacturer for each accessory or item of optional equipment physically attached to such automobile at the time of its delivery to the dealer that is not included within the price of such automobile as stated pursuant to 15 U.S.C. 1232(f)(1), as described in 15 U.S.C. 1232(f)(2).

(30) *Manufacturing.* Manufacturing, with respect to a battery component, means the industrial and chemical steps taken to produce a battery component.

(31) *Modified adjusted gross income*—(i) *Individuals.* Modified adjusted gross income, in the case of an individual, means adjusted gross income (as defined in section 62 of the Code) increased by any amount excluded from gross income under section 911, 931, or 933 of the Code.

(ii) *Estates and trusts.* Modified adjusted gross income, in the case of an estate or non-grantor trust, means adjusted gross income (as defined in section 67(e) of the Code).

(32) *New clean vehicle.* New clean vehicle means a vehicle that meets the requirements described in section 30D(d). Vehicles that may qualify as new clean vehicles include battery electric vehicles, plug-in hybrid electric vehicles, fuel cell motor vehicles, and plug-in hybrid fuel cell motor vehicles. A vehicle does not meet the requirements of section 30D(d) if—

(i) The qualified manufacturer fails to provide a periodic written report for such vehicle prior to the vehicle being placed in service reporting the vehicle identification number of such vehicle and certifying compliance with the requirement of section 30D(d);

(ii) The qualified manufacturer provides incorrect information with respect to the periodic written report for such vehicle;

(iii) The qualified manufacturer fails to update its periodic written report in the event of a material change with respect to such vehicle; or

(iv) For new clean vehicles placed in service after December 31, 2024, the qualified manufacturer fails to meet the requirements of § 1.30D–6(d).

(33) *New qualified fuel cell motor vehicle.* New qualified fuel cell motor vehicle means any new qualified fuel cell motor vehicle (as defined in section 30B(b)(3)) that meets the requirements under section 30D(d)(1)(G) (that is, the final assembly in North America requirement) and (H) (that is, the seller report requirement), and that does not have a clean vehicle battery.

(34) *North America.* North America means the territory of the United States, Canada, and Mexico as defined in 19 CFR part 182, Appendix A, § 1(1).

(35) *North American battery component.* North American battery component means North American battery component as defined in § 1.30D–3(c)(2)(ii).

(36) *Placed in service.* A new clean vehicle is considered to be placed in service on the date the taxpayer takes possession of the vehicle.

(37) *Processing.* Processing means the non-physical processes involved in the refining of non-recycled substances or materials, including the treating, baking, and coating processes used to convert such substances and materials into constituent materials. Processing includes the chemical or thermal processes involved in refining. Processing does not include the physical processes involved in refining.

(38) *Procurement chain.* Procurement chain means procurement chain as defined in § 1.30D–3(c)(1)(i).

(39) *Qualifying battery component content.* Qualifying battery component content means qualifying battery component content as defined in § 1.30D–3(c)(2)(iii).

(40) *Qualifying critical mineral. Qualifying critical mineral* means qualifying critical mineral as defined in § 1.30D–3(c)(1)(ii).

(41) *Qualifying critical mineral content.* Qualifying critical mineral content means qualifying critical mineral content as defined in § 1.30D–3(c)(1)(iii).

(42) *Qualified manufacturer.* A qualified manufacturer means a manufacturer that meets the requirements described in section 30D(d)(3) at the time the manufacturer submits a periodic written report to the IRS under a written agreement described in section 30D(d)(3). The term qualified manufacturer does not include any manufacturer whose qualified manufacturer status has been terminated by the IRS. The IRS may terminate qualified manufacturer status for fraud, intentional disregard, or gross negligence with respect to any requirements of section 30D, the section 30D regulations, or any guidance under section 30D, including with respect to the periodic written reports described in section 30D(d)(3) and paragraph (b)(32) of this section and any attestations, documentation, or certifications described in §§ 1.30D–3(d) and 1.30D–6(d), at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). *See* § 1.30D–6(f) for additional rules regarding inaccurate determinations and documentation. The IRS may also terminate qualified manufacturer status for fraud, intentional disregard, or gross negligence with respect to any requirement of section 25E or section 45W or any regulations thereunder.

(43) *Recycling*—(i) *In general.* Recycling means the series of activities during which recyclable materials containing critical minerals are transformed into specification-grade commodities and consumed in lieu of virgin materials to create new constituent materials; such activities result in new constituent materials contained in the clean vehicle battery. All physical, chemical, and thermal treatments or modifications that convert recycled feedstocks to specification grade constituent materials are included in recycling. However, recycled applicable critical minerals and associated constituent materials are only subject to the requirements under §§ 1.30D–3(a) and 1.30D–6 if the recyclable material contains an applicable critical mineral, contains material that was transformed from an applicable critical mineral, or if the recyclable material is used to produce an applicable critical mineral at any point during the recycling process. The requirements under §§ 1.30D–3(a) and 1.30D–6 only take into account activities that occurred during the recycling process.

(ii) *Example: Recycling of applicable critical mineral.* Mineral Z, an applicable critical mineral in a form

listed in section 45X(c)(6), was processed by A in a prior production process. Mineral Z subsequently was derived from recyclable material in a form not listed in section 45X(c)(6). Mineral Z was recycled by B. The requirements under §§ 1.30D–3 and 1.30D–6 only take into account the activities conducted by B.

(44) *Registered dealer.* Registered dealer means registered dealer as defined in § 1.30D–5(b)(8).

(45) *Section 30D regulations.* Section 30D regulations means § 1.30D–1, this section, and §§ 1.30D–3 through 1.30D–6.

(46) *Seller report.* Seller report means the report described in section 30D(d)(1)(H) that the seller of a new clean vehicle provides to the taxpayer and the IRS in the manner provided in, and containing the information described in, guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The seller report must be transmitted to the IRS electronically. The term seller report does not include a report rejected by the IRS due to the information contained therein not matching IRS records.

(47) *Time of sale.* Time of sale means time of sale as defined in § 1.30D–5(b)(9).

(48) *Total incremental value of battery components.* Total incremental value of battery components means total incremental value of battery components as defined in § 1.30D–3(c)(2)(iv).

(49) *Total incremental value of North American battery components.* Total incremental value of North American battery components means total incremental value of North American battery components as defined in § 1.30D–3(c)(2)(v).

(50) *Total traced qualifying value.* Total traced qualifying value means total traced qualifying value as defined in § 1.30D–3(c)(1)(iv).

(51) *Total value of critical minerals.* Total value of critical minerals means total value of critical minerals as defined in § 1.30D–3(c)(1)(v).

(52) *Total value of qualifying critical minerals.* Total value of qualifying critical minerals means total value of qualifying critical minerals as defined in § 1.30D–3(c)(1)(vi).

(53) *Traced qualifying value.* Traced qualifying value means traced qualifying value as defined in § 1.30D–3(c)(1)(vii).

(54) *Value.* Value, with respect to property, means the arm's-length price that was paid or would be paid for the property by an unrelated purchaser determined in accordance with the principles of section 482 of the Code and regulations thereunder.

(55) *Value added.* Value added means value added as defined in § 1.30D–3(c)(1)(viii).

(56) *Vehicle classification*—(i) *In general.* Vehicle classification means the vehicle classification of a new clean vehicle determined consistent with the rules and definitions provided in 40 CFR 600.315–08 and this paragraph (b)(56) for vans, sport utility vehicles, pickup trucks, and other vehicles.

(ii) *Van.* Van means a vehicle classified as a van or minivan under 40 CFR 600.315–08(a)(2)(iii) and (iv), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a).

(iii) *Sport utility vehicle.* Sport utility vehicle means a vehicle classified as a small sport utility vehicle or standard sport utility vehicle under 40 CFR 600.315–08(a)(2)(v) and (vi), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a).

(iv) *Pickup truck.* Pickup truck means a vehicle classified as a small pickup truck or standard pickup truck under 40 CFR 600.315–08(a)(2)(i) and (ii), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a).

(v) *Other vehicle.* Other vehicle means any vehicle classified in one of the classes of passenger automobiles listed in 40 CFR 600.315–08(a)(1), or otherwise so classified by the Administrator of the EPA pursuant to 40 CFR 600.315–08(a).

(c) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(d) *Applicability date.* This section applies to taxable years ending after December 4, 2023.

§ 1.30D–3 Critical minerals and battery components requirements.

(a) *Critical minerals requirement*—(1) *In general.* The critical minerals requirement described in section 30D(e)(1)(A) of the Internal Revenue Code (Code), with respect to a clean vehicle battery, is met if the qualifying critical mineral content of such battery is equal to or greater than the applicable critical minerals percentage (as defined in paragraph (a)(2) of this section), as certified by the qualified manufacturer, in such form or manner as prescribed by the Secretary of the Treasury or her delegate (Secretary).

(2) *Applicable critical minerals percentage*—(i) *In general.* For purposes of paragraph (a)(1) of this section, the *applicable critical minerals percentage,* which is based on the year in which a vehicle is placed in service by the taxpayer, is set forth in paragraphs (a)(2)(ii) through (vi) of this section. *See* section 30D(e)(1)(B).

(ii) *Vehicles placed in service between April 18, 2023, and December 31, 2023.* In the case of a vehicle placed in service after April 17, 2023, and before January 1, 2024, the applicable critical minerals percentage is 40 percent.

(iii) *Vehicles placed in service during calendar year 2024.* In the case of a vehicle placed in service during calendar year 2024, the applicable critical minerals percentage is 50 percent.

(iv) *Vehicles placed in service during calendar year 2025.* In the case of a vehicle placed in service during calendar year 2025, the applicable critical minerals percentage is 60 percent.

(v) *Vehicles placed in service during calendar year 2026.* In the case of a vehicle placed in service during calendar year 2026, the applicable critical minerals percentage is 70 percent.

(vi) *Vehicles placed in service during calendar year 2027 and later.* In the case of a vehicle placed in service after December 31, 2026, the applicable critical minerals percentage is 80 percent.

(3) *Determining qualifying critical mineral content*—(i) *In general.* Qualifying critical mineral content with respect to a clean vehicle battery is calculated as the percentage that results from dividing:

(A) The total traced qualifying value, by

(B) The total value of critical minerals.

(ii) *Separate determinations required for each procurement chain.* The traced qualifying value of an applicable critical mineral, including the percentage or percentages necessary to determine the traced qualifying value, must be determined separately for each procurement chain.

(iii) *Time for determining value.* A qualified manufacturer must select a date for determining the values described in paragraphs (a)(3)(i)(A) and (B) of this section. Such date must be after the final processing or recycling step for the applicable critical minerals relevant to the certification described in section 30D(e)(1)(A).

(iv) *Application of qualifying critical mineral content to vehicles.* A qualified manufacturer may determine qualifying

critical mineral content based on the value of the applicable critical minerals actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying critical mineral content for clean vehicle batteries in a group of vehicles, a qualified manufacturer may average the qualifying critical mineral content under this paragraph (a)(3)(iv) over a period of time (for example, a year, a calendar quarter, or a month) with respect to vehicles from the same model line, plant, class, or some combination thereof, with final assembly (as defined in section 30D(d)(5) of the Code and § 1.30D–2(b)(23)) within North America.

(4) *Temporary safe harbor for determining qualifying critical mineral content for vehicles for which a qualified manufacturer submits a periodic written report on or after May 6, 2024 and before January 1, 2027*—(i) *In general.* For vehicles for which a qualified manufacturer submits a periodic written report on or after May 6, 2024 and before January 1, 2027, qualifying critical mineral content with respect to a clean vehicle battery may be calculated as the percentage that results from dividing:

(A) The total value of qualifying critical minerals, by

(B) The total value of critical minerals.

(ii) *Separate determinations required for each procurement chain.* The portion of an applicable critical mineral that is a qualifying critical mineral must be determined separately for each procurement chain.

(iii) *Time for determining value.* A qualified manufacturer must select a date for determining the values described in paragraphs (a)(4)(i)(A) and (B) of this section. Such date must be after the final processing or recycling step for the applicable critical minerals relevant to the certification described in section 30D(e)(1)(A).

(iv) *Application of qualifying critical mineral content to vehicles.* A qualified manufacturer may determine qualifying critical mineral content based on the value of the applicable critical minerals actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying critical mineral content for clean vehicle batteries in a group of vehicles, a qualified manufacturer may average the qualifying critical mineral content calculation over a period of time (for example, a year, quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof, with final assembly (as defined in section 30D(d)(5) of the Code and § 1.30D–2(b)(23)) within North America.

(v) *Consistent determination required for all procurement chains.* A qualified manufacturer that makes a determination under this paragraph (a)(4) must use the rules of this paragraph for all procurement chains of the clean vehicle battery. If a qualified manufacturer averages qualifying critical mineral content as described in paragraph (a)(4)(iv) of this section, the qualified manufacturer must use the rules of such paragraph for all procurement chains for all clean vehicle batteries in the group of vehicles. Therefore, the qualified manufacturer may not use the rules of paragraph (a)(3) for some procurement chains and the rules of paragraph (a)(4) for other procurement chains for the same clean vehicle battery or clean vehicle batteries in the group of vehicles, as applicable.

(5) *Rule for determining qualifying critical mineral content for vehicles for which a qualified manufacturer submitted a periodic written report before May 6, 2024.* For vehicles for which a qualified manufacturer submitted a periodic written report before May 6, 2024, qualifying critical mineral content with respect to a clean vehicle battery must be calculated using the method described in paragraph (a)(4) of this section.

(b) *Battery components requirement*—(1) *In general.* The battery components requirement described in section 30D(e)(2)(A), with respect to a clean vehicle battery, is met if the qualifying battery component content of such battery is equal to or greater than the applicable battery components percentage (as defined in paragraph (b)(2) of this section), as certified by the qualified manufacturer, in such form or manner as prescribed by the Secretary.

(2) *Applicable battery components percentage*—(i) *In general.* For purposes of paragraph (b)(1) of this section, section 30D(e)(2)(B) provides the *applicable battery components percentage,* which is based on the year in which a vehicle is placed in service by the taxpayer as set forth in paragraphs (b)(2)(ii) through (vii) of this section.

(ii) *Vehicles placed in service between April 18, 2023, and December 31, 2023.* In the case of a vehicle placed in service after April 17, 2023, and before January 1, 2024, the applicable battery components percentage is 50 percent.

(iii) *Vehicles placed in service during calendar year 2024 or 2025.* In the case of a vehicle placed in service during calendar year 2024 or 2025, the applicable battery components percentage is 60 percent.

(iv) *Vehicles placed in service during calendar year 2026.* In the case of a vehicle placed in service during calendar year 2026, the applicable battery components percentage is 70 percent.

(v) *Vehicles placed in service during calendar year 2027.* In the case of a vehicle placed in service during calendar year 2027, the applicable battery components percentage is 80 percent.

(vi) *Vehicles placed in service during calendar year 2028.* In the case of a vehicle placed in service during calendar year 2028, the applicable battery components percentage is 90 percent.

(vii) *Vehicles placed in service in calendar year 2029 and later.* In the case of a vehicle placed in service after December 31, 2028, the applicable battery components percentage is 100 percent.

(3) *Determining qualifying battery component content*—(i) *In general.* Qualifying battery component content with respect to a clean vehicle battery of the vehicle is calculated as the percentage that results from dividing—

(A) The total incremental value of North American battery components, by

(B) The total incremental value of battery components.

(ii) *Time for determining value.* A qualified manufacturer must select a date for determining the incremental values described in paragraphs (b)(3)(i)(A) and (B) of this section. Such date must be after the last manufacturing or assembly step for the battery components relevant to the certification described in section 30D(e)(2)(A).

(iii) *Application of qualifying battery component content to vehicles.* A qualified manufacturer may determine qualifying battery component content based on the incremental values of the battery components actually contained in the clean vehicle battery of a specific vehicle. Alternatively, for purposes of calculating the qualifying battery component content for clean vehicle batteries in a group of vehicles, a qualified manufacturer may average the qualifying battery component content calculation over a period of time (for example, a year, quarter, or month) with respect to vehicles from the same model line, plant, class, or some combination of thereof, with final assembly (as defined in section 30D(d)(5) of the Code and § 1.30D–2(b)(23)) within North America.

(iv) *End point for determination.* For a clean vehicle battery that contains a

battery module or modules containing battery cells, the calculation under this paragraph (b) takes into account the value of the module and battery components contained in the module. In the case of a clean vehicle battery that contains battery cells but no battery modules, the calculation under this paragraph (b) takes into account the value of the battery cells and battery components contained in the battery cells.

(c) *Definitions*—(1) *Certain terms relevant to the critical minerals requirement.* The following definitions apply for purposes of the rules of section 30D(e)(1) and paragraph (a) of this section:

(i) *Procurement chain.* Procurement chain means a common sequence of extraction, processing, or recycling activities that occur in a common set of locations with respect to an applicable critical mineral, concluding in the production of constituent materials. Sources of a single applicable critical mineral may have multiple procurement chains if, for example, one source of the applicable critical mineral undergoes the same extraction, processing, or recycling process in different locations.

(ii) *Qualifying critical mineral*—(A) *In general.* Qualifying critical mineral means an applicable critical mineral that is extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or that is recycled in North America.

(B) *Extracted or processed in the United States or in any country with which the United States has a free trade agreement in effect.* An applicable critical mineral is extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, if:

(*1*) Fifty percent or more of the value added to the applicable critical mineral by extraction is derived from extraction that occurred in the United States or in any country with which the United States has a free trade agreement in effect; or

(*2*) Fifty percent or more of the value added to the applicable critical mineral by processing is derived from processing that occurred in the United States or in any country with which the United States has a free trade agreement in effect.

(C) *Recycled in North America.* An applicable critical mineral is recycled in North America if 50 percent or more of the value added to the applicable critical mineral by recycling is derived from recycling that occurred in North America.

(iii) *Qualifying critical mineral content.* Qualifying critical mineral content means the percentage of the value of the applicable critical minerals contained in a clean vehicle battery that is extracted or processed in the United States, or in any country with which the United States has a free trade agreement in effect, or that is recycled in North America.

(iv) *Total traced qualifying value.* Total traced qualifying value means the sum of the traced qualifying values of all applicable critical minerals contained in a clean vehicle battery.

(v) *Total value of critical minerals.* Total value of critical minerals means the sum of the values of all applicable critical minerals contained in a clean vehicle battery.

(vi) *Total value of qualifying critical minerals.* Total value of qualifying critical minerals means the sum of the values of all the qualifying critical minerals contained in a clean vehicle battery.

(vii) *Traced qualifying value*—(A) *Extracted or processed in the United States or in any country with which the United States has a free trade agreement in effect.* Traced qualifying value means, with respect to an applicable critical mineral that is extracted and processed into a constituent material, the value of the applicable critical mineral multiplied by the greater of:

(*1*) The value added to the applicable critical mineral by extraction that occurred in the United States or in any country with which the United States has a free trade agreement in effect, divided by the total value added by from extraction of the applicable critical mineral; or

(*2*) The value added to the applicable critical mineral by processing that occurred in the United States or in any country with which the United States has a free trade agreement in effect, divided by the total value added by processing of the applicable critical mineral.

(B) *Recycled in North America.* Traced qualifying value means, with respect to an applicable critical mineral that is recycled into a constituent material, the value of the applicable critical mineral multiplied by the percentage obtained by dividing the value added to the applicable critical mineral by recycling that occurred in North America by the total value added by recycling of the applicable critical mineral.

(viii) *Value added.* Value added, with respect to recycling, extraction, or processing of an applicable critical mineral, means the increase in the value of the applicable critical mineral attributable to the relevant activity. In the case of multiple applicable critical mineral procurement chains that are part of the same processing or recycling activity, value added should be allocated to each procurement chain based on relative mass.

(2) *Certain terms relevant to the battery components requirement.* The following definitions apply for purposes of the rules of section 30D(e)(2) and paragraph (b) of this section:

(i) *Incremental value.* Incremental value, with respect to a battery component, means the value determined by subtracting from the value of that battery component the value of the manufactured or assembled battery components, if any, that are contained in that battery component.

(ii) *North American battery component.* North American battery component means a battery component substantially all of the manufacturing or assembly of which occurs in North America, without regard to the location of the manufacturing or assembly activities of any components that make up the particular battery component.

(iii) *Qualifying battery component content.* Qualifying battery component content means the percentage of the value of the battery components contained in a clean vehicle battery that were manufactured or assembled in North America.

(iv) *Total incremental value of battery components.* Total incremental value of battery components means the sum of the incremental values of each battery component contained in a clean vehicle battery.

(v) *Total incremental value of North American battery components.* Total incremental value of North American battery components means the sum of the incremental values of each North American battery component contained in a clean vehicle battery.

(d) *Upfront review of critical minerals and battery components requirements.* For new clean vehicles anticipated to be placed in service after December 31, 2024, the qualified manufacturer must provide attestations, certifications, and documentation demonstrating compliance with the requirements of section 30D(e), at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The IRS, with analytical assistance from the Department of Energy, will review the attestations, certifications, and documentation.

(e) *New qualified fuel cell motor vehicles.* The requirements of section 30D(e) and this section are deemed to be satisfied with respect to new qualified fuel cell motor vehicles. The amount of

the credit with respect to such vehicles, under section 30D(b), is $7,500.

(f) *Examples.* The following examples illustrate the rules of this section.

(1) *Example 1: Critical minerals requirement*—(i) *Facts.* In 2028, Company A uses a clean vehicle battery that contains three applicable critical minerals, which are used for the clean vehicle batteries of the same group of vehicles for the purposes of averaging qualifying critical mineral content under paragraph (a)(3)(iv) of this section.

(A) Applicable critical mineral 1 (ACM–1) has a value of $100. ACM–1 has one procurement chain; in this procurement chain, extraction accounts for 20% ($20) of the total value added of ACM–1 and processing accounts for 80% ($80) of the total value added of ACM–1. Of the value added by extraction, 100% ($20) is in the United States or in a country with which the United States has a free trade agreement in effect. Of the value added by processing, 100% ($80) is in the United States or in a country with which the United States has a free trade agreement in effect.

(B) Applicable critical mineral 2 (ACM–2) has a value of $200. ACM–2 has two procurement chains. The value of ACM–2 is $100 per procurement chain. In the first procurement chain for ACM–2, extraction accounts for 50% ($50) of the value added, while processing accounts for 50% ($50). Of the value added by extraction, 50% ($25) is in United States or in a country with which the United States has a free trade agreement in effect. Of the value added by processing, 25% ($12.50) is in the United States or in a country with which the United States has a free trade agreement in effect. In the second procurement chain for ACM–2, extraction accounts for 50% ($50) of the value added, and processing accounts for 50% ($50) of the value added. Of the value added by extraction, 75% ($37.50) is in the United States or in a country with which the United States has a free trade agreement in effect. Of the value added by processing, 100% ($50) is in the United States or in a country with which the United States has a free trade agreement in effect.

(C) Applicable critical mineral 3 (ACM–3) has a value of $100. ACM–3 has one procurement chain. Extraction accounts for 10% ($10) of the value added and processing accounts for 90% ($90) of the value added. Of the value added by extraction, 50% ($5) is in the United States or in a country with which the United States has a free trade agreement in effect. Of the value added by processing, 75% ($67.50) is in the United States or in a country with which the United States has a free trade agreement in effect.

(ii) *Analysis*—(A) First, Company A determines each procurement chain. ACM–1 has one procurement chain. ACM–2 has two procurement chains. ACM–3 has one procurement chain.

(B) Second, Company A determines, for each procurement chain, the traced qualifying value, and then determines the total traced qualifying value.

(*1*) With respect to ACM–1, Company A divides the value added by extraction that is in the United States or in any country with which the United States has a free trade agreement in effect by the total value added from extraction of the applicable critical mineral: $20/$20, which equals 100%. Company A divides the value added by processing that is in the United States or in any country with which the United States has a free trade agreement in effect by the total value added from processing of the applicable critical mineral: $80/$80, which equals 100%. Because the percentages for extraction and processing are equal, that percentage (100%) is used to determine traced qualifying value. Therefore, Company A multiplies 100% by the total value of the applicable critical mineral ($100) to obtain $100 as the traced qualifying value for the procurement chain of ACM–1.

(*2*) With respect to the first procurement chain of ACM–2, Company A divides the value added by extraction that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from extraction of the applicable critical mineral: $25/$50, which equals 50%. Company A divides the value added by processing that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from processing of the applicable critical mineral: $12.50/$50, which equals 25%. Of these percentages, the one for extraction is greater (50%). Therefore, Company A multiplies 50% by the total value of the applicable critical minerals ($100) to obtain $50 as the traced qualifying value for the first procurement chain of ACM–2.

(*3*) With respect to the second procurement chain of ACM–2, Company A divides the value added by extraction that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from extraction of the applicable critical mineral: $37.50/$50, which equals 75%. Company A divides the value added by processing that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from processing of the applicable critical mineral: $50/$50, which equals 100%. Of these percentages, the one for processing is greater (100%). Therefore, Company A multiplies 100% by the total value of the applicable critical mineral ($100) to obtain $100 as the traced qualifying value for the second procurement chain of ACM–2.

(*4*) With respect to ACM–3, Company A divides the value added by extraction that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from extraction of the applicable critical mineral: $5/$10, which equals 50%. Company A divides the value added by processing that is in the United States or a country with which the United States has a free trade agreement in effect by the total value added from processing of the applicable critical mineral: $67.50/$90, which equals 75%. Of these percentages, the one for processing is greater (75%). Company A therefore multiplies 75% by the total value of the applicable critical mineral ($100) to obtain $75 as the traced qualifying value for the procurement chain of ACM–3.

(*5*) The total traced qualifying value is the sum of the traced qualifying values of all applicable critical minerals contained in the clean vehicle battery of the vehicle, or $325 ($100 + $50 + $100 + $75).

(C) Third, Company A determines the qualifying critical mineral content by taking the total traced qualifying value ($325, determined in step 2) divided by the total value of the critical minerals in the battery ($400). The qualifying critical mineral content is therefore 81.25%. Company A uses this percentage to calculate the average qualifying critical mineral content for the clean vehicle batteries of a group of vehicles and compares that average percentage to the applicable critical minerals percentage of section 30D(e)(2) and § 1.30D–3(a)(2).

(2) *Example 2: Critical minerals requirement temporary safe harbor*—(i) *Facts.* The facts are the same as in paragraph (f)(1)(i) of this section (facts of *Example 1*). However, Company A is eligible to apply the temporary safe harbor of § 1.30D–3(a)(4) to determine its qualifying critical mineral content and chooses to do so. The applicable critical minerals are used for the clean vehicle batteries of the same group of vehicles for the purposes of averaging qualifying critical mineral content under paragraph (a)(4)(iv) of this section.

(ii) *Analysis*—(A) First, Company A determines each procurement chain, as in paragraph (f)(1) of this section (*Example 1*).

(B) Second, Company A determines whether ACM–1, ACM–2, and ACM–3 are qualifying critical minerals. ACM–1 is a qualifying critical mineral because, for both extraction and processing, 100% of the value added is derived from extraction and processing that occurs in the United States or in a country with which the United States has a free trade agreement in effect. With respect to its first procurement chain, ACM–2 is a qualifying critical mineral because 50% of the value added from extraction is derived from extraction that occurs in the United States or a country with which the United States has a free trade agreement in effect. With respect to its second procurement chain, ACM–2 is a qualifying critical mineral because 75% of the value added from extraction, and 100% of the value added from processing are derived from extraction and processing, respectively, that occur in the United States or in a country with which the United States has a free trade agreement in effect. ACM–3 is a qualifying critical mineral because 50% of the value added for extraction, and 75% of the value added for processing, are derived from extraction and processing, respectively, that occur in the United States or in a country with which the United States has a free trade agreement in effect. The total value of the qualifying critical minerals is the sum of the value of all of the qualifying critical minerals contained in the clean vehicle battery of the vehicle, or $400 ($100 + $100 + $100 + $100).

(C) Third, Company A determines qualifying critical mineral content by taking the total value of qualifying critical minerals ($400, determined in step 2) and dividing by the total value of critical minerals in the battery ($400). The qualifying critical mineral content of the battery is 100%. Company A uses this percentage to calculate average qualifying critical mineral content for the clean vehicle batteries of a group of vehicles and compares that average percentage to the applicable critical minerals percentage of section 30D(e)(2) and § 1.30D–3(a)(2).

(3) *Example 3: Battery components requirement*—(i) *Facts.* Company B uses a battery cell comprised of a cathode electrode, anode electrode, separator, and electrolyte. The cathode electrode has a value of $4,000 and is manufactured in North America. The anode electrode has a value of $1,000 and is manufactured outside of North America. The separator has a value of $1,000 and is manufactured in North America. The electrolyte has a value of $800 and is manufactured in North America. The battery cell has a value of $7,500 and is manufactured in North America. The battery components are used for the clean vehicle batteries of the same group of vehicles for the purposes of averaging qualifying critical mineral content under paragraph (b)(3)(iii) of this section.

(ii) *Analysis*—(A) First, Company B determines whether each battery component in a battery is a North American battery component. The cathode electrode, separator, and battery cell are North American battery components.

(B) Second, Company B determines the total incremental value of North American battery components. The incremental value of the battery cell ($700) is determined by subtracting from the value of the battery cell ($7,500) the total value of its battery components ($6,800). The incremental value of the cathode electrode is $4,000. The incremental value of the separator is $1,000. The incremental value of the electrolyte is $800. The total incremental value of North American battery components is $6,500 ($700 + $4,000 + $1,000 + $800).

(C) Third, Company B determines the total incremental value of battery components. The anode electrode is not a North American battery component because it is manufactured outside of North America. The incremental value of the anode electrode is $1,000. The total incremental value of battery components is $6,500 plus $1,000 or $7,500.

(D) Fourth, Company B determines the qualifying battery component content by taking the total incremental value of North American battery components ($6,500, determined in Step 2) divided by the total incremental value of battery components ($7,500, determined in Step 3). The qualifying battery component content is therefore 86.7%. Company B uses this percentage to calculate the average battery component content for the clean vehicle batteries of a group of vehicles and compares that average percentage to the applicable battery components percentage of section 30D(e)(2) and § 1.30D–3(b)(2).

(g) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(h) *Applicability date*—(1) *In general.* Except as provided in paragraph (h)(2) of this section, this section applies to new clean vehicles placed in service after April 17, 2023, in taxable years ending after April 17, 2023.

(2) *Upfront review and traced qualifying value.* Paragraphs (a)(3) and (4) (relating to traced qualifying value test) and (d) (relating to upfront review of critical minerals and battery components requirements) of this section apply to taxable years ending after May 6, 2024.

§ 1.30D–4 Special rules.

(a) *No double benefit*—(1) *In general.* Under section 30D(f)(2) of the Internal Revenue Code (Code), the amount of any deduction or other credit allowable under chapter 1 of the Code for a vehicle for which a credit is allowable under section 30D(a) must be reduced by the amount of the section 30D credit allowed for such vehicle (determined without regard to section 30D(c)).

(2) *Interaction between section 30D and section 25E credits.* A section 30D credit that has been allowed with respect to a vehicle in a taxable year before the year in which a credit under section 25E of the Code is allowable for that vehicle does not reduce the amount allowable under section 25E.

(3) *Interaction between section 30D and section 45W credits.* Pursuant to section 45W(d)(3) of the Code, no credit is allowed under section 45W with respect to any vehicle for which a credit was allowed under section 30D.

(b) *Limitation based on modified adjusted gross income*—(1) *In general.* Under section 30D(f)(10)(A), no credit is allowed under section 30D(a) for any taxable year if—

(i) The lesser of—

(A) The modified adjusted gross income of the taxpayer for such taxable year, or

(B) The modified adjusted gross income of the taxpayer for the preceding taxable year, exceeds

(ii) The threshold amount.

(2) *Threshold amount.* For purposes of section 30D(f)(10)(A) and paragraph (b)(1) of this section, the threshold amount applies to taxpayers based on the return filing status for the taxable year, as set forth in paragraphs (b)(2)(i) through (iii) of this section. *See* section 30D(f)(10)(B).

(i) In the case of a joint return or a surviving spouse (as defined in section 2(a) of the Code), the threshold amount is $300,000,

(ii) In the case of a head of household (as defined in section 2(b)), the threshold amount is $225,000.

(iii) In the case of a taxpayer not described in paragraph (b)(2)(i) or (ii) of this section, the threshold amount is $150,000.

(3) *Special rule for change in filing status.* If the taxpayer's filing status for the taxable year differs from the taxpayer's filing status in the preceding taxable year, then the taxpayer satisfies the limitation described in section 30D(f)(10) and paragraph (b)(1) of this section if the taxpayer's modified adjusted gross income does not exceed the threshold amount in either year based on the applicable filing status for that taxable year.

(4) *Application to estates and trusts*—(i) *Estates and non-grantor trusts.* In the case of a new clean vehicle placed in service by an estate or a non-grantor trust, the threshold amount of paragraph (b)(2)(iii) of this section applies for purposes of the modified adjusted gross income limitation of section 30D(f)(10) and this paragraph (b). For purposes of the modified adjusted gross income limitation, an estate or non-grantor trust is treated as having modified adjusted gross income above the threshold amount for any year in which the estate or non-grantor trust is not in existence.

(ii) *Grantor trusts.* In the case of a new clean vehicle placed in service by a grantor trust, the modified adjusted gross income limitation of section 30D(f)(10) and this paragraph (b) applies based on the modified adjusted gross income of the grantor or other deemed owner of the trust, and not the modified adjusted gross income of the trust or any beneficiary of the trust other than the grantor or other deemed owner.

(5) *Application to passthrough entities.* In the case of a new clean vehicle placed in service by a partnership or an S corporation, if the section 30D credit is claimed by individuals, non-grantor trusts, or estates who are direct or indirect partners of that partnership or shareholders of that S corporation, the modified gross income limitation of section 30D(f)(10) and this paragraph (b) applies at the partner or shareholder level in accordance with the rules of this paragraph (b).

(6) *Other taxpayers.* The modified adjusted gross income limitation of this paragraph (b) does not apply in the case of a new clean vehicle placed in service by a corporation or by a taxpayer that is not an individual, estate, trust, or entity as provided in paragraph (b)(4) or (b)(5) of this section.

(c) *Credit may generally be claimed on only one tax return*—(1) *In general.* Except as provided in paragraph (c)(2) of this section, the amount of the section 30D credit attributable to a new clean vehicle may be claimed on only one Federal income tax return, including on a joint return in which one of the spouses is listed on the seller report. In the event a new clean vehicle is placed in service by multiple taxpayers who do not file a joint tax return (for example, in the case of married individuals filing separate returns), no allocation or proration of the section 30D credit is available.

(2) *Exception for passthrough entities.* In the case of a new clean vehicle placed in service by a partnership or an S corporation, the section 30D credit is allocated among the partners of the partnership under § 1.704–1(b)(4)(ii), or among the shareholder(s) of the S corporation under sections 1366(a) and 1377(a) of the Code, and claimed on the Federal income tax returns of the individual partners or S corporation shareholder(s).

(3) *Seller reporting*—(i) *In general.* The name and taxpayer identification number of the taxpayer claiming the section 30D credit must be listed on the seller report pursuant to section 30D(d)(1)(H). The credit will be allowed only on the Federal income tax return of the taxpayer listed in the seller report.

(ii) *Passthrough entities.* In the case of a new clean vehicle placed in service by a partnership or S corporation, the name and tax identification number of the partnership or S corporation that placed the new clean vehicle in service must be listed on the seller report pursuant to section 30D(d)(1)(H).

(4) *Example.* A married couple jointly purchases and places in service a new clean vehicle that qualifies for the section 30D credit and puts both of their names on the title. The couple files separate Federal income tax returns by using the married filing separately filing status. Only one spouse may claim the section 30D credit with respect to the new clean vehicle on that spouse's respective return, and the other spouse may not claim any amount of the section 30D credit with respect to that new clean vehicle. The spouse that claims the section 30D credit must be the same spouse listed on the seller report.

(d) *Grantor trusts.* To the extent that the grantor or another person is treated as owning all or part of a trust under sections 671 through 679 of the Code, the section 30D credit is allocated to such grantor or other person in accordance with § 1.671–3(a)(1).

(e) *Recapture rules*—(1) *In general.* This paragraph (e) provides rules under section 30D(f)(5) regarding the recapture of the section 30D credit.

(i) *Cancelled sale.* If the sale of a vehicle between the taxpayer and seller is cancelled before the taxpayer places the vehicle in service, then—

(A) The taxpayer may not claim the section 30D credit with respect to the vehicle;

(B) The sale will be treated as not having occurred and the vehicle will be considered available for original use by another taxpayer (regardless of the cancelled sale), and the vehicle will, therefore, still be eligible for the section 30D credit upon a subsequent sale that meets the requirements of section 30D and the section 30D regulations;

(C) The seller report must be rescinded by the seller in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter); and

(D) The taxpayer cannot make a credit transfer election under section 30D(g) and § 1.30D–5(d) with respect to the cancelled sale.

(ii) *Vehicle return.* If a taxpayer returns to the seller a vehicle within 30 days of placing such vehicle in service, then—

(A) The taxpayer cannot claim the section 30D credit with respect to the vehicle;

(B) The vehicle will no longer be considered available for original use by another taxpayer, and, therefore, the vehicle will no longer be eligible for the section 30D credit;

(C) The seller report must be updated by the seller in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter); and

(D) A credit transfer election under 30D(g) and § 1.30D–5(d), if applicable, will be treated as nullified and any advance payment made pursuant to section 30D(g) and § 1.30D–5(f), if applicable, will be collected from the eligible entity as an excessive payment pursuant to § 1.30D–5(g)(2).

(iii) *Resale.* If a taxpayer resells a vehicle within 30 days of placing the vehicle in service, then the taxpayer is treated as having purchased such vehicle with the intent to resell, and—

(A) The taxpayer cannot claim the section 30D credit with respect to the vehicle;

(B) The vehicle will no longer be considered available for original use by another taxpayer, and, therefore, the vehicle will no longer be eligible for the section 30D credit;

(C) The seller report will not be updated;

(D) A credit transfer election under 30D(g) and § 1.30D–5(d), if applicable, will remain in effect and any advance payment made pursuant to section 30D(g) and § 1.30D–5(f) will not be collected from the eligible entity; and

(E) The value of any transferred credit will be collected from the taxpayer as an

increase in tax imposed by chapter 1 of the Code for the taxable year in which the vehicle is placed in service.

(iv) *Other vehicle returns and resales.* In the case of a return of a new clean vehicle not described in paragraph (e)(1)(ii) of this section or a resale not described in paragraph (e)(1)(iii) of this section, the vehicle will no longer be considered available for original use by another taxpayer, and, therefore, will no longer be eligible for the section 30D credit upon a subsequent sale.

(2) *Recapture rules in the case of a credit transfer election.* For additional recapture rules that apply in the case of a credit transfer election, see § 1.30D–5(g)(1). For excessive payment rules that apply in the case of an advance payment made to an eligible entity, see § 1.30D–5(g)(2).

(3) *Example: Demonstrator vehicle.* A dealer purchases, registers, and titles a vehicle in its name and uses it as a demonstrator vehicle for customers. The dealer resells the vehicle more than 30 days after placing the vehicle in service. The dealer claimed the section 30D credit on its Federal tax return for the tax year the vehicle is placed in service. The credit recapture provision in § 1.30D–4(e)(1)(iii) does not apply because the vehicle was resold more than 30 days after being placed in service.

(f) *Seller registration.* A seller must register with the IRS in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) for purposes of filing seller reports (as defined in § 1.30D–2(b)(46)).

(g) *Requirement to file return.* No section 30D credit is allowed unless the taxpayer claiming such credit files a Federal income tax return or information return, as appropriate, for the taxable year in which the new clean vehicle is placed in service. The taxpayer must attach to such return a completed Form 8936, *Clean Vehicle Credits,* or successor form that includes all information required by the form and instructions. The taxpayer must also attach a completed Schedule A (Form 8936), *Clean Vehicle Credit Amount,* or successor form or schedule that includes all information required by the schedule and instructions, such as the vehicle identification number of the previously-owned clean vehicle.

(h) *Taxpayer reliance on manufacturer certifications and periodic written reports to the IRS.* A taxpayer that acquires a new clean vehicle and places it in service may rely on the manufacturer's certification concerning the manufacturer's status as a qualified manufacturer. A taxpayer also may rely on the information and certifications contained in the qualified manufacturer's written reports to the IRS. The procedures for such periodic written reports are established in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). To the extent a taxpayer relies on certifications or attestations from the qualified manufacturer regarding certain section 30D requirements, the new clean vehicle the taxpayer acquires will be deemed to meet the requirements of section 30D(d)(1)(C) through (F), (d)(7), and (e). *See* § 1.30D–5(g)(3)(ii) for an example that illustrates the interplay between the rule in this paragraph (h) and the excessive payment rule in § 1.30D–3(g)(2).

(i) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions shall continue in effect.

(j) *Applicability date.* This section applies to taxable years ending after December 4, 2023.

§ 1.30D–5 Transfer of credit.

(a) *In general.* This section provides rules related to the transfer and advance payment of the section 30D credit pursuant to section 30D(g) of the Internal Revenue Code (Code). Under the rules of section 30D(g) and this section, a taxpayer may elect to transfer a section 30D credit to an eligible entity, and the eligible entity may receive an advance payment for such credit, provided certain requirements are met. *See* paragraph (d) of this section for rules applicable to credit transfer elections. *See* paragraph (f) of this section for rules applicable to advance payments of transferred section 30D credits. Section 30D(g)(2) sets forth certain requirements that a dealer must satisfy to be an eligible entity for credit transfer and advance payment purposes. Section 30D(g)(2)(A) requires registration with the IRS. *See* paragraph (c) of this section for rules related to dealer registration. Section 30D(g)(2)(B) through (D) and paragraph (f)(2) of this section impose additional requirements that a registered dealer must satisfy in order to be an eligible entity for credit transfer and advance payment purposes.

(b) *Definitions.* This paragraph (b) provides definitions that apply for purposes of section 30D(g) and this section. *See* § 1.30D–2(b) for definitions that are generally applicable to section 30D and the section 30D regulations.

(1) *Advance payment program.* Advance payment program means the program described in paragraph (f)(1) of this section.

(2) *Credit transfer election.* Credit transfer election has the meaning provided in section 30D(g) and paragraph (d) of this section.

(3) *Dealer.* Dealer has the meaning provided in section 30D(g)(8), except that, for purposes of this section, the term does not include persons licensed solely by a territory of the United States, and includes a dealer licensed by any jurisdiction (other than one licensed solely by a territory of the United States) that makes sales at sites outside of the jurisdiction in which it is licensed.

(4) *Dealer tax compliance.* Dealer tax compliance means the dealer has filed all required Federal information and tax returns, including for Federal income and employment tax purposes, and the dealer has paid all Federal tax, penalties, and interest due as of the time of sale. A dealer that has entered into an installment agreement with the IRS for which a dealer is current on its obligations (including filing obligations) is treated as in dealer tax compliance.

(5) *Electing taxpayer.* Electing taxpayer means an individual who purchases and places in service a new clean vehicle and elects to transfer the section 30D credit that would otherwise be allowable to such individual to an eligible entity pursuant to section 30D(g) and paragraph (d) of this section. A taxpayer is an electing taxpayer only if the taxpayer makes certain attestations to the registered dealer, pursuant to procedures provided in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter), including that the taxpayer does not anticipate exceeding the modified adjusted gross income limitation of section 30D(b)(1) and § 1.30D–4(b) and that the taxpayer will use the vehicle predominantly for personal use.

(6) *Eligible entity.* Eligible entity has the meaning provided in section 30D(g)(2) and paragraph (f)(2) of this section.

(7) *Incentive.* For purposes of the eligible entity requirements of section 30D(g)(2)(B)(ii) and (D), incentive means any reduction in price available to the taxpayer from the dealer or manufacturer, including in combination with other incentives, other than a reduction in the form of a partial payment or down payment for the purchase of a new clean vehicle pursuant to section 30D(g)(2)(C).

(8) *Registered dealer.* Registered dealer means a dealer that has completed registration with the IRS as provided in paragraph (c) of this section.

(9) *Sale price.* The sale price of a new clean vehicle means the total price agreed upon by the taxpayer and dealer in a written contract at the time of sale, including any delivery charges and after the application of any incentives. The sale price of a new clean vehicle does not include separately stated taxes and fees required by State or local law. The sale price of a new clean vehicle is determined before the application of any trade-in value.

(10) *Time of sale.* Time of sale means the date the new clean vehicle is placed in service, as defined in § 1.30D–2(b)(36).

(c) *Dealer registration*—(1) *In general.* A dealer must register with the IRS in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) for the dealer to receive credits transferred by an electing taxpayer pursuant to section 30D(g) and paragraph (d) of this section.

(2) *Dealer tax compliance required.* A dealer must be in dealer tax compliance to complete and maintain its registration with the IRS and paragraph (d) of this section. If the dealer is not in dealer tax compliance for any of the taxable periods during the last five taxable years, then the dealer may complete its initial registration with the IRS, but the dealer will not be eligible for the advance payment program (and, therefore, the dealer will not be eligible to receive transferred section 30D credits) until the compliance issue is resolved. The IRS will notify the dealer in writing that the dealer is not in dealer tax compliance, and the dealer will have the opportunity to address any failure through regular procedures. If the failure is corrected, the IRS will complete the dealer's registration, and, provided all other requirements of section 30D(g) and this section are met, the dealer will then be allowed to receive transferred section 30D credits and participate in the advance payment program. Additional procedural guidance regarding this paragraph is set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(3) *Suspension of registration.* A registered dealer's registration may be suspended pursuant to the procedures described in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). Any decision made by the IRS relating to the suspension of a registered dealer's registration is not subject to administrative appeal to the IRS Independent Office of Appeals unless the IRS and the IRS Independent Office of Appeals agree that such review is available and the IRS provides the time and manner for such review.

(4) *Revocation of registration.* A registered dealer's registration may be revoked pursuant to the procedures described in guidance published in the *Internal Revenue Bulletin* (see § 601.601). Any decision made by the IRS relating to the revocation of a dealer's registration is not subject to administrative appeal to the IRS Independent Office of Appeals unless the IRS and the IRS Independent Office of Appeals agree that such review is available and the IRS provides the time and manner for such review.

(d) *Credit transfer election by electing taxpayer.* For a new clean vehicle placed in service after December 31, 2023, an electing taxpayer may elect to apply the rules of section 30D(g) and this section to make a credit transfer election with respect to the vehicle so that the section 30D credit with respect to the vehicle is allowed to the eligible entity specified in the credit transfer election (and not to the electing taxpayer) pursuant to the advance payment program described in paragraph (f) of this section. The electing taxpayer, as part of the credit transfer election, must transfer the entire amount of the credit that would otherwise be allowable to the electing taxpayer under section 30D with respect to the vehicle, and the eligible entity specified in the credit transfer election must pay the electing taxpayer an amount equal to the amount of the credit included in the credit transfer election. A credit transfer election must be made no later than the time of sale, and must be made in the manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). Once made, a credit transfer election is irrevocable. No credit transfer election may be made to transfer an amount of credit that would otherwise be allowed to the electing taxpayer under section 38.

(e) *Federal income tax consequences of the credit transfer election*—(1) *Tax consequences for electing taxpayer.* In the case of a credit transfer election, the Federal income tax consequences for the electing taxpayer are as follows—

(i) The credit amount under section 30D that the electing taxpayer elects to transfer to the eligible entity under section 30D(g) and paragraph (d) of this section may exceed the electing taxpayer's regular tax liability (as defined in section 26(b)(1) of the Code) for the taxable year in which the sale occurs, and the excess, if any, is not subject to recapture on the basis that it exceeded the electing taxpayer's regular tax liability;

(ii) The payment made by an eligible entity to an electing taxpayer under section 30D(g)(2)(C) and paragraph (d) of this section to an electing taxpayer pursuant to the credit transfer election is not includible in the gross income of the electing taxpayer; and

(iii) The payment made by an eligible entity to an electing taxpayer under section 30D(g)(2)(C) and paragraph (d) of this section is treated as repaid by the electing taxpayer to the eligible entity as partial payment of the sale price of the new clean vehicle. Thus, the repayment by the electing taxpayer is included in the electing taxpayer's basis in the new clean vehicle prior to the application of the basis reduction rule in section 30D(f)(1).

(2) *Tax consequences for eligible entity.* In the case of a credit transfer election, the Federal income tax consequences for the eligible entity are as follows—

(i) The eligible entity is allowed the section 30D credit with respect to the new clean vehicle and may receive an advance payment pursuant to section 30D(g)(7) and paragraph (f) of this section;

(ii) Advance payments received by the eligible entity are not treated as a tax credit in the hands of the eligible entity and may exceed the eligible entity's regular tax liability (as defined in section 26(b)(1)) for the taxable year in which the sale occurs;

(iii) An advance payment received by the eligible entity is not included in the gross income of the eligible entity;

(iv) The payment made by an eligible entity under section 30D(g)(2)(C) and paragraph (d) of this section to an electing taxpayer is not deductible by the eligible entity;

(v) The payment made by an eligible entity to an electing taxpayer under section 30D(g)(2)(C) and paragraph (d) of this section is treated as repaid by the electing taxpayer to the eligible entity as partial payment of the sale price of the new clean vehicle. Thus, the repayment by the electing taxpayer is treated as an amount realized by the eligible entity under section 1001 of the Code and the regulations under section 1001; and

(vi) If the eligible entity is a partnership or an S corporation, then—

(A) The IRS will make the advance payment to such partnership or S corporation equal to the amount of the section 30D credit allowed that is transferred to the eligible entity;

(B) Such section 30D credit is reduced to zero and is, for any other purpose of the Code, deemed to have been allowed solely to such entity (and not allocated or otherwise allowed to its partners or shareholders) for such taxable year; and

(C) The amount of the advance payment is not treated as tax exempt income to the partnership or S corporation for purposes of the Code.

(3) *Form of payment from eligible entity to electing taxpayer.* The tax treatment of the payment made by the eligible entity to the electing taxpayer described in paragraphs (e)(1) and (2) of this section is the same regardless of whether the payment is made in cash, in the form of a partial payment or down payment for the purchase of the new clean vehicle, or as a reduction in sale price (without the payment of cash) of the new clean vehicle.

(4) *Additional requirements.* In the case of a credit transfer election, the following additional rules apply—

(i) The requirements of section 30D(f)(1) (regarding basis reduction) and 30D(f)(2) (regarding no double benefit) apply to the electing taxpayer as if the credit transfer election were not made (so, for example, the electing taxpayer must reduce the electing taxpayer's basis in the vehicle by the amount of the section 30D credit, regardless of the credit transfer election);

(ii) Section 30D(f)(6) (regarding the election not to take the credit) will not apply (in other words, by electing to transfer the credit, the electing taxpayer is electing to take the credit);

(iii) Section 30D(f)(9) (regarding the vehicle identification number requirement) will be treated as satisfied if the eligible entity provides the vehicle identification number of such vehicle to the IRS in the form and manner set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The electing taxpayer must also provide the vehicle identification number with their tax return for the taxable year in which the vehicle is placed in service. *See* section 6213(g)(2)(T) of the Code and § 301.6213–2 of this chapter for rules relating to the omission of a correct vehicle identification number.

(5) *Examples.* The following examples illustrate the rules of paragraph (e) of this section.

(i) *Example 1: Electing taxpayer's regular tax liability less than amount of credit*—(A) *Facts.* T, an individual, purchases a new clean sport utility vehicle from a dealer, D, which is a C corporation. T satisfies the requirements to be an electing taxpayer and elects to transfer the section 30D credit to D. D is a registered dealer and satisfies the requirements to be an eligible entity. The sale price of the vehicle is $57,500. The section 30D credit otherwise allowable to T is $7,500. D makes the payment required to be made to T in the form of a cash payment of $7,500. T uses the $7,500 as a partial payment for the vehicle. T pays D an additional $50,000 from other funds. T's regular tax liability for the year is less than $7,500.

(B) *Analysis.* Under paragraph (e)(1)(i) of this section, T may transfer the credit to D, even though T's regular tax liability is less than $7,500, and no amount of the credit will be recaptured from T on the basis that the allowable credit exceeds T's regular tax liability. D's $7,500 payment to T is not included in T's gross income, and the sale price of the vehicle is $57,500 (including both the $7,500 payment and the additional $50,000 paid by T from other funds), prior to the application of the basis reduction rule of section 30D(f)(1). After application of the basis reduction rule, T's basis in the vehicle is $50,000. D is eligible to receive an advance payment of $7,500 for the transferred section 30D credit as provided in section 30D(g)(7) and paragraph (f) of this section. Under paragraph (e)(2) of this section, D may receive the advance payment irrespective of the fact that D's regular tax liability is less than $7,500. The advance payment is not treated as a credit toward D's tax liability (if any), nor is it included in D's gross income. Further, D's $7,500 payment to T is not deductible, and D's amount realized is $57,500 upon the sale of the vehicle (including both the $7,500 payment from D to T that T uses as a partial payment, and the additional $50,000 paid by T from other funds).

(ii) *Example 2: Non-cash payment by eligible entity to electing taxpayer*—(A) *Facts.* The facts are the same as in paragraph (e)(5)(i)(A) of this section (facts of *Example 1*), except that D makes the payment to T in the form of a reduction in the sale price of the vehicle (rather than as a cash payment).

(B) *Analysis.* Paragraph (e)(3) of this section provides that the application of paragraphs (e)(1) and (2) of this section is not dependent on the form of payment from an eligible entity to an electing taxpayer (for example, a payment in cash or a payment in the form of a reduction in sale price). Thus, the analysis is the same as in paragraph (e)(5)(i)(B) of this section (analysis of *Example 1*).

(iii) *Example 3: Eligible entity is a partnership*—(A) *Facts.* The facts are the same as in paragraph (e)(5)(i)(A) of this section (facts of *Example 1*), except that D is a partnership.

(B) *Analysis.* The analysis as to T is the same as in paragraph (e)(5)(i)(B) of this section (analysis of *Example 1*). Because D is a partnership, paragraph (e)(2)(vi) of this section applies. Thus, the advance payment is made to the partnership, the credit is reduced to zero and is, for any other purpose of the Code, deemed to have been allowed solely to the partnership (and not allocated or otherwise allowed to its partners) for such taxable year. The amount of the advance payment is not treated as tax-exempt income to the partnership for purposes of the Code.

(f) *Advance payments received by eligible entities*—(1) *In general.* An eligible entity may receive advance payments from the IRS (corresponding to the amount of the section 30D credit for which a credit transfer election was made by an electing taxpayer to transfer the credit to the eligible entity pursuant to section 30D(g) and paragraph (d) of this section) before the eligible entity files its Federal income tax return or information return, as appropriate, for the taxable year with respect to which the credit transfer election corresponds. This advance payment program is the exclusive mechanism for an eligible entity to receive the section 30D credit transferred pursuant to section 30D(g) and paragraph (d) of this section. An eligible entity receiving a transferred section 30D credit may not claim the credit on a tax return.

(2) *Requirements for a registered dealer to become an eligible entity.* A registered dealer qualifies as an eligible entity, and may therefore receive an advance payment, in connection with a credit transfer election, if it meets the following requirements:

(i) The registered dealer submits required registration information and is in dealer tax compliance;

(ii) The registered dealer retains information regarding the credit transfer election for three calendar years beginning with the year immediately after the year in which the vehicle is placed in service, as described in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter);

(iii) The registered dealer meets any other requirements set forth in guidance published in the *Internal Revenue Bulletin* (see § 601.601 of this chapter) or in forms and instructions; and

(iv) The registered dealer meets any other requirements of section 30D(g), including those in section 30D(g)(2)(B) through (E).

(g) *Increase in tax*—(1) *Recapture if electing taxpayer exceeds modified adjusted gross income limitation.* If an electing taxpayer has modified adjusted gross income that exceeds the limitation in section 30D(f)(10) and § 1.30D–4(b), then the income tax imposed on such taxpayer under chapter 1 of the Code (chapter 1) for the taxable year in which such vehicle was placed in service is

increased by the amount of the payment received by the taxpayer. The electing taxpayer must recapture such amounts on the return described in paragraph (h) of this section.

(2) *Excessive payments*—(i) *In general.* This paragraph provides rules under section 30D(g)(7)(B), which provides that rules similar to the rules of section 6417(d)(6) of the Code apply to the advance payment program. In the case of any advance payment to an eligible entity that the IRS determines constitutes an excessive payment, the tax imposed on the eligible entity under chapter 1, regardless of whether such entity would otherwise be subject to tax under chapter 1, for the taxable year in which such determination is made will be increased by the sum of the following amounts—

(A) The amount of the excessive payment; plus

(B) An amount equal to 20 percent of such excessive payment.

(ii) *Reasonable cause.* The amount described in paragraph (g)(2)(i)(B) of this section will not apply to an eligible entity if the eligible entity demonstrates to the satisfaction of the IRS that the excessive payment resulted from reasonable cause. In the case of a new clean vehicle (with respect to which a credit transfer election was made by the electing taxpayer) that is returned to the eligible entity within 30 days of being placed in service, the eligible entity will be treated as having demonstrated that the excessive payment resulted from reasonable cause.

(iii) *Excessive payment defined.* Excessive payment means an advance payment made—

(A) To a registered dealer that fails to meet the requirements to be an eligible entity provided in section 30D(g)(2) and paragraph (f)(2) of this section, or

(B) Except as provided in paragraph (g)(2)(iv) of this section, to an eligible entity with respect to a new clean vehicle to the extent the payment exceeds the amount of the credit that, without application of section 30D(g) and this section, would be otherwise allowable to the electing taxpayer with respect to the vehicle for such tax year.

(iv) *Special rule for cases in which the electing taxpayer's modified adjusted gross income exceeds the limitation.* Any excess described in paragraph (g)(2)(iii)(B) of this section that arises due to the electing taxpayer exceeding the limitation based on modified adjusted gross income in section 30D(f)(10) and § 1.30D–4(b) is not an excessive payment. Instead, the amount of the advance payment is recaptured from the electing taxpayer under section 30D(g)(10) and paragraph (g)(1) of this section.

(3) *Examples.* The following examples illustrate the excessive payment rules in paragraph (g)(2) of this section.

(i) *Example 1: Registered dealer is not an eligible entity*—(A) *Facts.* In 2024, D, a registered dealer, receives an advance payment of $7,500 with respect to a credit transferred under section 30D(g)(1) and paragraph (d) of this section for a new clean vehicle V. In 2025, the IRS determines that D was not an eligible entity with respect to new clean vehicle V at the time of the receipt of the advance payment in 2024, because D failed to satisfy one of the requirements of section 30D(g)(2) and paragraph (f)(2) of this section. D is unable to show reasonable cause for the failure.

(B) *Analysis.* Under paragraph (g)(2)(i) of this section, the tax imposed on D is increased by the amount of the excessive payment if the advance payment received by D constitutes an excessive payment. Under paragraph (g)(2)(iii) of this section, the entire amount of the $7,500 advance payment received by D is an excessive payment because D did not meet the requirements to be an eligible entity under section 30D(g)(2) and paragraph (f)(2) of this section. Additionally, because D cannot show reasonable cause for its failure to meet these requirements, the tax imposed under chapter 1 on D is increased by $9,000 in 2025 (the taxable year of the IRS determination). This is comprised of the $7,500 value of the credit plus the $1,500 penalty, calculated as a 20% penalty on such $7,500 (20% × $7,500 = $1,500). This treatment applies regardless of whether D is otherwise subject to tax under chapter 1 (for example, if D is a partnership).

(ii) *Example 2: Incorrect manufacturer certifications*—(A) *Facts.* In 2024, T, a taxpayer, makes an election to transfer a credit under section 30D(g)(1) and paragraph (d) of this section to E, a registered dealer, for a new clean vehicle V. M, the manufacturer of such vehicle, certified to the IRS that vehicle V was eligible for a $7,500 credit because it met both the critical minerals and the battery components requirements. T transfers the $7,500 credit to E. Subsequent to T's purchase and election to transfer the $7,500 credit to E, M reports to the IRS that vehicle V was only eligible for a $3,750 credit because it did not meet the critical minerals requirement.

(B) *Analysis.* Under § 1.30D–4(h), T may rely on the information and certifications provided in M's written report to the IRS regarding vehicle V's eligibility for the section 30D credit. Under paragraph (g)(2)(iii)(B) of this section, an advance payment to an eligible entity with respect to a vehicle is an excessive payment to the extent the payment exceeds the amount of the credit that, without a credit transfer election, would be otherwise allowable to the electing taxpayer with respect to the vehicle for such taxable year. Because the amount of the credit that would be allowable to T for 2024 is $7,500, and T transferred the $7,500 credit to E, there is no excessive payment with respect to E.

(h) *Return requirement.* An electing taxpayer that makes a credit transfer election must file a Federal income tax return or information return, as appropriate, for the taxable year in which the credit transfer election is made and indicate such election on the return in accordance with the instructions to the form on which the return is made. The electing taxpayer must attach a completed Form 8936, *Clean Vehicle Credits,* or successor form, and a completed Schedule A (Form 8936), *Clean Vehicle Credit Amount,* or successor form or schedule, including the vehicle identification number of the new clean vehicle and such other information as provided in forms and instructions.

(i) *Two credit transfer elections per year.* A taxpayer may make no more than two credit transfer elections per taxable year, consisting of either two elections to transfer section 30D credits, or one election to transfer a section 30D credit and one election to transfer a section 25E credit. In the case of taxpayers who file a joint return, each individual taxpayer may make no more than two credit transfer elections per taxable year.

(j) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions will continue in effect.

(k) *Applicability date.* This section applies to new clean vehicles placed in service after December 31, 2023, in taxable years ending after December 31, 2023.

§ 1.30D–6 Foreign entity of concern restriction.

(a) *In general.* This section provides rules related to the excluded entities provision of section 30D(d)(7) of the Internal Revenue Code (Code), which imposes certain restrictions on the extraction, processing, or recycling of applicable critical minerals, and the manufacturing or assembly of battery

components contained in a clean vehicle battery by a foreign entity of concern (FEOC). Specifically, section 30D(d)(7) provides that the term *new clean vehicle* does not include any vehicle placed in service after December 31, 2023, with respect to which any of the battery components in the clean vehicle battery were manufactured or assembled by a FEOC, or any vehicle placed in service after December 31, 2024, with respect to which any of the applicable critical minerals contained in the clean vehicle battery were extracted, processed, or recycled by a FEOC (FEOC restriction). *See* § 1.30D–2(b) for definitions applicable to section 30D(d)(7) and this section.

(b) *Due diligence required*—(1) *In general.* The qualified manufacturer must conduct due diligence with respect to all battery components and applicable critical minerals (and associated constituent materials) that are relevant to determining whether such components or minerals are FEOC-compliant. Such due diligence must comply with standards of tracing for battery materials available in the industry at the time of the attestation or certification that enables the qualified manufacturer to know with reasonable certainty the provenance of applicable critical minerals, associated constituent materials, and battery components. Reasonable reliance on a supplier attestation or certification will be considered due diligence if the qualified manufacturer, or any third-party manufacturer or supplier, does not know or have reason to know that such supplier attestation or certification is incorrect. *See* paragraph (c)(5) of this section for rules related to third-party manufacturers and suppliers. The qualified manufacturer must conduct due diligence prior to the qualified manufacturer determining the information necessary to establish any compliant-battery ledger under paragraph (d) of this section, and the qualified manufacturer must continue to conduct due diligence on an ongoing basis.

(2) *Transition rule for impracticable-to-trace battery materials.* For any new clean vehicles for which the qualified manufacturer provides a periodic written report before January 1, 2027, the due diligence requirement of paragraph (b)(1) of this section may be satisfied by excluding identified impracticable-to-trace battery materials. To use this transition rule, a qualified manufacturer must submit a report during the up-front review process described in paragraph (d)(2)(ii) of this section demonstrating how the qualified manufacturer will comply with the FEOC restriction of section 30D(d)(7) and this section, including information about efforts made to date to secure a FEOC-compliant supply of these battery materials once the transition rule is no longer in effect.

(c) *FEOC compliance*—(1) *In general.* In the case of any new clean vehicle placed in service after December 31, 2023, the clean vehicle battery or batteries of the vehicle must be FEOC-compliant. A serial number or other identification system must be used to physically track FEOC-compliant batteries to specific new clean vehicles. The determination that a clean vehicle battery is FEOC-compliant is made as follows:

(i) *Step 1.* The qualified manufacturer determines whether battery components and applicable critical minerals (and associated constituent materials) are FEOC-compliant, in accordance with paragraph (c)(4) of this section.

(ii) *Step 2.* The FEOC-compliant battery components and FEOC-compliant applicable critical minerals (and associated constituent materials) are physically tracked to specific battery cells, in accordance with paragraph (c)(3)(i) of this section. Alternatively, FEOC-compliant applicable critical minerals and associated constituent materials (but not battery components) may be allocated to battery cells, without physical tracking, in accordance with paragraph (c)(3)(ii) of this section. In addition, the determination of whether a battery cell is FEOC-compliant may be made by applying the transition rule for impracticable-to-trace battery materials, in accordance with paragraph (c)(3)(iii) of this section.

(iii) *Step 3.* The battery components, including battery cells, are physically tracked to specific clean vehicle batteries, in accordance with paragraph (c)(2) of this section.

(2) *FEOC-compliant batteries.* The determination that a clean vehicle battery is FEOC-compliant must be made by physically tracking FEOC-compliant battery components (including battery cells) to such battery. With respect to battery cells, a serial number or other identification system must be used to physically track FEOC-compliant battery cells to such batteries.

(3) *FEOC-compliant battery cells*—(i) *In general.* Except as provided in paragraph (c)(3)(ii) of this section, the determination that a battery cell contains FEOC-compliant battery components and FEOC-compliant applicable critical minerals and their associated constituent materials must be made by physically tracking FEOC-compliant battery components to specific battery cells, and by physically tracking the mass of FEOC-compliant applicable critical minerals and their associated constituent materials to specific battery cells.

(ii) *Allocation-based determination for applicable critical minerals and associated constituent materials of a battery cell*—(A) *In general.* The determination that a battery cell is FEOC-compliant may be based on an allocation of available mass, procured or contracted for, of applicable critical minerals and their associated constituent materials to specific battery cells manufactured or assembled in a battery cell production facility, without the physical tracking of mass of applicable critical minerals and associated constituent materials to specific battery cells.

(B) *Allocation limited to applicable critical minerals in the battery cell.* The rules of this paragraph (c)(3)(ii) are limited to applicable critical minerals and their associated constituent materials that are incorporated into a battery cell or its battery components. Battery components must be physically tracked.

(C) *Separate allocation required for each type of associated constituent material*—(*1*) *In general.* Any allocation under this paragraph (c)(3)(ii) with respect to the mass of an applicable critical mineral must be made within the type of associated constituent material (such as powders of cathode active materials, powders of anode active materials, or foils) in which such applicable critical mineral is contained. Masses of an applicable critical mineral may not be aggregated across constituent materials with which such applicable critical mineral is not associated, and an allocation of a mass of an applicable critical mineral may not be made from one type of constituent material to another.

(*2*) *Example.* M, a qualified manufacturer, operates a battery cell production facility. M manufactures a line of battery cells that contains applicable critical mineral Z (ACM–Z) in constituent material 1 and in constituent material 2. With respect to constituent material 1, M procures 20,000,000 kilograms (kg) of ACM–Z for the battery cell production facility, of which 4,000,000 kg are FEOC-compliant and 16,000,000 kg are not FEOC-compliant. With respect to constituent material 2, M procures another 15,000,000 kg of ACM–Z for the battery cell production facility, of which 7,500,000 kg are FEOC-compliant and 7,500,000 kg are not FEOC-compliant. M determines which battery cells are FEOC-compliant through an allocation-

based determination with respect to battery cells manufactured or assembled in the battery cell production facility. Under this paragraph (c)(3)(ii)(C), any allocation with respect to the mass of ACM–Z must be made within the type of constituent material in which ACM–Z is contained. Thus, M may not aggregate the 4,000,000 kg of FEOC-compliant ACM–Z contained in constituent material 1 with the 7,500,000 kg of FEOC-compliant ACM–Z contained in constituent material 2, and allocations may not be made from constituent material 1 to constituent material 2. As a result, overall FEOC compliance is constrained by the 20% of constituent material 1 that is FEOC-compliant due to having 4,000,000 kg of ACM–Z, even though 33% (4,000,000 + 7,500,000)/(20,000,000 + 15,000,000) of the total mass of ACM–Z is FEOC-compliant.

(D) *Allocation within each product line of battery cells.* Any allocation under this paragraph (c)(3)(ii) with respect to applicable critical minerals and their associated constituent materials must be allocated within one or more specific battery cell product lines of the battery cell production facility.

(E) *Limitation on number of FEOC-compliant battery cells.* If a qualified manufacturer uses an allocation-based determination described in this paragraph (c)(3)(ii), the number of FEOC-compliant battery cells that can be produced from such allocation may not exceed the total number of battery cells for which there is enough of every FEOC-compliant applicable critical mineral. That number will necessarily be limited by the applicable critical mineral that has the lowest percentage of FEOC-compliant supply. For example, if a qualified manufacturer allocates applicable critical mineral A, which is 20 percent FEOC-compliant, and applicable critical mineral B, which is 60 percent FEOC-compliant, to a battery cell product line, no more than 20 percent of the battery cells in that battery cell product line will be treated as FEOC-compliant.

(iii) *Transition rule for impracticable-to-trace battery materials.* For any new clean vehicles for which the qualified manufacturer provides a periodic written report before January 1, 2027, the qualified manufacturer's determination of whether a battery cell is FEOC-compliant under this paragraph (c)(3) may be satisfied by excluding identified impracticable-to-trace battery materials (and associated constituent materials).

(4) *FEOC-compliant battery components and applicable critical minerals*—(i) *In general.* The determination of whether battery components and applicable critical minerals (and their associated constituent materials) are FEOC-compliant must be made prior to any determination under paragraphs (c)(2) and (3) of this section.

(ii) *Timing of determination of FEOC or FEOC-compliant status.* Whether an entity is a FEOC is determined at the time of the entity's performance of the relevant activity, which for applicable critical minerals is the time of extraction, processing, or recycling, and for battery components is the time of manufacturing or assembly. The determination of whether an applicable critical mineral is FEOC-compliant is determined at the end of processing or recycling the applicable critical mineral into a constituent material, taking into account all applicable steps through and including final processing or recycling.

(iii) *Example: Timing of FEOC compliance determination.* Mineral X, an applicable critical mineral, was not extracted by a FEOC but was later processed by a FEOC. Mineral X is not FEOC-compliant because one step of the extraction and processing was performed by a FEOC. Therefore, any battery containing Mineral X is not FEOC-compliant.

(5) *Third-party manufacturers or suppliers.* The determinations under paragraphs (c)(2) through (4) of this section, which are generally made by the qualified manufacturer, may be made by a third-party manufacturer or supplier that operates a battery cell production facility, provided the third-party manufacturer satisfies the requirements of paragraph (c)(5)(i) through (iii) of this section, and paragraph (c)(5)(iv) of this section, if applicable.

(i) *Due diligence required.* The third-party manufacturer or supplier must perform the due diligence described in paragraph (b) of this section.

(ii) *Provision of required information to qualified manufacturer.* The third-party manufacturer or supplier must provide the qualified manufacturer of the new clean vehicle information sufficient to establish a basis for the determinations under paragraphs (c)(2) through (4) of this section, including information related to the due diligence described in paragraph (c)(5)(i) of this section.

(iii) *Contractual obligations.* The third-party manufacturer or supplier must be contractually required to provide the information in paragraph (c)(5)(ii) of this section to the qualified manufacturer and must be contractually required to inform the qualified manufacturer of any change in the supply chain that affects the determinations of FEOC compliance under paragraph (c)(2) through (4) of this section.

(iv) *Additional requirements in case of multiple third-party manufacturers or suppliers.* If there are multiple third-party manufacturers or suppliers (such as a case in which a qualified manufacturer contracts with a battery manufacturer, that, in turn, contracts with a battery cell manufacturer or supplier that operates a battery cell production facility), the due diligence and information requirements of this paragraph (c) must be satisfied by each third-party manufacturer or supplier, either by providing all required information directly to the qualified manufacturer or indirectly through contractual relationships.

(d) *Compliant-battery ledger*—(1) *In general.* For new clean vehicles placed in service after December 31, 2024, the qualified manufacturer must determine and provide information to the IRS to establish a compliant-battery ledger for each calendar year, as described in paragraphs (d)(2)(i) and (ii) of this section. The qualified manufacturer may establish one compliant-battery ledger for all vehicles for a calendar year, or separate ledgers for specific models or classes of vehicles to account for different battery cell chemistries or differing quantities of cells in each clean vehicle battery.

(2) *Determination of number of batteries*—(i) *In general.* To establish a compliant-battery ledger for a calendar year, the qualified manufacturer must determine the number of clean vehicle batteries, with respect to new clean vehicles for which the qualified manufacturer anticipates providing a periodic written report during the calendar year, that it knows or reasonably anticipates will be FEOC-compliant, pursuant to the requirements of paragraphs (b) and (c) of this section. The determination is based on the battery components and applicable critical minerals (and associated constituent materials) that are procured or contracted for the calendar year and that are known or reasonably anticipated to be FEOC-compliant battery components or FEOC-compliant applicable critical minerals, as applicable.

(ii) *Upfront review.* The qualified manufacturer must attest to the number of FEOC-compliant clean vehicle batteries determined under paragraph (d)(2)(i) of this section and provide the basis for the determination, including attestations, certifications and documentation demonstrating

compliance with paragraphs (b) and (c) of this section, at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). The IRS, with analytical assistance from the Department of Energy (DOE), will review the attestations, certifications, and documentation. Once the IRS determines that the qualified manufacturer provided the required attestations, certifications, and documentation, the IRS will approve or reject the determined number of FEOC-compliant batteries. The IRS may approve the determined number in whole or part. The approved number is the initial balance in the compliant-battery ledger.

(iii) *Decrease or increase to compliant-battery ledger*—(A) Once the compliant-battery ledger is established with respect to a calendar year, the qualified manufacturer must determine and take into account any decrease in the number of FEOC-compliant batteries for such calendar year and any of the prior three calendar years for which the qualified manufacturer had a compliant-battery ledger, within 30 days of discovery. In addition, the qualified manufacturer may determine and take into account any increase in the number of FEOC-compliant batteries. Such determinations, and any supporting attestations, certifications, and documentation, must be provided on a periodic basis, in accordance with paragraph (d)(2)(ii) of this section and the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(B) The decrease described in paragraph (d)(2)(iii)(A) of this section may decrease the compliant-battery ledger below zero, creating a negative balance in the compliant-battery ledger.

(C) If any decrease described in paragraph (d)(2)(iii)(A) of this section is determined subsequent to the calendar year to which it relates, the decrease must be taken into account in the year in which the change is discovered.

(D) Any remaining balance in the compliant-battery ledger at the end of the calendar year, whether positive or negative, will be included in the compliant-battery ledger for the subsequent calendar year. If a qualified manufacturer has multiple negative compliant-battery accounts, any negative balance will first be included in the compliant-battery ledger for the same model or class of vehicles for the subsequent calendar year. However, if there is no ledger for the same model or class of vehicles in the subsequent calendar year, the IRS can account for such negative balance in the ledger of a different model or class of vehicles of the qualified manufacturer.

(3) *Tracking FEOC-compliant batteries.* The compliant-battery ledger for a calendar year must be updated to track the qualified manufacturer's available FEOC-compliant batteries, by reducing the balance in the ledger as the qualified manufacturer submits periodic written reports reporting the vehicle identification numbers of new clean vehicles as eligible for the credit under section 30D, at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). If the balance in the compliant-battery ledger of the qualified manufacturer for a calendar year is zero or less than zero, the qualified manufacturer may not submit additional periodic written reports with respect to section 30D until the number of available FEOC-compliant batteries is increased as described in paragraph (d)(2)(iii)(A) of this section.

(4) *Reconciliation of battery estimates.* After the end of any calendar year for which a compliant-battery ledger is established, the IRS may require a qualified manufacturer to provide attestations, certifications, and documentation to support the accuracy of the number of the qualified manufacturer's FEOC-compliant batteries for such calendar year, including with respect to any changes described in paragraph (d)(2)(iii) of this section, at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(e) *Rule for 2024*—(1) *In general.* For new clean vehicles that are placed in service after December 31, 2023, and prior to January 1, 2025, the qualified manufacturer must determine whether the battery components contained in the vehicles satisfy the requirements of section 30D(d)(7)(B), and whether batteries contained in the vehicles are FEOC-compliant under the rules of paragraphs (b) and (c) of this section. The qualified manufacturer must make an attestation with respect to such determinations at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter). However, for any new clean vehicles for which the qualified manufacturer provides a periodic written report before June 5, 2024, provided that the qualified manufacturer has determined that its supply chains for each battery component with respect such vehicles contain only FEOC-compliant battery components:

(i) For purposes of paragraphs (c)(2) and (3) of this section, the determination of which battery cells or clean vehicle batteries, as applicable, contain FEOC-compliant battery components may be made without physical tracking;

(ii) For purposes of paragraph (c)(2) of this section, the determination of which clean vehicle batteries contain FEOC-compliant battery cells may be made without physical tracking (and without the use of a serial number or other identification system); and

(iii) For purposes of paragraph (c)(1) of this section, the determination of which vehicles contain FEOC-compliant batteries may be made without physical tracking (and without the use of a serial number or other identification system).

(2) *Determination.* The determination that a qualified manufacturer's supply chains of each battery component contain only FEOC-compliant battery components may be made with respect to specific models or classes of vehicles.

(f) *Inaccurate attestations, certifications, or documentation*—(1) *In general.* If the IRS determines, with analytical assistance from the DOE and after review of the attestations, certification, and documentation described in paragraph (d) of this section, that a qualified manufacturer has provided attestations, certifications, or documentation that contain inaccurate information, the IRS may take appropriate action, as described in paragraphs (f)(2) and (3) of this section. Such action would affect vehicles and qualified manufacturers on a prospective basis.

(2) *Inadvertence*—(i) *Inaccurate information may be cured by qualified manufacturer.* If the IRS determines that the qualified manufacturer's attestations, certifications, or documentation for a specific new clean vehicle contain inaccurate information due to inadvertence, the qualified manufacturer may, within a reasonable period of time after discovery of the inaccurate information, cure the errors, including by a decrease in the compliant-battery ledger as described in paragraph (d)(2)(iii) of this section. If the qualified manufacturer has multiple compliant-battery ledgers, the IRS may determine which ledger is to be decreased.

(ii) *Consequences if errors not cured.* If the qualified manufacturer does not cure the errors, the IRS may take any of the following actions:

(A) In the case of a new clean vehicle that has not been placed in service but for which the qualified manufacturer has submitted a periodic written report certifying compliance with the requirements of section 30D(d), the IRS may determine that such vehicle is no

longer considered a new clean vehicle eligible for the section 30D credit.

(B) In the case of a new clean vehicle that has not been placed in service and for which the qualified manufacturer has not submitted a periodic written report certifying compliance with the requirements of section 30D(d), the qualified manufacturer may not submit such periodic written report.

(C) In the case of a new clean vehicle that has been placed in service, the IRS may require a decrease in the qualified manufacturer's compliant-battery ledger as described in paragraph (d)(2)(iii) of this section. If the qualified manufacturer has multiple compliant-battery ledgers, the IRS may determine which ledger is to be decreased.

(3) *Intentional disregard or fraud.* If the IRS determines that a qualified manufacturer intentionally disregarded attestation, certification, or documentation requirements, or reported information fraudulently or with intentional disregard, the IRS may take any of the actions described in paragraph (f)(3)(i) or (ii) of this section.

(i) *All vehicles ineligible for credit.* The IRS may determine that all vehicles manufactured by the qualified manufacturer that have not been placed in service are no longer considered new clean vehicles eligible for the section 30D credit.

(ii) *Termination of written agreement.* The IRS may terminate the written agreement between the IRS and the manufacturer, thereby terminating the manufacturer's status as a qualified manufacturer. In such instance, the manufacturer would be required to submit a new written agreement to reestablish qualified manufacturer status at the time and in the manner provided in the *Internal Revenue Bulletin* (see § 601.601 of this chapter).

(g) *Rules inapplicable to new qualified fuel cell motor vehicles.* The requirements of section 30D(d)(7) and this section do not apply to new qualified fuel cell motor vehicles.

(h) *Examples.* The following examples illustrate the rules under paragraphs (b) through (e) of this section:

(1) *Example 1: In general*—(i) *Facts.* M is a manufacturer of new clean vehicles and batteries. M also manufactures and assembles battery cells at its own battery cell production facility. M manufactures a line of new clean vehicles that it anticipates will be placed in service in calendar year 2025. Each vehicle contains one clean vehicle battery, and each clean vehicle battery contains 1,000 battery cells. All battery cells are produced at the same battery cell production facility. The battery cells are not manufactured or assembled by a FEOC. Each battery cell contains 10 units of battery component A. M has procured or is under contract to procure 10,000,000 units of battery component A for the battery cell production facility, of which 6,000,000 units are from supplier 1 and 4,000,000 units are from supplier 2.

(ii) *Analysis*—(A) Under paragraph (b) of this section, M must conduct due diligence on all battery components and applicable critical minerals (and associated constituent materials) that are contained in the clean vehicle batteries to determine whether such components or minerals are FEOC-compliant.

(B) Under paragraph (c)(4) of this section, M must first determine whether the battery components and applicable critical minerals (and associated constituent materials) are FEOC-compliant. From its due diligence, M determines that, of the 10,000,000 units of battery component A, the 6,000,000 units from supplier 1 are FEOC-compliant while the 4,000,000 units from supplier 2 are not FEOC-compliant. M determines that all other battery components and applicable critical minerals (and associated constituent materials) of the battery cells are FEOC-compliant, that the battery cell is not manufactured or assembled by a FEOC, and that all battery components (excluding components of the battery cell) of the clean vehicle batteries are FEOC-compliant.

(C) Under paragraph (c)(3) of this section, M must determine which battery cells are FEOC-compliant through the physical tracking of the 6,000,000 units of FEOC-compliant battery component A to determine which 600,000 (6,000,000/10) battery cells are FEOC-compliant. Under paragraph (c)(2) of this section, M must use a serial number or other identification system to track the 600,000 FEOC-compliant battery cells to 600 (600,000/1,000) specific clean vehicle batteries.

(D) Under paragraph (d)(1) of this section, a compliant-battery ledger must be established for calendar year 2025. For purposes of paragraph (d)(2)(i) of this section, M determines that it will manufacture 600 batteries for calendar year 2025 that are FEOC-compliant. Under paragraph (d)(2)(ii) of this section, M attests to the 600 FEOC-compliant batteries and provides the basis for the determination, including attestations, certifications, and documentation demonstrating compliance with paragraphs (b) and (c) of this section. Once the IRS, with analytical assistance from the DOE, approves the number, a compliant-battery ledger is established with a balance of 600 FEOC-compliant batteries.

(E) M manufactures 100 vehicles that it anticipates will be placed in service in 2025, for which it provides periodic written reports providing the vehicle identification numbers of the vehicles and indicating that such vehicles qualify for the section 30D credit. Under paragraph (d)(3) of this section, the compliant-battery ledger is updated to track the number of FEOC-compliant batteries. The number of FEOC-compliant batteries contained in the compliant-battery ledger is reduced from 600 to 500. Assuming all of the other requirements of section 30D and the regulations thereunder are met, the 100 vehicles are new clean vehicles for purposes of section 30D.

(2) *Example 2: Rules for third-party suppliers*—(i) *Facts.* The facts are the same as in paragraph (h)(1)(i) of this section (facts of *Example 1*), except that M contracts with a battery manufacturer, BM, for the provision of clean vehicle batteries, and BM contracts with a battery cell supplier, BCS, that operates a battery cell production facility, for the provision of battery cells.

(ii) *Analysis.* Under paragraph (c)(5) of this section, BCS may make the determination in paragraphs (c)(2) through (4) of this section, provided that M, BM, and BCS perform due diligence as described in paragraph (b) of this section. In addition, BM and BCS must provide M with information sufficient to establish a basis for the determinations under paragraphs (c)(2) through (4) of this section, including information related to due diligence. Finally, BM and BCS must be contractually required to provide the required information to M, and must also be required to inform the qualified manufacturer of any change in supply chains that affects the determinations of FEOC compliance under paragraphs (c)(2) and (4) of this section. The contractual requirement may be satisfied if BM and BCS each have the contractual obligation to M. Alternatively, it may be satisfied if BCS has a contractual obligation to BM and BM, in turn, has a contractual obligation to M.

(3) Example *3: Applicable critical minerals*—(i) *Facts.* The facts are the same as in paragraph (h)(1)(i) of this section (facts of *Example 1*). In addition, each battery cell contains 20 kilograms (kg) of applicable critical mineral Z (ACM–Z) contained in a constituent material. M has procured or is under contract to procure 20,000,000 kg of ACM–Z for the battery cell production

facility, of which 4,000,000 kg are from supplier 3 and 16,000,000 kg are from supplier 4.

(ii) *Analysis.* The analysis is the same as in paragraph (h)(1)(ii) of this section (analysis of *Example 1*). In addition, from its due diligence, M determines that of the 20,000,000 kg of ACM–Z, the 4,000,000 kg from supplier 3 is FEOC-compliant while the 16,000,000 kg from supplier 4 is not FEOC-compliant. Under paragraph (c)(3) of this section, M may determine which battery cells are FEOC-compliant through the physical tracking of the 4,000,000 kg of FEOC-compliant ACM–Z to 200,000 (4,000,000/20) of the battery cells that also contain battery component A, in order to determine which 200,000 battery cells are FEOC-compliant. Alternatively, M may determine which 200,000 battery cells are FEOC-compliant through an allocation of ACM–Z (but not battery component A) to battery cells, without physical tracking, under paragraph (c)(3)(ii) of this section. Under paragraph (c)(2) of this section, M must use a serial number or other identification system to track the 200,000 FEOC-compliant battery cells to 200 (200,000/1,000) specific clean vehicle batteries.

(4) *Example 4: Comprehensive example*—(i) *Facts.* M is a manufacturer of new clean vehicles and batteries. M also manufactures or assembles battery cells at its own battery cell production facility. M manufactures a line of new clean vehicles. Each vehicle contains one battery. All battery cells are produced at the same battery cell production facility. The battery cells are not manufactured or assembled by a FEOC. Each battery contains 1,000 NMC 811 battery cells. M anticipates manufacturing 1,000,000 such battery cells for a line of new clean vehicles that it anticipates will be placed in service in calendar year 2025.

(A) Each battery cell contains 1 cathode electrode, 1 anode electrode, 1 separator, and 1 liquid electrolyte. Thus, M procures 1,000,000 units of each battery component for the battery cell production facility.

(B) In addition, each NMC 811 cathode incorporates cathode active material (a constituent material) produced using 2.5 kg of applicable critical minerals, consisting of 0.5 kg of lithium hydroxide, 1.6 kg of nickel sulfate, 0.2 kg of cobalt sulfate, and 0.2 kg of manganese sulfate. Thus, M procures 2,500 metric tons (2.5 kg × 1,000,000/1,000) of applicable critical minerals for the battery cell production facility, resulting in purchase agreements for 500 metric tons of lithium, 1,600 metric tons of nickel, 200 metric tons of cobalt, and 200 metric tons of manganese.

(ii) *Analysis*—(A) Under paragraph (b) of this section, M must conduct due diligence on all battery components and applicable critical minerals (and associated constituent materials) that are contained in the clean vehicle batteries to determine whether such components or minerals are FEOC-compliant.

(B) Under paragraph (c)(4) of this section, M must first determine whether the battery components and applicable critical minerals (and associated constituent materials) are FEOC-compliant. From its due diligence M determines that, of the cathode electrodes, 600,000 are not manufactured by a FEOC and are therefore FEOC-compliant; 400,000 are manufactured by a FEOC and are therefore non-compliant. Because each battery cell contains 1 cathode electrode, a maximum of 600,000 battery cells would be FEOC-compliant. Of the critical minerals that M has procured, M determines that 250 metric tons of lithium hydroxide, 1,200 metric tons of nickel sulfate, and all of the cobalt sulfate and manganese sulfate are FEOC-compliant. M determines that all other battery components and applicable critical minerals of the battery cells are FEOC-compliant.

(C) Under paragraph (c)(3) of this section, M must determine which battery cells are FEOC-compliant through the physical tracking of battery components. M may determine which battery cells are FEOC-compliant through the physical tracking of applicable critical minerals. Alternatively, M may determine which battery cells are FEOC-compliant through an allocation of applicable critical minerals (and associated constituent materials) but not battery components.

(D) Under an allocation-based determination, M has procured 500 metric tons of lithium hydroxide incorporated into a constituent material for the battery cell production facility, of which 50% (250/500 metric tons) is FEOC-compliant. M has procured 1,600 metric tons of nickel sulfate incorporated into a constituent material for the battery cell production facility, of which 75% (1,200/1,600 metric tons) is FEOC-compliant. Because the lithium hydroxide is the least compliant applicable critical mineral or component, M allocates the FEOC-compliant lithium hydroxide mass to 50% or 500,000 (50% × 1,000,000) of the total battery cells, and to battery cells that contain FEOC-compliant cathode electrodes and have been allocated FEOC-compliant nickel sulfate. Under paragraph (c)(3)(ii)(E) of this section, the quantity of FEOC-compliant battery cells is limited by the applicable critical mineral (lithium hydroxide) that has the lowest percentage (50%) of FEOC-compliant supply.

(E) Under paragraph (c)(2) of this section, M must use a serial number or other identification system to track the 500,000 FEOC-compliant battery cells to 500 (500,000/1,000) specific clean vehicle batteries.

(F) Under paragraph (d)(1) of this section, a compliant-battery ledger must be established for calendar year 2025. For purposes of paragraph (d)(2)(i) of this section, M determines that it will manufacture 500 batteries for calendar year 2025 that are FEOC-compliant, allocating its FEOC-compliant applicable critical minerals to the cells containing FEOC-compliant battery components. Under paragraph (d)(2)(ii) of this section, M attests to the 500 FEOC-compliant batteries and provides the basis for the determination, including attestations, certifications, and documentation demonstrating compliance with paragraphs (b) and (c) of this section. Once the IRS, with analytical assistance from the DOE, has approved the number, a compliant-battery ledger is established with a balance of 500 FEOC-compliant batteries.

(i) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agencies' intention that the remaining provisions will continue in effect.

(j) *Applicability date.* This section applies to new clean vehicles placed in service after December 31, 2023, in taxable years ending after December 31, 2023.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par 4.** The authority citation for part 301 is amended by adding an entry in numerical order for § 301.6213–2 to read, in part, as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 301.6213–2 also issued under 26 U.S.C. 6213.

* * * * *

■ **Par 5.** Section 301.6213–2 is added to read as follows:

§ 301.6213–2 Omission of correct vehicle identification number.

(a) *In general.* The definition of the term *mathematical or clerical error* in

section 6213(g)(2) of the Internal Revenue Code (Code) includes:

(1) Under section 6213(g)(2)(T), an omission of a correct vehicle identification number required under section 30D(f)(9) of the Code (relating to credit for new clean vehicles) to be included on a return;

(2) Under section 6213(g)(2)(U), an omission of a correct vehicle identification number required under section 25E(d) of the Code (relating to credit for previously-owned clean vehicles) to be included on a return; and

(3) Under section 6213(g)(2)(V), an omission of a correct vehicle identification number required under section 45W(e) of the Code (relating to credit for qualified commercial clean vehicles) to be included on a return.

(b) *Omission of a correct vehicle identification number.* For purposes of paragraph (a) of this section, a taxpayer is treated as having omitted a correct vehicle identification number if:

(1) The vehicle identification number required to be reported under section 30D(f)(9), 25E(d), or 45W(e) is not included on the return of tax;

(2) The vehicle identification number included on the return of tax is not that of a vehicle eligible for a credit under section 30D, 25E, or 45W.

(3) The vehicle identification number included on the return of tax is not that of a vehicle eligible for a credit under section 30D, 25E, or 45W for the year in which it is claimed;

(4) The vehicle identification number included on the return of tax differs from the vehicle identification number reported to the IRS and the taxpayer under section 30D(d)(1)(H) for each new clean vehicle placed in service during the taxable year by the taxpayer who was issued the report; or

(5) The vehicle identification number included on the return of tax differs from the vehicle identification number reported to the IRS and the taxpayer under section 25E(c)(1)(D)(i) for each previously-owned clean vehicle placed in service during the taxable year by the taxpayer who was issued the report.

(c) *Applicability date.* This section applies to taxable years beginning after December 31, 2023.

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: April 21, 2024.

Aviva Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–09094 Filed 5–3–24; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 89 Monday,
No. 88 May 6, 2024

Part VI

Department of Energy

10 CFR Parts 429 and 430
Energy Conservation Program: Energy Conservation Standards for Consumer Water Heaters; Final Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE 2017–BT–STD–0019]

RIN 1904–AD91

Energy Conservation Program: Energy Conservation Standards for Consumer Water Heaters

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including consumer water heaters. EPCA also requires the U.S. Department of Energy (''DOE'' or ''the Department'') to periodically determine whether more stringent standards would be technologically feasible and economically justified, and would result in significant energy savings. In this final rule, DOE is adopting amended energy conservation standards for consumer water heaters. It has determined that the new and amended energy conservation standards for these products would result in significant conservation of energy, and are technologically feasible and economically justified.

DATES: The effective date of this rule is July 5, 2024. Compliance with the new and amended standards established for consumer water heaters in this final rule is required on and after May 6, 2029.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov*. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2017-BT-STD-0019*. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Melanie Lampton, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 751–5157. Email: *Melanie.Lampton@hq.doe.gov*.

For further information on how to review the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Synopsis of the Final Rule

The Energy Policy and Conservation Act, Public Law 94–163, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B of EPCA [2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include consumer water heaters, the subject of this rulemaking. As discussed in section II.B.3 of this document, DOE is finalizing standards for all consumer water heaters, with the exception of gas-fired instantaneous water heaters, in this Final Rule.

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m))

In accordance with these and other statutory provisions discussed in this document, DOE analyzed the benefits and burdens of six trial standard levels (''TSLs'') for consumer water heaters. The TSLs and their associated benefits and burdens are discussed in detail in sections V.A through V.C of this document. As discussed in section V.C of this document, DOE has determined that TSL 2 represents the maximum improvement in energy efficiency that is technologically feasible and economically justified. The adopted standards, which are expressed in terms of uniform energy factor (''UEF''), are shown in Table I.1. These standards apply to all products listed in Table I.1 and manufactured in, or imported into, the United States starting on May 6, 2029.

BILLING CODE 6450–01–P

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

Table I.1 Energy Conservation Standards for Consumer Water Heaters (Compliance Starting May 6, 2029)

Product Class	Effective Storage Volume and Input Rating *(if applicable)*	Draw Pattern	Uniform Energy Factor*
Gas-fired Storage Water Heater	< 20 gal	Very Small	$0.2062 - (0.0020 \times V_{eff})$
		Low	$0.4893 - (0.0027 \times V_{eff})$
		Medium	$0.5758 - (0.0023 \times V_{eff})$
		High	$0.6586 - (0.0020 \times V_{eff})$
	≥ 20 gal and ≤ 55 gal	Very Small	$0.3925 - (0.0020 \times V_{eff})$
		Low	$0.6451 - (0.0019 \times V_{eff})$
		Medium	$0.7046 - (0.0017 \times V_{eff})$
		High	$0.7424 - (0.0013 \times V_{eff})$
	>55 gal and ≤ 100 gal	Very Small	$0.6470 - (0.0006 \times V_{eff})$
		Low	$0.7689 - (0.0005 \times V_{eff})$
		Medium	$0.7897 - (0.0004 \times V_{eff})$
		High	$0.8072 - (0.0003 \times V_{eff})$
	> 100 gal	Very Small	$0.1482 - (0.0007 \times V_{eff})$
		Low	$0.4342 - (0.0017 \times V_{eff})$
		Medium	$0.5596 - (0.0020 \times V_{eff})$
		High	$0.6658 - (0.0019 \times V_{eff})$
Oil-fired Storage Water Heater	≤ 50 gal	Very Small	$0.2909 - (0.0012 \times V_{eff})$
		Low	$0.5730 - (0.0016 \times V_{eff})$
		Medium	$0.6478 - (0.0016 \times V_{eff})$
		High	$0.7215 - (0.0014 \times V_{eff})$
	> 50 gal	Very Small	$0.1580 - (0.0009 \times V_{eff})$
		Low	$0.4390 - (0.0020 \times V_{eff})$
		Medium	$0.5389 - (0.0021 \times V_{eff})$
		High	$0.6172 - (0.0018 \times V_{eff})$
Very Small Electric Storage Water Heater	< 20 gal	Very Small	$0.5925 - (0.0059 \times V_{eff})$
		Low	$0.8642 - (0.0030 \times V_{eff})$
		Medium	$0.9096 - (0.0020 \times V_{eff})$
		High	$0.9430 - (0.0012 \times V_{eff})$
Small Electric Storage Water Heater	≥ 20 gal and ≤ 35 gal	Very Small	$0.8808 - (0.0008 \times V_{eff})$
		Low	$0.9254 - (0.0003 \times V_{eff})$
Electric Storage Water Heaters	> 20 and ≤ 55 gal (excluding small electric storage water heaters)	Very Small	2.30
		Low	2.30
		Medium	2.30
		High	2.30
	> 55 gal and ≤120 gal	Very Small	2.50
		Low	2.50
		Medium	2.50
		High	2.50
	> 120 gal	Very Small	$0.3574 - (0.0012 \times V_{eff})$
		Low	$0.7897 - (0.0019 \times V_{eff})$
		Medium	$0.8884 - (0.0017 \times V_{eff})$
		High	$0.9575 - (0.0013 \times V_{eff})$
Tabletop Water Heater	< 20 gal	Very Small	$0.5925 - (0.0059 \times V_{eff})$
		Low	$0.8642 - (0.0030 \times V_{eff})$
	≥ 20 gal	Very Small	$0.6323 - (0.0058 \times V_{eff})$
		Low	$0.9188 - (0.0031 \times V_{eff})$
Instantaneous Gas-fired Water Heater**	<2 gal and >50,000 Btu/h	Very Small	0.80
		Low	0.81
		Medium	0.81
		High	0.81
Instantaneous Oil-fired Water Heater	< 2 gal and ≤ 210,000 Btu/h	Very Small	0.61
		Low	0.61

		Medium	0.61
		High	0.61
	≥ 2 gal and ≤ 210,000 Btu/h	Very Small	$0.2780 - (0.0022 \times V_{eff})$
		Low	$0.5151 - (0.0023 \times V_{eff})$
		Medium	$0.5687 - (0.0021 \times V_{eff})$
		High	$0.6147 - (0.0017 \times V_{eff})$
Instantaneous Electric Water Heater	< 2 gal	Very Small	0.91
		Low	0.91
		Medium	0.91
		High	0.92
	≥ 2 gal	Very Small	$0.8086 - (0.0050 \times V_{eff})$
		Low	$0.9123 - (0.0020 \times V_{eff})$
		Medium	$0.9252 - (0.0015 \times V_{eff})$
		High	$0.9350 - (0.0011 \times V_{eff})$
Grid-Enabled Water Heater	> 75 gal	Very Small	$1.0136 - (0.0028 \times V_{eff})$
		Low	$0.9984 - (0.0014 \times V_{eff})$
		Medium	$0.9853 - (0.0010 \times V_{eff})$
		High	$0.9720 - (0.0007 \times V_{eff})$

* V_{eff} is the Effective Storage Volume (in gallons), as determined pursuant to 10 CFR 429.17.
** As discussed in section II.B.3 of this document, DOE is still considering amended energy conservation standards for gas-fired instantaneous water heaters.

BILLING CODE 6450–01–C

A. Benefits and Costs to Consumers

Table I.2 summarizes DOE's evaluation of the economic impacts of the adopted standards on consumers of consumer water heaters, as measured by the average life-cycle cost (''LCC'') savings and the simple payback period (''PBP'').[3] The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of consumer water heaters, which is estimated to be about 15 years for storage water heaters (*see* section IV.F of this document).

Table I.2 Impacts of Adopted Energy Conservation Standards on Consumers of Consumer Water Heaters

Product Class	Effective Storage Volume and Input Rating *(if applicable)*	Average LCC Savings *2022$*	Simple Payback *years*
Gas-fired Storage Water Heater	≥20 gal and ≤55 gal	29	9.1
Oil-fired Storage Water Heater	≤50 gal	141	6.5
Electric Storage Water Heaters	Small Electric Storage Water Heaters ≥20 gal and ≤35 gal (<51 gal FHR)	N/A	N/A
	≥20 gal and ≤55 gal, Excluding Small Electric Storage Water Heaters	859	5.6
	>55 gal and ≤120 gal	458	0.2

DOE's analysis of the impacts of the adopted standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers

The industry net present value (''INPV'') is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2023–2059). Using a real discount rate of 9.6 percent, DOE estimates that the INPV for manufacturers of consumer water heaters in the case without amended standards is $1,478.8 million in 2022$. Under the adopted standards, DOE estimates the change in INPV to range

[3] The average LCC savings refer to consumers that are affected by a standard and are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of new or amended standards (*see* section IV.F.9 of this document). The simple PBP, which is designed to compare specific efficiency levels, is measured relative to the baseline product (*see* section IV.C of this document).

from −18.6 percent to 1.9 percent, which is a loss of $275.3 million to a gain of $28.2 million. In order to bring products into compliance with amended standards, it is estimated that industry will incur total conversion costs of $239.8 million.

DOE's analysis of the impacts of the adopted standards on manufacturers is described in sections IV.J and V.B.2 of this document.

C. National Benefits and Costs [4]

DOE's analyses indicate that the adopted energy conservation standards for consumer water heaters would save a significant amount of energy. Relative to the case without amended standards, the lifetime energy savings for consumer water heaters purchased in the 30-year period that begins in the anticipated year of compliance with the amended standards (2030–2059), amount to 17.6 quadrillion British thermal units (''Btu''), or quads.[5] This represents a savings of 10 percent relative to the energy use of these products in the case without amended standards (referred to as the ''no-new-standards case'').

The cumulative net present value (''NPV'') of total consumer benefits of the standards for consumer water heaters ranges from $25 billion (at a 7-percent discount rate) to $82 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product and installation costs for consumer water heaters purchased during the period 2030–2059.

In addition, the adopted standards for consumer water heaters are projected to yield significant environmental benefits. DOE estimates that the standards will result in cumulative emission reductions (over the same period as for energy savings) of 332 million metric tons (''Mt'') [6] of carbon dioxide (''CO_2''), 90 thousand tons of sulfur dioxide (''SO_2''), 665 thousand tons of nitrogen oxides (''NO_X''), 3,058 thousand tons of methane (''CH_4''), 2.9 thousand tons of nitrous oxide (''N_2O''), and 0.6 tons of mercury (''Hg'').[7]

DOE estimates the value of climate benefits from a reduction in greenhouse gases (''GHG'') using four different estimates of the social cost of CO_2 (''SC–CO_2''), the social cost of methane (''SC–CH_4''), and the social cost of nitrous oxide (''SC–N_2O''). Together these represent the social cost of GHG (''SC–GHG''). DOE used interim SC–GHG values (in terms of benefit per ton of GHG avoided) developed by an Interagency Working Group on the Social Cost of Greenhouse Gases (''IWG'').[8] The derivation of these values is discussed in section IV.L of this document. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3-percent discount rate are estimated to be $17 billion. DOE does not have a single central SC–GHG point estimate and it emphasizes the value of considering the benefits calculated using all four sets of SC–GHG estimates. DOE notes, however, that the adopted standards would be economically justified even without inclusion of monetized benefits of reduced GHG emissions.

DOE estimated the monetary health benefits of SO_2 and NO_X emissions reductions, using benefit per ton estimates from the Environmental Protection Agency,[9] as discussed in section IV.L of this document. DOE estimated the present value of the health benefits would be $12 billion using a 7-percent discount rate, and $33 billion using a 3-percent discount rate.[10] DOE is currently only monetizing health benefits from changes in ambient fine particulate matter ($PM_{2.5}$) concentrations from two precursors (SO_2 and NO_X), and from changes in ambient ozone from one precursor (for NO_X), but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

Table I.3 summarizes the monetized benefits and costs expected to result from the amended standards for consumer water heaters. There are other important unquantified effects, including certain unquantified climate benefits, unquantified public health benefits from the reduction of toxic air pollutants and other emissions, unquantified energy security benefits, and distributional effects, among others.

BILLING CODE 6450–01–P

[4] All monetary values in this document are expressed in 2022 dollars.

[5] The quantity refers to full-fuel-cycle (FFC) energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, *see* section IV.H.1 of this document.

[6] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

[7] DOE calculated emissions reductions relative to the no-new-standards-case, which reflects key assumptions in the *Annual Energy Outlook 2023* (''*AEO2023*''). *AEO2023* reflects, to the extent possible, laws and regulations adopted through mid-November 2022, including the Inflation Reduction Act. *See* section IV.K of this document for further discussion of *AEO2023* assumptions that affect air pollutant emissions.

[8] To monetize the benefits of reducing GHG emissions this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Intereim Estimates Under Executive Order 13990* published in February 2021 by the IWG. (''February 2021 SC–GHG TSD''). *www.whitehouse.gov/wp-content/uploads/2021/02/Technical/SupportDocument_SocialCostof CarbonMethaneNitrousOxide.pdf.*

[9] U.S. EPA. Estimating the Benefit per Ton of Reducing Directly Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Available at *www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

[10] DOE estimates the economic value of these emissions reductions resulting from the considered TSLs for the purpose of complying with the requirements of Executive Order 12866.

Table I.3 Summary of Monetized Benefits and Costs of Adopted Energy Conservation Standards for Consumer Water Heaters

	Billion $2022
3% discount rate	
Consumer Operating Cost Savings	124
Climate Benefits*	17
Health Benefits**	33
Total Benefits†	175
Consumer Incremental Product Costs‡	42
Net Benefits	132
Change in Producer Cashflow (INPV)‡‡	(0.28) - 0.03
7% discount rate	
Consumer Operating Cost Savings	47
Climate Benefits* (3% discount rate)	17
Health Benefits**	12
Total Benefits†	76
Consumer Incremental Product Costs‡	22
Net Benefits	54
Change in Producer Cashflow (INPV)‡‡	(0.28) - 0.03

Note: This table presents the costs and benefits associated with consumer water heaters shipped during the period 2030–2059. These results include consumer, climate, and health benefits that accrue after 2059 from the products shipped during the period 2030–2059.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate) (see section IV.L of this document). Together these represent the global SC-GHG. For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown; however, DOE emphasizes the value of considering the benefits calculated using all four sets of SC-GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.L of this document for more details.

† Total and net benefits include those consumer, climate, and health benefits that can be quantified and monetized. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.*, manufacturer impact analysis, or "MIA"). *See* section IV.J of this document. In the

detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. Change in INPV is calculated using the industry weighted average cost of capital value of 9.6 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the final rule technical support document ("TSD") for a complete description of the industry weighted average cost of capital). For consumer water heaters, the change in INPV ranges from -$275 million to $28 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A-4 and E.O. 12866. If DOE were to include the INPV into the net benefit calculation for this final rule, the net benefits would range from $131.7 billion to $132.0 billion at 3-percent discount rate and would range from $53.7 billion to $54.0 billion at 7-percent discount rate.

BILLING CODE 6450–01–C

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are (1) the reduced consumer operating costs, minus (2) the increase in product purchase prices and installation costs, plus (3) the value of climate and health benefits of emission reductions, all annualized.[11]

The national operating cost savings are domestic private U.S. consumer monetary savings that occur as a result of purchasing the covered products and are measured for the lifetime of consumer water heaters shipped during the period 2030–2059. The benefits associated with reduced emissions achieved as a result of the adopted standards are also calculated based on the lifetime of consumer water heaters shipped during the period 2030–2059. Total benefits for both the 3-percent and 7-percent cases are presented using the average GHG social costs with 3-percent discount rate. Estimates of total benefits are presented for all four SC–GHG value discount rates in section IV.L.1 of this document.

Table I.4 presents the total estimated monetized benefits and costs associated with the proposed standard, expressed in terms of annualized values. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced NO_X and SO_2 emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the standards adopted in this rule is $2,623 million per year in increased equipment costs, while the estimated annual benefits are $5,655 million in reduced equipment operating costs, $1,051 in monetized climate benefits, and 1,416 in monetized health benefits. In this case, the net benefit would amount to $5,499 per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the standards is $2,586 million per year in increased equipment costs, while the estimated annual benefits are $7,566 million in reduced operating costs, $1,051 million in monetized climate benefits, and $2,033 million in monetized health benefits. In this case, the net benefit would amount to $8,065 million per year.

BILLING CODE 6450–01–P

[11] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2022, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2020 or 2030), and then discounted the present value from each year to 2022. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

Table I.4 Annualized Benefits and Costs of Adopted Standards for Consumer Water Heaters

	Million 2022$/year		
	Primary Estimate	Low-Net-Benefits Estimate	High-Net-Benefits Estimate
3% discount rate			
Consumer Operating Cost Savings	7,566	7,078	8,065
Climate Benefits*	1,051	1,039	1,063
Health Benefits**	2,033	2,009	2,058
Total Benefits†	10,650	10,125	11,186
Consumer Incremental Product Costs‡	2,586	3,023	2,398
Net Benefits	8,065	7,102	8,788
Change in Producer Cashflow (INPV)‡‡	(28) - 3	(28) - 3	(28) - 3
7% discount rate			
Consumer Operating Cost Savings	5,655	5,294	6,024
Climate Benefits* (3% discount rate)	1,051	1,039	1,063
Health Benefits**	1,416	1,400	1,432
Total Benefits†	8,122	7,732	8,519
Consumer Incremental Product Costs‡	2,623	2,984	2,467
Net Benefits	5,499	4,748	6,052
Change in Producer Cashflow (INPV)‡‡	(28) - 3	(28) - 3	(28) - 3

Note: This table presents the costs and benefits associated with consumer water heaters shipped during the period 2030–2059. These results include consumer, climate, and health benefits that accrue after 2059 from the products shipped during the period 2030–2059. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the *AEO2023* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a low decline rate in the Low Net Benefits Estimate, and a high decline rate in the High Net Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.F.4 of this document. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC-GHG (see section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown; however, DOE emphasizes the value of considering the benefits calculated using all four sets of SC-GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of this document for more details.

† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate.

‡ Costs include incremental equipment costs as well as installation costs.

‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts

analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.*, manufacturer impact analysis, or "MIA"). *See* section IV.J of this document. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 9.6 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the final rule TSD for a complete description of the industry weighted average cost of capital). For consumer water heaters, the annualized change in INPV ranges from -$28 million to $3 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A-4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this final rule, the annualized net benefits would range from $8,037 million to $8,068 million at 3-percent discount rate and would range from $5,471 million to $5,502 million at 7-percent discount rate.

BILLING CODE 6450–01–C

DOE's analysis of the national impacts of the adopted standards is described in sections IV.H, IV.K, and IV.L of this document.

D. Conclusion

DOE concludes that the standards adopted in this final rule represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy. Specifically with regards to technological feasibility, products achieving these standard levels are already commercially available for all product classes covered by this rule. As for economic justification, DOE's analysis shows that the estimated benefits of the standards exceed, to a great extent, the estimated burdens of the standards.

Using a 7-percent discount rate for consumer benefits and costs and NO_X and SO_2 reduction benefits, and a 3-percent discount rate case for GHG social costs, the estimated cost of the standards for consumer water heaters is $2,623 million per year in increased product costs, while the estimated annual benefits are $5,655 million in reduced product operating costs, $1,051 million in climate benefits, and $1,416 million in health benefits. The net benefit amounts to $5,499 million per year.

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[12] For example, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis.

As previously mentioned, the standards are projected to result in estimated cumulative national energy savings of 17.6 quads (full-fuel cycle (''FFC'')), the equivalent of the primary annual energy use of 116 million homes. In addition, they are projected to reduce CO_2 emissions by 332 Mt. Based on these findings, DOE has determined the energy savings from the standard levels adopted in this final rule are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B). A more detailed discussion of the basis for these conclusions is contained in the remainder of this document and the accompanying TSD.

[12] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

II. Introduction

The following section briefly discusses the statutory authority underlying this final rule, as well as some of the relevant historical background related to the establishment of standards for consumer water heaters.

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include consumer water heaters, the subject of this document. (42 U.S.C. 6292(a)(4)) EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(e)(1)), and directs DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(e)(4)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

The energy conservation program under EPCA, consists essentially of four parts: (1) testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4)

certification and enforcement procedures. Relevant provisions of the EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (*See* 42 U.S.C. 6297(d))

Subject to certain statutory criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and 42 U.S.C. 6295(r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for consumer water heaters appear at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix E (''appendix E'').

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including consumer water heaters. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary of Energy determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3))

Moreover, DOE may not prescribe a standard (1) for certain products, including consumer water heaters, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (''Secretary'') considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA, as codified, also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of products that has the same function or intended use if DOE determines that products within such group (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Finally, pursuant to the amendments contained in the Energy Independence and Security Act of 2007 (EISA 2007), Public Law 110–140, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) In this rulemaking, DOE is applying the UEF metric (which addresses standby mode and off mode energy use) to all product classes of consumer water heaters, including those product classes for which there are no currently applicable UEF-based standards.

B. Background

1. Current Standards

As directed by EPCA (42 U.S.C. 6295(e)(4)), DOE conducted two cycles of rulemakings to determine whether to amend the statutory standards for consumer water heaters found in 42 U.S.C. 6295(e)(1). The most recent rulemaking from April 2010 resulted in amended standards using the energy factor (''EF'') metric originally prescribed by EPCA with a requirement for compliance starting on April 16, 2015. 75 FR 20112 (the ''April 2010 Final Rule''). Later amendments to

EPCA directed DOE to establish a uniform efficiency metric for consumer water heaters (*see* 42 U.S.C. 6295(e)(5)(B)).[13] The Federal test procedure was revised to use a new metric, UEF, in a final rule published on July 11, 2014 (the ''July 2014 UEF TP Final Rule''). 79 FR 40542. In a final rule published in the **Federal Register** on December 29, 2016, the existing EF-based energy conservation standards were then translated from EF to UEF using a ''conversion factor'' method for water heater basic models that were in existence at the time. 81 FR 96204 (''December 2016 Conversion Factor Final Rule'').

These standards are set forth in DOE's regulations at 10 CFR 430.32(d) and are repeated in Table II.1.

BILLING CODE 6450–01–P

[13] The requirement for a consumer water heater test procedure using uniform energy factor as a metric, as well as the requirement for DOE to undertake a conversion factor rulemaking to translate existing consumer water heater standards denominated in terms of EF to ones denominated in terms of UEF, were part of the amendments to EPCA contained in the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (Dec. 18, 2012).

Table II.1 Current UEF-Based Federal Energy Conservation Standards for Consumer Water Heaters

Product Class	Rated Storage Volume and Input Rating *(if applicable)*	Draw Pattern*	Uniform Energy Factor**
Gas-fired Storage Water Heater	≥ 20 gal and ≤ 55 gal	Very Small	$0.3456 - (0.0020 \times V_r)$
		Low	$0.5982 - (0.0019 \times V_r)$
		Medium	$0.6483 - (0.0017 \times V_r)$
		High	$0.6920 - (0.0013 \times V_r)$
	> 55 gal and ≤ 100 gal	Very Small	$0.6470 - (0.0006 \times V_r)$
		Low	$0.7689 - (0.0005 \times V_r)$
		Medium	$0.7897 - (0.0004 \times V_r)$
		High	$0.8072 - (0.0003 \times V_r)$
Oil-fired Storage Water Heater	≤ 50 gal	Very Small	$0.2509 - (0.0012 \times V_r)$
		Low	$0.5330 - (0.0016 \times V_r)$
		Medium	$0.6078 - (0.0016 \times V_r)$
		High	$0.6815 - (0.0014 \times V_r)$
Electric Storage Water Heaters	≥ 20 gal and ≤ 55 gal	Very Small	$0.8808 - (0.0008 \times V_r)$
		Low	$0.9254 - (0.0003 \times V_r)$
		Medium	$0.9307 - (0.0002 \times V_r)$
		High	$0.9349 - (0.0001 \times V_r)$
	> 55 gal and ≤ 120 gal	Very Small	$1.9236 - (0.0011 \times V_r)$
		Low	$2.0440 - (0.0011 \times V_r)$
		Medium	$2.1171 - (0.0011 \times V_r)$
		High	$2.2418 - (0.0011 \times V_r)$
Tabletop Water Heater	≥ 20 gal and ≤ 120 gal	Very Small	$0.6323 - (0.0058 \times V_r)$
		Low	$0.9188 - (0.0031 \times V_r)$
		Medium	$0.9577 - (0.0023 \times V_r)$
		High	$0.9884 - (0.0016 \times V_r)$
Instantaneous Gas-fired Water Heater	< 2 gal and >50,000 Btu/h	Very Small	0.80
		Low	0.81
		Medium	0.81
		High	0.81
Instantaneous Electric Water Heater	< 2 gal	Very Small	0.91
		Low	0.91
		Medium	0.91
		High	0.92
Grid-enabled Water Heater	> 75 gal	Very Small	$1.0136 - (0.0028 \times V_r)$
		Low	$0.9984 - (0.0014 \times V_r)$
		Medium	$0.9853 - (0.0010 \times V_r)$
		High	$0.9720 - (0.0007 \times V_r)$

* The draw pattern dictates the frequency and duration of hot water draws during the 24-hour simulated use test, and is an indicator of delivery capacity of the water heater. Draw patterns are assigned based on the first hour rating ("FHR"), for non-flow-activated water heaters, or maximum GPM rating ("Max GPM"), for flow-activated water heaters. For the specific FHR and Max GPM ranges which correspond to each draw pattern, see section 5.4.1 of appendix E to subpart B of 10 CFR part 430.

** V_r is the rated storage volume (in gallons), as determined pursuant to 10 CFR 429.17.

BILLING CODE 6450–01–C

In the December 2016 Conversion Factor Final Rule, DOE declined to develop conversion factors and UEF-based standards for consumer water heaters of certain sizes (by rated storage volume or input rating) and of certain types (*i.e.,* oil-fired instantaneous water heaters) where models did not exist on the market at the time to inform the analysis of the standards conversion. 81 FR 96204, 96210–96211. For consumer water heaters that did not receive converted UEF-based standards, DOE provided its interpretation that the original statutory standards—found at 42 U.S.C. 6295(e)(1) and expressed in terms of the EF metric—still applied; however, DOE would not enforce those statutorily-prescribed standards until such a time conversion factors are developed for these products and they can be converted to UEF. *Id.* Thus, the EF-based standards specified by EPCA apply to any consumer water heaters which do not have UEF-based standards found at 10 CFR 430.32(d). These EF-based standards are set forth at 42 U.S.C. 6295(e)(1) and are repeated in Table II.2.

Table II.2 EF-Based Federal Energy Conservation Standards for Consumer Water Heaters

Product Class	Energy Factor*
Gas water heaters	$0.62 - (0.0019 \times V_r)$
Oil water heaters	$0.59 - (0.0019 \times V_r)$
Electric water heaters	$0.95 - (0.00132 \times V_r)$

* V_r is the rated storage volume (in gallons), as determined pursuant to 10 CFR 429.17.

2. History of Standards Rulemaking for Consumer Water Heaters

On May 21, 2020, DOE initiated the current rulemaking by publishing in the **Federal Register** a request for information (''May 2020 RFI''), soliciting public comment on various aspects of DOE's planned analyses to help DOE determine whether to amend energy conservation standards for consumer water heaters. 85 FR 30853 (May 21, 2020). DOE subsequently published a notice requesting feedback on its preliminary analysis and technical support document (''preliminary TSD'') on March 1, 2022 (the ''March 2022 Preliminary Analysis'') with a 60-day comment period. 87 FR 11327 (Mar. 1, 2022). The comment period was extended by 14 days in a notice published on May 4, 2022. 87 FR 26303.

On October 21, 2022, DOE received a set of recommendations on amended energy conservation standards for consumer water heaters from a coalition of seven public- and private-sector organizations, including two water heater manufacturers, three energy efficiency organizations, one environmental group, and one consumer organization—collectively the Joint Stakeholders [14]—which addressed standards for electric storage water heaters, gas-fired storage water heaters, and gas-fired instantaneous water heaters. This coalition's submission is herein referred to as the ''Joint Stakeholder Recommendation.''

On July 28, 2023, DOE published in the **Federal Register** a notice of proposed rulemaking (''July 2023 NOPR'') and technical support document (''NOPR TSD'') with a 60-day comment period. 88 FR 49058 (Jul. 28, 2023). In the July 2023 NOPR, DOE proposed new and amended standards for consumer water heaters and addressed stakeholder feedback on the March 2022 Preliminary Analysis, including the Joint Stakeholder Recommendation. On September 13, 2023, DOE presented the proposed standards and accompanying analysis at a public meeting.

DOE received 2,950 comments in response to the July 2023 NOPR from interested parties, some of which were docketed together as multiple comments or commenters, resulting in a total of 1,140 docketed items. Note that of these total comments, 2,800 comments were ''form letter'' email submissions. In total, four distinct form letters were received. Additionally, several commenters submitted more than one comment to the docket. DOE directly references 54 of these written submissions in this final rule, which contain substantive comments regarding product classes within the scope of this final rule and are shown in Table II.3. The remainder of the comments were from individual commenters either expressing general opposition or support for the rulemaking. Total counts of both supportive and non-supportive comments received are included in section III.A of this document.

BILLING CODE 6450–01–P

[14] In this final rule, ''Joint Stakeholders'' refers to the group of stakeholders who submitted and continued to support the October 21, 2022, comment even though the makeup of this group has changed since the July 2023 NOPR. Specifically, BWC removed itself as a signatory after the July 2023 NOPR.

Table II.3 List of Commenters with Written Submissions in Response to the July 2023 NOPR

Commenter(s)	Abbreviation	Comment No. in the Docket	Commenter Type
GreenTECH Innovation Corp	GreenTECH	0071	Manufacturer
Individual	Ravnitzky	0073	Individual
NPGA, APGA, AGA, and Rinnai	NPGA, APGA, AGA, and Rinnai	0441	Trade Associations and Manufacturer
Crystal IS, Inc.	Crystal	0577	Manufacturer
Uponor, Inc.	Uponor	0606	Manufacturer
American Enterprise Institute	AEI	0817	Consumer Advocate
Jackson Energy Authority	JEA	0865	Utility
Watertown Municipal Utilities	WMU	0872	Utility
Southeast Gas	Southeast Gas	0887	Utility
Sunrise Movement Pittsburgh	Sunrise Pittsburgh	0905	Consumer Advocate
Tennessee Valley Authority	TVA	0978	Utility
National Apartment Association and National Multifamily Housing Council	NMHC and NAA	0996	Trade Association
Chesapeake Utilities Corporation	CHPK	1008	Utility
Attorneys General of NY, CO, CT, IL, ME, MD, MN, NV, OR, VT, WA, MA, PA, DC, NYC	Joint State Attorneys General	1035	State Official/Agency
Advanced Water Heating Initiative	AWHI	1036	Efficiency Organization
Eccotemp Systems, LLC	Ecotemp	1092	Manufacturer
National Rural Electric Cooperative Association	NRECA	1127	Utility Association
Gas Analytics and Advisory Services, LLC (GAAS) (Formally Gas End-use Advocacy Group GEAG)	GAAS	1139	Utility Association
National Caucus of Environmental Legislators	NCEL	1144	Utility Association

Commenter(s)	Abbreviation	Comment No. in the Docket	Commenter Type
Tennessee Attorney General's Office	Attorney General of TN	1149	State Official/Agency
Plumbing-Heating-Cooling Contractors Association	PHCC	1151	Trade Association
Midwest Energy Efficiency Alliance, Northeast Energy Efficiency Partnerships, Northwest Energy Efficiency Alliance, South-central Partnership for Energy Efficiency as a Resource, Southeast Energy Efficiency Alliance, Southwest Energy Efficiency Project	Joint Regional Advocacy Groups	1154	Efficiency Organization
American Council for an Energy-Efficient Economy, Natural Resources Defense Council, Appliance Standards Awareness Project, Northwest Energy Efficiency Alliance, Consumer Federation of America, Rheem Manufacturing	Joint Stakeholders	1156	Coalition
Puget Sound Energy, Until, Avangrid, ConEd, PG&E Corporation, National Grid, Eversource	Joint Utilities	1158	Utility Associations
153 various organizations	Joint Commenters	1159	Efficiency Organization, Coalition, Environmental/Consumer Advocate
American Supply Association	ASA	1160	Efficiency Organization
Bradford White Corporation	BWC	1164	Manufacturer
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, CLASP, Natural Resources Defense Council, Oregon Department of Energy, Southwest Energy Efficiency Project, Washington State Department of Commerce	Joint Advocacy Groups	1165	Efficiency Organization
Air-conditioning, Heating, and Refrigeration Institute	AHRI	1167	Trade Association
RV Industry Association	RVIA	1168	Trade Association
New York State Public Service Commission	NYSPSC	1169	State Official/Agency
Association for Energy Affordability, Green & Healthy Homes Initiative, Consumer Federation of America, NC Justice Center, Consumer Reports, Pennsylvania Utility Law Project, Green Energy Consumers Alliance, Poder Latinx	Consumer Advocates	1172	Consumer Advocate
California Energy Commission	CEC	1173	State Official/Agency
Pacific Gas and Electric Company; Southern California Edison; and San Diego Gas & Electric Company	CA IOUs	1175	Utility
Rheem Manufacturing Company	Rheem	1177	Manufacturer

Commenter(s)	Abbreviation	Comment No. in the Docket	Commenter Type
American Lung Association, American Public Health Association, Asthma and Allergy Foundation of America, Climate Psychiatry Alliance, National Association of Pediatric Nurse Practitioners, Physicians for Social Responsibility, Public Health Institute	Health Advocates	1179	Consumer Advocate
AGA, APGA, NPGA, Spire	Gas Association Commenters	1181	Utility Association
A. O. Smith Corporation	A.O. Smith	1182	Manufacturer
Atmos Energy	Atmos Energy	1183	Utility
Electric Cooperatives of South Carolina	ECSC	1185	Utility Association
Rinnai America Corporation	Rinnai	1186	Manufacturer
Multiple Individual Architecture Firms	Joint Architects	1188	Trade Association
Earthjustice	Earthjustice	1189	Efficiency Organization
SkyCentrics	SkyCentrics	1191	Manufacturer
New York State Energy Research and Development Authority	NYSERDA	1192	State Official/Agency
Armada Power, LLC	Armada	1193	Manufacturer
Essency Water Heaters	Essency	1194	Manufacturer
Physicians for Social Responsibility	PSR	1196	Consumer Advocate
Individual	Stanonik	1197	Individual
Edison Electric Institute	EEI	1198	Utility Association
Northwest Energy Efficiency Alliance	NEEA	1199	Efficiency Organization
ONE Gas, Inc.	ONE Gas	1200	Utility
Noritz America Corporation	Noritz	1202	Efficiency Organization
GE Appliances, a Haier company	GEA	1203	Manufacturer
Robert Bosch LLC	Bosch	1204	Manufacturer
Vermont Department of Public Service, New Jersey Board of Public Utilities, Maine Governor's Energy Office, New York State Energy Research and Development Authority, Washington State Department of Commerce, Government of the District of Columbia, Colorado Energy Office, Maryland Energy Administration, New Mexico State Energy Office, Oregon Department of Energy	State Agencies	1213	State Official/Agency

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[15] To the extent that interested parties have provided written comments that are substantively consistent with any oral comments provided during the September 13, 2023, public meeting, DOE cites the written comments throughout this final rule. Any oral comments provided during the webinar that are not substantively addressed by written comments are summarized and cited separately throughout this final rule.

Additionally, DOE received comments from stakeholders in response to the July 2023 NOPR regarding the scope and classification of circulating water heaters as defined at 10 CFR 430.2 by the June 2023 TP Final

[15] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for consumer water heaters. (Docket No. EERE–2017–BT–STD–0019, which is maintained at *www.regulations.gov*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

Rule. DOE subsequently published a supplemental notice of proposed rulemaking on December 27, 2023 (''December 2023 SNOPR''), that discussed the comments received on this topic and proposed to amend the definition for ''circulating water heater'' to reclassify these products as storage-type water heaters. 88 FR 89330. DOE received 195 comments in response to the December 2023 SNOPR from interested parties. DOE directly references 14 of these written submissions which provided remarks about the rulemaking analysis pertinent to standards for circulating water heaters or comments relevant to the issues discussed in the December 2023 SNOPR, and these submissions are shown in Table II.4.

Table II.4 List of Commenters with Written Submissions in Response to the December 2023 SNOPR

Commenter(s)	Abbreviation	Comment No. in the Docket	Commenter Type
Individual	Great Plains Resource	1267	Individual
Individual	Johnson	1271	Individual
Individual	Harley	1341	Individual
Air-conditioning, Heating, and Refrigeration Institute	AHRI	1389	Trade Association
Francis R. Pickering	Pickering	1399	Individual
New York State Energy Research and Development Authority	NYSERDA	1406	State Official/Agency
Appliance Standards Awareness Project; American Council for an Energy-Efficient Economy; National Consumer Law Center; Natural Resources Defense Council	ASAP et al.	1407	Efficiency Organization
Rheem Manufacturing Company	Rheem	1408	Manufacturer
Pacific Gas and Electric Company; Southern California Edison; San Diego Gas & Electric Company	CA IOUs	1409	Utility
A.O. Smith Corporation	A.O. Smith	1411	Manufacturer
California Energy Commission	CEC	1412	State Official/Agency
Bradford White Corporation	BWC	1413	Manufacturer
Northwest Energy Efficiency Alliance	NEEA	1414	Efficiency Organization
Rinnai America Corporation	Rinnai	1415	Manufacturer

BILLING CODE 6450–01–C

3. Scope of This Final Rule

Following review of comments on the July 2023 NOPR and December 2023 SNOPR, DOE has decided to finalize at this time standards for all consumer water heaters with the exception of gas-fired instantaneous water heaters, as defined in 10 CFR 430.2 and replicated in section III.B of this final rule. DOE is not summarizing or responding to any comments specific to gas-fired instantaneous water heaters in this document, nor discussing any analytical methodologies or results for this product class as DOE continues to consider the comments submitted in response to the July 2023 NOPR and December 2023 SNOPR in informing DOE's decision on amended energy conservation standards for GIWHs.

III. General Discussion

DOE developed this final rule after considering oral and written comments, data, and information from interested parties that represent a variety of interests. The following discussion addresses issues raised by these commenters.

A. General Comments

This section summarizes general comments received from interested parties regarding rulemaking timing and process.

1. General Support

In response to the July 2023 NOPR, DOE received 966 [16] general comments (those which provided general remarks on the impact of the rulemaking) [17] related to product classes within the scope of this final rule, with 931, or 96 percent of, these comments expressing support of the proposed standards and a majority acknowledging the significant energy savings that would result from the adoption of the proposed standards.[18]

NYSERDA, GreenTECH, the CA IOUs, NCEL, Joint Regional Advocacy Groups, Joint Stakeholders, Joint Utilities, Joint Commenters, Joint Advocacy Groups, NYSPSC, Consumer Advocates, Health

[16] The number of comments reflects the number of individual party submissions. Specifically, form letters with multiple submissions count each submission individually.

[17] Commenters who are directly referenced in this final rule and appear in Table II.3 are not counted in these statistics because these submitters typically expressed detailed views that could not be generalized as either clear support or clear opposition for all aspects of the proposal.

[18] One comment in support of the proposed standards had 8,357 signatories.

Advocates, Joint Architects, PSR, NEEA and State Agencies all stated their support of the standards proposed in the July 2023 NOPR. These commenters highlighted the associated benefits of the proposal including utility bill savings, reduced GHG emissions, protection of human health, reduced energy consumption, and the ability to design more energy efficient buildings. (NYSERDA, No. 1192 at p. 1; GreenTECH, No. 71 at p. 1; CA IOUs, No. 1175 at pp. 1–2; NCEL, No. 1144 at p. 1; Joint Regional Advocacy Groups, No. 1154 at p. 1; Joint Stakeholders, No. 1156 at p. 1; Joint Utilities, No. 1158 at p. 1; Joint Commenters, No. 1159 at p. 1–2; Joint Advocacy Groups, No. 1165 at p. 1; NYSPSC, No. 1169 at p. 1; Consumer Advocates, No. 1172 at p. 1; Health Advocates, No. 1179 at p. 1; Joint Architects, No. 1188 at p. 1; PSR, No. 1196 at p. 1–2; NEEA, No. 1199 at p. 2; State Agencies, No. 1213 at p. 1–2)

NCEL noted that, according to a report by the Appliance Standards Awareness Project, water heaters represent the largest potential for emissions reductions among regulated consumer products, and the proposed standards would reduce CO_2 emissions by more than 500 Mt over 30 years of sales, helping the United States meet its climate goals. (NCEL, No. 1144 at p. 1) The Joint Regional Advocacy Groups supported, specifically, the proposed standards for electric storage water heaters at heat pump efficiency levels. (Joint Regional Advocacy Groups, No. 1154 at p. 1) The Joint State Attorneys General also commented in support of the proposed standards for consumer water heaters and recommended that DOE finalize the proposed rule as soon as possible. The Joint State Attorneys General further emphasized that the proposed standards would significantly improve the energy efficiency of both electric and gas water heaters while providing economic benefits to consumers. The Joint State Attorneys General stated that the proposed standards for consumer water heaters are projected to yield significant environmental benefits, climate benefits, and monetized health benefits. The Joint State Attorneys General also commented that the transition to more efficient consumer water heating will be increasingly cost effective and affordable as time progresses, particularly considering the Federal investment in weatherization, energy efficiency, and beneficial electrification programs that would help address cost concerns related to installing new or replacement products. (Joint State Attorneys General, No. 1035 at pp. 1–3) State Agencies claimed that while State regulations have the potential to reduce GHG emissions, individual States cannot adopt standards for products for which the Federal government has promulgated an existing standard (such as consumer water heaters) and that collaboration is required for impactful climate action. (State Agencies, No. 1213 at p. 1) DOE understands the commenter to be referring to provisions at 42 U.S.C. 6297, by which Federal energy standards supersede State regulations with exceptions for certain products that do not include consumer water heaters. State Agencies also indicated that the proposed standards would reduce the energy burden for low-income households, which spend larger portions of their income on energy bills. (State Agencies, No. 1213 at p. 2)

Rheem generally supported DOE's proposed amended standards and the analysis behind them but expressed concern regarding potential unintended consequences of the proposed standards for certain product classes caused in part by the application of the high-temperature test method and effective storage volume metric. Rheem suggested possible solutions to resolve these issues, which are discussed further in section V.D of this document. (Rheem, No. 1177 at p. 1) Rheem stated that, for electric storage water heaters between 20 and 120 gallons (except for small electric storage water heaters), heat pump-level standards are appropriate. Rheem recommended that DOE act to prevent a market shift away from heat pump technologies if standards are amended to require this for a larger fraction of the electric storage water heater market because not only would it result in reduction of energy savings, but it also would pose a risk to manufacturers' return on investment in heat pump water heater development in a timely manner. Rheem noted that there would be significant changes to product design and manufacturing facilities as a result of a heat pump standard in this rulemaking. (*Id.* at p. 7)

The Joint Stakeholders stated that the proposed standards for gas-fired water heaters are consistent with their recommendations and noted that the proposal follows the established rationale that separate standards be maintained for gas-fired storage water heaters and their instantaneous counterparts. (Joint Stakeholders, No. 1156 at p. 2) NEEA, the Joint Regional Advocacy Groups (citing the estimated FFC and monetary savings), and Bosch supported the proposed standards for gas-fired storage water heaters. (NEEA, No. 1199 at p. 9; Joint Regional Advocacy Groups, No. 1154 at p. 1; Bosch, No. 1204 at p. 2)

The CA IOUs encouraged DOE to set more stringent standards for gas-fired storage water heaters. According to the CA IOUs, more stringent standards for all gas-fired consumer water heater subclasses, specifically at condensing efficiencies, would result in significant savings of natural gas in California and across the United States. (CA IOUs, No. 1175 at p. 2) AWHI also encouraged DOE to set more stringent standards for gas-fired storage water heaters. (AWHI, No. 1036 at pp. 3–4)

NYSERDA stated that the proposals in the July 2023 NOPR substantially aligned with the Joint Stakeholder Recommendation, which was supported by NYSERDA. The commenter noted that, by allowing less stringent standards for small electric storage water heaters, DOE would ensure that there are replacement units available for lowboy water heaters, while still allowing innovation and expansion for heat pump water heaters. (NYSERDA, No. 1192 at p. 2)

Additionally, some commenters offered general support in response to the December 2023 SNOPR.

NYSERDA commented that the proposals in the December 2023 SNOPR fully address their concerns raised at the NOPR stage regarding the potential use of electric resistance circulating water heaters in place of heat pump electric storage water heaters. (NYSERDA, No. 1406 at p. 2) NEEA expressed support for the changes proposed in the December 2023 SNOPR and urged DOE to move forward with these proposals, as well as those made in the July 2023 NOPR. (NEEA, No. 1414 at p. 1) NEEA reiterated its support for effective storage volume-based standards and high temperature test methods to prevent small, overheated products from being used in place of products that meet the proposed standards. (NEEA, No. 1414 at p. 2) CEC reiterated its appreciation for DOE's efforts to address potential loopholes in the proposed regulatory language for circulating water heaters and high temperature test methods. (CEC, No. 1412 at p. 2)

2. General Opposition

Of the 966 general comments DOE received in response to the July 2023 NOPR related to product classes within the scope of this final rule, 29, or 3 percent, were in opposition of new standards, with the majority of opposition comments focused on the concerns of government overreach and interference with a free market, impacts on product cost, and overestimation of energy savings. Commenters also

expressed concerns about potential outsourcing to foreign companies due to the proposed standards, installation costs for gas-fired and heat pump water heaters, and the performance of heat pump water heaters. These topics are discussed in this section through section III.A.3 of this document.

Ravnitzky supported DOE's efforts to improve the energy efficiency of consumer water heaters and reduce greenhouse gas emissions but expressed concern for the impact of the proposed standards on consumers and manufacturers. Ravnitzky urged DOE to reconsider the proposed standards and account for the efficiency potential and resiliency benefits of non-heat pump water heaters. (Ravnitzky, No. 73 at p. 1)

Ravnitzky stated that the proposed standards do not account for the resiliency benefits of non-heat pump water heaters, which can operate without electricity. Ravnitzky stated that heat pump water heaters cannot function during a power outage, which could inconvenience consumers and result in health risks. Ravnitzky also stated that gas-fired water heaters are beneficial to consumers prone to natural disasters and extreme weather events that disrupt the power grid because they do not require electricity to operate. (Ravnitzky, No. 73 at p. 1)

Throughout this rulemaking, DOE has assessed the impacts of potential amended standards on consumers and manufacturers, specifically quantifying these impacts as national benefits and costs (*see* section I of this document). In response to the concerns raised by Ravnitzky, DOE notes that gas-fired water heaters will still be available as an option to consumers at the levels adopted in this final rule. Further, DOE notes that, while for certain classes of electric storage water heaters the adopted standards are currently only met through use of heat pump technology, electric storage water heaters that rely on electric resistance technology also require a continuous supply of electricity to operate. Therefore, without a backup supply of electricity a power outage would render both types of electric storage water heaters inoperable. DOE also notes that some gas-fired water heaters do require electricity to operate. However, as discussed in the July 2023 NOPR, DOE maintains its interpretation of EPCA at 42 U.S.C. 6295(q)(1) that gas-fired water heaters that do not require electricity should not be treated differently (*i.e.,* constitute a separate product class) from gas-fired water heaters that do. 88 FR 49058, 49079.

AEI stated its belief that the rule is based on the need to confront the global climate crisis, and therefore it is fatally flawed and should not be finalized due to the lack of evidence of a climate ''threat'' or ''crisis.'' (AEI, No. 817 at p. 2)

DOE is finalizing amendments to the test procedure and energy conservation standards for consumer water heaters based on its authority described in section II.A of this document, which requires the Department to consider seven (7) factors prior to finalizing such amendments. This final rule outlines DOE's analysis of all seven factors, with additional details provided in the TSD.

The Attorney General of TN commented that the proposed standards have significant federalism implications within the meaning of Executive Order 13132 for the following reasons: (1) DOE's standards have a preemptive effect on States' procurement standards; and (2) States own and purchase water heaters, and therefore the proposed standards' effect on water heater costs directly affect States as purchasers. (Attorney General of TN, No. 1149 at pp. 2–3) The Attorney General of TN commented that DOE must show that the intrastate activity covered by the proposed standards substantially affects the interstate market for water heaters and there is no such analysis in the July 2023 NOPR. The Attorney General of TN commented that the proposed standards will dominate the regulation of consumer goods—authority traditionally belonging to the States. (Attorney General of TN, No. 1149 at p. 3)

DOE responds that it believes the scope of both the standard proposed in the July 2023 NOPR and the amended standard adopted in this final rule properly includes all consumer water heaters distributed in commerce for personal use or consumption because intrastate state activity regulated by 42 U.S.C. 6291(17) and 6302 is inseparable from and substantially affects interstate commerce. DOE has clear authority under EPCA to regulate the energy use of a variety of consumer products and certain commercial and industrial equipment, including the subject consumer water heaters. *See* 42 U.S.C. 6295. Based on this statutory authority, DOE has a long-standing practice of issuing energy conservation standards with the same scope as the standard in this final rule. For example, DOE has maintained a similar scope of products in the April 2010 Final Rule and in the December 2016 Conversion Factor Final Rule. DOE disagrees with the Attorney General of TN's contention that the Commerce Clause, the Tenth Amendment, the Major Questions Doctrine, or any canons of statutory construction limit DOE's clear and long-standing authority under EPCA to adopt the standard, including its scope, in this final rule. A further discussion regarding the Attorney General of TN's Federalism concerns can be found at section VI.E of this document.

BWC, a former signatory to the Joint Stakeholder Recommendation, urged DOE to reconsider re-aligning certain aspects of its proposal to what was originally recommended by the Joint Stakeholder Recommendation. (BWC, No. 1164 at p. 1)

The July 2023 NOPR proposed product classes and efficiency levels incorporating the feedback from the Joint Stakeholder Recommendation; however, the Department did not align entirely with the Joint Stakeholder Recommendation. DOE provided its rationale for product class definitions, efficiency level selection, and effective storage volume throughout the July 2023 NOPR (*see* section IV of the July 2023 NOPR). These topics are discussed further in this final rule in sections IV.A.1.f, IV.C.1.a, and V.D.1 of this document, respectively.

BWC noted that the July 2023 NOPR was published only shortly after the June 2023 TP Final Rule, and that this period of time was too short for manufacturers to provide adequate feedback on new aspects of the test procedure, such as effective storage volume and high temperature testing. BWC expressed its concern over this and the 60-day comment period provided for the July 2023 NOPR, noting that these were both deviations from appendix A. The Gas Association Commenters and Rinnai also commented on this deviation, with ASA and the Gas Association Commenters stating that the 60-day comment period was insufficient to develop responses to the July 2023 NOPR and Rinnai stating that DOE did not have an adequate basis to depart from the standard 75-day comment period. ASA recommended extending the comment period to provide commenters additional time for research and feedback and the Gas Association Commenters stated this deviation placed undue burden on commenters to review and evaluate a proposal that could have significant ramifications on the water heater industry and consumers. Rinnai claimed that DOE has rushed the rulemaking process by relying on a preliminary TSD from 2022 and not producing a final TSD with the July 2023 NOPR and believed the compressed schedule between the September 2023 Webinar and the end of the comment period was

unjustified (BWC, No. 1164 at pp. 6–7; Gas Association Commenters, No. 1181, pp. 37–38; Rinnai, No. 1186 at p. 35; ASA, No. 1160 at p. 1) JEA, WMU, and Southeast Gas commented that as members of APGA, they supported APGA's submitted comments that offer more details on their concerns. (JEA, No. 865 at p. 2; WMU, No. 872 at p. 2; Southeast Gas, No. 887 at p. 1)

DOE has determined that the length of the comment period was appropriate and provided a meaningful opportunity to comment on the NOPR. In the July 2023 NOPR, DOE explained its deviation from section 6(f)(2) of 10 CFR part 430, subpart C, appendix A,[19] which specifies that the length of the public comment period for a NOPR be not less than 75 calendar days. However, with respect to NOPRs, EPCA requires at least a 60-day comment period. (42 U.S.C. 6295(p)(2)), and similarly, Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993) states that in most cases a comment period should not be less than 60 days. On April 8, 2024, DOE published in the **Federal Register** a final rule amending section 6 of appendix A to specify that comment periods for standards rulemaking documents will be determined on a case-by-case basis with a minimum 60-day comment period for NOPRs based on the requirements of EPCA and recommendations in E.O. 12866. 89 FR 24360 (April 8, 2024). As discussed in the July 2023 NOPR, DOE determined that a 60-day comment period provided sufficient time because the NOPR relied on many of the same analytical assumptions and approaches as used in the preliminary assessment, on which the public had an opportunity to comment. 88 FR 49058. In particular, a 60-day comment period (followed by 14-day extension) was provided for the March 2022 Preliminary Analysis, and a 45-day period for the May 2020 RFI. 87 FR 11327; 85 FR 30853.

In response to the December 2023 SNOPR, DOE received 176 comments, or 90 percent of comments, in opposition of new standards along similar concerns as those expressed in response to the July 2023 NOPR.

DOE also received feedback from some stakeholders that the comment period provided for the December 2023 SNOPR was too short. AHRI requested that DOE extend the comment period to provide stakeholders adequate time to properly respond. (AHRI, No. 1389 at p. 1) BWC stated that the opportunity to comment on the December 2023 SNOPR was severely limited due to its seasonal timing and comment period duration. (BWC, No. 1413 at p. 3) Rinnai stated that there was little meaningful time for a detailed assessment of the December 2023 SNOPR due to the timing of the comment period and that only a limited number of inputs were collected. (Rinnai, No. 1415 at p. 1)

The scope of the December 2023 SNOPR was limited to a definitional change for circulating water heaters, with only two requests for comment, and therefore DOE believes the comment period was sufficient. The CA IOUs, NEEA, CEC, and NYSERDA expressed support for the December 2023 SNOPR comment period being limited to 14 days because its scope is limited to circulating water heaters. (CA IOUs, No. 1409 at p. 1; NEEA, No. 1414 at p. 2; CEC, No. 1412 at p. 3; NYSERDA, No. 1406 at p. 1)

Additionally, DOE's proposal in the SNOPR was mainly responsive to more substantive stakeholder feedback received in response to the July 2023 NOPR, as discussed throughout that notice (*see* 88 FR 89330).

Many individual commenters also expressed concerns regarding the implementation of heat pump water heaters due to efficiency concerns in colder areas and weather, lack of expertise in maintaining a more complex product, reliability, potential for mold, and potentially high purchase and installation costs and requirements for a product with the same expected lifetime as a standard electric water heater. Individual commenters also stated that the proposed standards are counterproductive because heat pump water heaters eject cold air into the house which then has to be heated up by the household HVAC system. Individual commenters stated that consumers may face high costs and long wait times associated with retrofitting due to the proposed standards, and due to increased insulation, which results in larger products. These high costs will increase the cost of home ownership and may prevent first-time buyers from obtaining a home.

DOE accounts for differences between rated efficiency and on-site efficiency in its energy use analysis, which considers factors like climate and heating load. Heat pump water heaters can help with cooling demand in the summer but can work against the home heating system in the winter if they are not ducted separately. DOE's energy use analysis includes these impacts (*see* appendix 7B to the TSD). DOE quantifies these impacts in the energy use analysis to include them in the expected operating expenses for the LCC analysis.

One individual commenter requested that equipment and repair costs be factored into savings and that consumers should decide the return in savings when investing in new equipment. (Johnson, No. 1271 at p. 1) Great Plains Resource supported the proposed standard and stated that if a redesign of water heaters helps to control pollution, it should be passed. Great Plains Resource stated, however, that DOE should plan to mitigate costs for consumers associated with manufacturers increasing costs of water heaters. Other commenters suggested that DOE subsidize new water heater technologies or introduce a tax incentive rather than seeking energy efficiency through regulations. Great Plains Resource suggested that DOE should consider extending the time frame to help manufacturers create new equipment and create competition to control cost of equipment to consumers. (Great Plains Resource, No. 1267 at p. 1) An individual commented that condensing gas-fired water heaters use expensive vent pipes due to the corrosiveness of condensation. (Harley, No. 1341 at p. 1)

DOE notes that its analysis incorporates installation and equipment costs into its analysis, including the necessary venting, as well as repair and maintenance costs. Pickering expressed concern that the definitions proposed in the December 2023 SNOPR for circulating water heaters may not be compatible with solar photovoltaic direct water heating systems, which the commenter described as a low-cost system where DC electric output from the solar photovoltaic panel is wired (without grid connection) directly to the heating elements of an electric resistance storage water heater. (Pickering, No. 1399, at pp. 1–3)

DOE understands this comment to be opposing the proposed heat pump-level standards for most electric storage water heaters due to the fact that the direct solar photovoltaic water heating systems described by the commenter is dependent upon a DC-compatible electric storage water heater. DOE notes that electric resistance storage water heaters will still be available within the small electric storage water heater (and grid-enabled water heater product classes for cases where the home is still connected to a utility grid), however.

According to NPGA, APGA, AGA, and Rinnai, DOE is seeking to promote the market for electric heat pumps at the expense of gas-fired water heaters, diminishing competition and profoundly affecting consumer choice. They also stated that the proposed rule fails to meet EPCA's 3-year rebuttable

[19] In reference to appendix A as it appeared at the time of the publication of the July 2023 NOPR.

presumption of economic justification under pure economic terms and would be an enormous burden on manufacturing and on competition between gas and electric water heaters. (NPGA, APGA, AGA, and Rinnai, No. 441 at pp. 3–4) EEI noted that while the proposed standards for electric storage water heaters increase by 21 to 140 percent in efficiency, the July 2023 NOPR only proposed an increase of 0 to 9.7 percent for gas-fired and oil-fired storage water heaters, and this disparity would cause fuel-fired storage water heaters to gain a competitive advantage because buyers' decisions are strongly motivated by cost considerations. (EEI, No. 1198 at pp. 3–4) Sunrise Pittsburgh stated that the proposed standard would require electric and gas-fired water heaters to meet vastly different standards, which could potentially result in consumers switching to gas-fired water heaters given the lower upfront cost associated with gas-fired water heaters compared to heat pump water heaters. In turn, Sunrise Pittsburgh stated this may result in more carbon emissions. According to Sunrise Pittsburgh, revising the proposed standard to apply the same standard across all water heaters regardless of the technology or fuel source used would benefit consumers, especially it removes gas-fired water heaters from the market, as this would save consumers from asthma and carcinogens as well as dangerous gas-fired water heater explosions associated with gas fueled products. (Sunrise Pittsburgh, No. 905 at pp. 1–2)

In this rulemaking DOE has provided its analytical approach and results which have led to the selection of more stringent standards for some product classes compared to others. When determining whether the benefits of amended standards outweigh the burdens, DOE considers the trial standards levels, which are comprised of different efficiency levels for each product class. The construction of trial standards levels is discussed in section V.A of this document. In the shipments analysis, which is detailed in section IV.G of this document, DOE considers the impacts of product life-cycle costs on consumer purchasing decisions, which ultimately is used to assess the total energy savings, economic impacts to consumers, and impacts to health (summarized in section I.C of this document).

With respect to Sunrise Pittsburgh's suggestion to apply the same standard across all water heaters regardless of the technology or fuel source, DOE establishes separate standards for different product classes of consumer water heaters based on statutory requirements from EPCA, which includes a consideration for products that consume different types of energy (*e.g.,* electricity, oil, or gas). (42 U.S.C. 6295(q)(1)-(2)) The product classes established by this final rule are discussed in section IV.A.1 of this document.

3. Selection of Standards Levels

DOE received several comments regarding the selection of proposed efficiency levels.

CEC agreed with DOE's analysis recognizing that the majority of electric storage water heaters can meet heat pump-level standards but encouraged DOE to consider improving the minimum standard for electric storage water heaters >20 and ≤55 gal to a level closer to EL 2. CEC noted that while a UEF of 2.3 (as proposed) is sufficient to drive the core shift in technology, the least efficient heat pump water heaters on the market today have a UEF of 2.8 or greater. (CEC, No. 1173 at pp. 3–4)

As stated in the July 2023 NOPR, split-system and 120-volt heat pump water heaters may not be able to achieve the same efficiency levels as conventional 240-volt products, as suggested by less stringent ENERGY STAR Residential Water Heaters Specification Version 5.0 (''ENERGY STAR v5.0'') criteria at 2.20 UEF. DOE has observed products certified to both the ENERGY STAR database and DOE's Compliance Certification Database (''CCD'') capable of meeting these criteria and determined EL 2 such that novel 120-volt products would not be prevented from entering the market. 88 FR 49058, 49090. DOE continued to consider these factors when evaluating the standard levels for this final rule.

DOE received comments from BWC regarding the potential manufacturer impacts and capacity constraints related to transitioning all electric storage water heater products to heat pump designs. BWC stated appreciation that DOE recognized that a 5-year compliance window may be challenging for many manufacturers to redesign 100 percent of electric storage water heater products to incorporate heat pump designs. BWC noted that change of this scale would indeed require a commitment of significant time, resources, and capital to ensure these units can be produced at a rate that would satisfy sharply increased demand while meeting and exceeding consumers' needs and expectations. (BWC, No. 1164 at pp. 14–15)

NRECA recommended that DOE delay implementation of the proposed electric storage water heater standard for 40-gallon model sizes to allow more time for manufacturers to innovate and design heat pump water heaters that are more adaptable to a variety of installation scenarios. NRECA also recommended that DOE allow electric resistance options for storage tank sizes up to 50 gallons for space constrained installations, and that DOE apply the proposed standard for electric storage water heaters to new construction only, since new homes can be designed to accommodate heat pump water heaters. (NRECA, No. 1127 at p. 13)

In response, DOE notes that the timing of amended standards for consumer water heaters is mandated by EPCA. Furthermore, DOE finds that a 5-year lead time is sufficient for manufacturers to prepare given that heat pump water heaters available today can be installed in a variety of installation scenarios. For consumer water heaters DOE does not have the authority to regulate water heaters in new construction only. As discussed in section V.C of this document, DOE has fully weighed the burdens of its proposed standards for electric storage water heaters against its benefits in determining the appropriate standards level.

DOE acknowledges that requiring all electric storage water heater products to utilize heat pump designs would require notably higher levels of investment and development effort compared to only requiring a portion of the electric storage water heater market to transition to heat pump designs. In this final rule, DOE is adopting TSL 2, which, for electric storage water heaters, includes standards for larger products that are met through the use of heat pump technology while leaving standards for smaller products that can be met through the use of electric resistance heating. *See* section V.C.1 of this document for the benefits and burdens of the TSLs considered in this rulemaking.

In this rulemaking, DOE did not analyze more stringent standards for product classes for which there are currently no UEF-based standards. Several commenters raised the concern that establishing such standards for certain product classes and then raising standards for other product classes would create a market condition where manufacturers can shift their models to meet the requirements of the new product classes with less stringent standards, hence undermining the energy savings potential of this rulemaking. This issue is discussed in detail throughout this document. The creation of separate product classes for the models that do not have current

UEF-based standards is detailed in section IV.A.1 of this document. The selection of standards for these products is explained in section IV.C.1 of this document. Finally, the impact of market transition (*i.e.,* product class switching) is addressed in the shipments analysis in section IV.G of this document.

DOE received comments from some stakeholders regarding the impact of the proposed standards for electric storage water heaters (which correspond to efficiencies attainable by heat pump water heaters) on electric grids.

Armada claimed that the proposed standards would cause serious business harm to companies that provide technologies to convert traditional electric storage water heaters into demand-response products. (Armada, No. 1193 at p. 3) Armada emphasized the importance of American-made technologies for grid-reliability as critical to tackling the climate crisis and advancing environmental justice initiatives, but these technologies are at risk of being regulated out of existence by the proposed standards. (Armada, No. 1193 at p. 7) Armada commented that due to the long recovery cycle of heat pump water heaters, these products are limited in their demand response capabilities. Armada stated that while they can be used for scheduled time-of-use programs, they do not work well responding to grid congestion or to the intermittent availability of renewable energy sources (*e.g.,* wind or solar) because water heater energy use times do not line up with when renewable energy resources are available during the day. (Armada, No. 1193 at p. 3)

NRECA stated that heat pump water heaters may be beneficial to electrical grid demand peaks because they draw lower demand than electric resistance storage water heaters, however they expressed concern that heat pump water heaters may not yield enough savings for demand response programs to be cost-effective. NRECA also stated that most electric cooperatives use load control switches to manage electric water heater demand, but have found that this strategy is generally incompatible with heat pump water heaters, which take more time to reboot after a cut in power than an electric resistance storage water heater. NRECA added that heat pump water heater can be managed using more sophisticated strategies such as CTA 2045, AHRI 1430, or the manufacturer's API; however, NRECA commented that electric cooperatives are concerned about the time, expense, and security risks associated with implementing a new control strategy. (NRECA, No. 1127 at p. 11) NRECA stated many of their member electric cooperatives mitigate demand peaks by running demand response programs, using both grid-enabled water heaters and 50-gallon electric storage water heaters and added that few of the cooperatives they interviewed include or plan to include heat pump water heaters, due to incompatible load control strategies or reduced grid management benefits. (NRECA, No. 1127 at p. 11)

ECSC urged DOE to retain electric resistance options for electric storage water heater installations where heat pump water heaters impose a time-consuming, costly burden, and to consider restrictions on tankless electric water heaters instead. ECSC stated that if consumers cannot afford or install heat pump water heaters, the remaining options of a small electric storage water heater (''ESWH'') or a tankless electric water heater pose a significant threat to existing electric grid demand management programs, which rely on electric storage water heaters as a thermal resource. ECSC added that the proposed standards for electric storage water heaters will likely disproportionately harm low-to-moderate income consumers. (ECSC, No. 1185 at p. 2)

NEEA, however, noted that heat pump water heaters have been successfully deployed in demand response programs in the Pacific Northwest, and added that, similar to electric resistance storage water heaters, heat pump water heaters are capable of shifting load from on-peak to off-peak hours, and are also capable of handling load-up events since they have both electric resistance backup elements and a compressor. NEEA cited a pilot program conducted by Bonneville Power Administration and Portland General Electric which enrolled 175 heat pump water heaters and 90 electric resistance water heaters in a demand response program and controlled them through 600 events over the course of 220 days. NEEA noted the pilot found that electric resistance and heat pump water heaters alike were able to reduce load substantially. (NEEA, No. 1199 at pp. 8–9)

NRECA's comment indicates that utilities may employ more strategies for water heater load management than CTA–2045 or OpenADR communication protocols. DOE reviewed load control switch technology in more detail.[20] These load control switches appear to be capable of implementing schedule-based control. However, if utilities need to cut power to water heaters at unplanned times to manage electricity demand, heat pump water heaters are expected to still be able to return to operation in a reasonable amount of time. DOE's teardown analyses of heat pump water heaters on the market show that nearly all heat pump water heater designs today have backup electric resistance elements should the household require a faster recovery rate. DOE does not expect heat pump water heaters to remove these backup elements as a result of amended standards. Additionally, DOE finds that the studies conducted by NEEA provide evidence towards the compatibility of heat pump water heaters with present-day load control strategies.

In response to ECSC, there is an increasing number of heat pump water heaters available with demand-response capabilities. The ENERGY STAR v5.0 specification incentivizes the manufacture of heat pump water heaters that meet a list of criteria for connected product design, including the use of the standardized CTA–2045 or OpenADR communications protocols for utilities to send signals to enrolled water heaters. Load management strategies are expected to still be compatible with heat pump water heater designs. Additionally, DOE reiterates that electric resistance storage water heaters which elevate the storage tank temperature beyond 135 °F when responding to utility load management signals are exempt from having to test to the high temperature test method and will likely remain on the market. Beyond small electric storage water heaters and heat pump water heaters, grid-enabled water heaters (which are larger than 75 gallons of rated storage volume) are designed for this explicit purpose. DOE does not expect the availability of grid-enabled water heaters to decline as a result of this final rule (because no substantial amendments to the standards for these products are being adopted in this rulemaking), so there will remain electric resistance products available to consumers to connect to utility grid programs.

NPGA, APGA, AGA, and Rinnai stated that DOE should consider the effects the additional demand for electricity for water heaters may have on the energy grid as it has presently failed to consider such an impact its proposed standards may have on grid reliability. According to NPGA, APGA, AGA, and Rinnai, DOE should heed the guidance of the Government Accountability Office and analyze options for grid resilience to avoid enhanced strain

[20] See, for example, the Generac ARA Load Control Switch. Product literature can be found online at: *www.generacgs.com/wp-content/uploads/2023/04/ARA_LoadControlSwitch_SpecSheet_B-1.pdf* (Last accessed Oct. 11, 2023).

without a demand management or supply plan and would benefit by reviewing analysis of grid strain during extreme weather events. (NPGA, APGA, AGA, and Rinnai, No. 441 at p. 4) NMHC and NAA also advised that such an increase in electric product usage should be coupled with efforts to ensure the electric grid is prepared and suggested that DOE consider the costs and barriers in this rulemaking. (NMHC and NAA, No. 996 at p. 5)

DOE does not expect a significant fraction of consumers to switch from gas-fired or oil-fired water heaters to electric water heaters as a result of this rulemaking. *See* section IV.F.10 of this document. DOE does expect a significant fraction of consumers to switch from electric resistance storage water heaters to heat pump water heaters as a result of the more stringent standards for electric storage water heaters, however. Heat pump water heaters are significantly more efficient than electric resistance storage water heaters, and, as a result, consume significantly less electricity than electric resistance storage water heaters, which actually reduces strain on electrical grids.

The Attorney General of TN commented that the proposed rulemaking does not address the additional strain these standards would place on the national energy infrastructure and power grid. The Attorney General of TN stated that, by encouraging a 5 percent to 63 percent shift among consumers from gas-fired water heaters to those powered by electric pumps, the demand for additional electricity will place further stress on an already overworked energy grid. (Attorney General of TN, No. 1149 at p. 3)

DOE has carefully considered the potential impact of proposed standards on the national energy infrastructure and power grid. With reduced energy consumption and appropriate configuration, the proposed standards would actually benefit national energy infrastructure and power grid.

B. Scope of Coverage and Definitions

As discussed in section II.B.3 of this document, this final rule covers those consumer products that meet the definition of ''water heater,'' as codified at 10 CFR 430.2 and as described by EPCA at 42 U.S.C. 6291(27), with the exception of ''Gas-fired instantaneous water heater,'' as codified at 10 CFR 430.2.

Generally, DOE defines a ''water heater,'' consistent with EPCA's definition, as a product which utilizes oil, gas, or electricity to heat potable water for use outside the heater upon demand, including:

(a) Storage type units which heat and store water at a thermostatically controlled temperature, including gas storage water heaters with an input of 75,000 Btu per hour or less, oil storage water heaters with an input of 105,000 Btu per hour or less, and electric storage water heaters with an input of 12 kilowatts (kW) or less;

(b) Instantaneous type units which heat water but contain no more than one gallon of water per 4,000 Btu per hour of input, including gas instantaneous water heaters with an input of 200,000 Btu per hour or less, oil instantaneous water heaters with an input of 210,000 Btu per hour or less, and electric instantaneous water heaters with an input of 12 kilowatts or less; and

(c) Heat pump type units, with a maximum current rating of 24 amperes at a voltage no greater than 250 volts,[21] which are products designed to transfer thermal energy from one temperature level to a higher temperature level for the purpose of heating water, including all ancillary equipment such as fans, storage tanks, pumps, or controls necessary for the device to perform its function.

10 CFR 430.2; (42 U.S.C. 6291(27))

In addition, at 10 CFR 430.2, DOE further defines several specific categories of consumer water heaters as follows:

- ''Electric instantaneous water heater'' means a water heater that uses electricity as the energy source, has a nameplate input rating of 12 kW or less, and contains no more than one gallon of water per 4,000 Btu per hour of input.
- ''Electric storage water heater'' means a water heater that uses electricity as the energy source, has a nameplate input rating of 12 kW or less, and contains more than one gallon of water per 4,000 Btu per hour of input.
- ''Gas-fired instantaneous water heater'' means a water heater that uses gas as the main energy source, has a nameplate input rating less than 200,000 Btu per hour, and contains no more than one gallon of water per 4,000 Btu per hour of input.
- ''Gas-fired storage water heater'' means a water heater that uses gas as the main energy source, has a nameplate input rating of 75,000 Btu per hour or less, and contains more than one gallon of water per 4,000 Btu per hour of input.
- ''Grid-enabled water heater'' means an electric resistance water heater that—
  - Has a rated storage tank volume of more than 75 gallons;
  - Is manufactured on or after April 16, 2015;
  - Is equipped at the point of manufacture with an activation lock; and
  - Bears a permanent label applied by the manufacturer that—
    - Is made of material not adversely affected by water;
    - Is attached by means of non-water-soluble adhesive; and
    - Advises purchasers and end-users of the intended and appropriate use of the product with the following notice printed in 16.5 point Arial Narrow Bold font: ''IMPORTANT INFORMATION: This water heater is intended only for use as part of an electric thermal storage or demand response program. It will not provide adequate hot water unless enrolled in such a program and activated by your utility company or another program operator. Confirm the availability of a program in your local area before purchasing or installing this product.''
- ''Oil-fired instantaneous water heater'' means a water heater that uses oil as the main energy source, has a nameplate input rating of 210,000 Btu/h or less, and contains no more than one gallon of water per 4,000 Btu per hour of input.
- ''Oil-fired storage water heater'' means a water heater that uses oil as the main energy source, has a nameplate input rating of 105,000 Btu/h or less, and contains more than one gallon of water per 4,000 Btu per hour of input.

In the June 2023 Test Procedure Final Rule, DOE amended 10 CFR 430.2 (effective on July 21, 2023), adding the following definitions for circulating, low-temperature, and tabletop water heaters:

- ''Circulating water heater'' means an instantaneous or heat pump-type water heater that does not have an operational scheme in which the burner, heating element, or compressor initiates and/or terminates heating based on sensing flow; has a water temperature sensor located at the inlet or the outlet of the water heater or in a separate storage tank that is the primary means of initiating and terminating heating; and must be used in combination with a recirculating pump and either a separate storage tank or water circulation loop in order to achieve the water flow and temperature conditions recommended in the manufacturer's installation and operation instructions.
- ''Low-temperature water heater'' means an electric instantaneous water heater that is not a circulating water heater and cannot deliver water at a

[21] In the June 2023 TP Final Rule, DOE amended the definition of ''commercial heat pump water heater'' at 10 CFR 431.102 to align with the amperage and voltage requirements for consumer heat pump type units as specified in EPCA.

temperature greater than or equal to the set point temperature specified in section 2.5 of appendix E to subpart B of this part when supplied with water at the supply water temperature specified in section 2.3 of appendix E to subpart B of part 430 and the flow rate specified in section 5.2.2.1 of appendix E to subpart B of part 430.

• ''Tabletop water heater'' means a water heater in a rectangular box enclosure designed to slide into a kitchen countertop space with typical dimensions of 36 inches high, 25 inches deep, and 24 inches wide.

As stated in section I of this document, EPCA prescribed energy conservation standards for all consumer water heaters (*i.e.,* those that meet the definition of ''water heater'' above). For the purposes of this final rule, DOE is considering all consumer water heaters, as defined by EPCA, with the exception of ''gas-fired instantaneous water heaters.'' This rulemaking does include consumer water heaters for which there are no current UEF-based standards codified at 10 CFR 430.32(d).

In the July 2023 NOPR, DOE responded to inquiries concerning coverage of hot water dispensing products (not to be confused with low-temperature electric instantaneous water heaters or point-of-use electric storage water heaters), which operate at less than 2 kW of power and generally provide water at temperatures between 160 °F and 210 °F for food preparation purposes. DOE stated that while it has the authority to set standards for products that meet the definition of a consumer water heater (42 U.S.C. 6292(a)(4)), this rulemaking is not currently considering standards for hot water dispensing products. 88 FR 49058, 49070.

Additionally, DOE received comments from stakeholders in response to the July 2023 NOPR regarding the scope and classification of circulating water heater as defined at 10 CFR 430.2 by the June 2023 TP Final Rule. DOE subsequently published an SNOPR on December 27, 2023 (''December 2023 SNOPR''), that discussed the comments received on this topic and proposed to amend the definition for ''circulating water heater'' to reclassify these products as storage-type water heaters. 88 FR 89330. In the December 2023 SNOPR, DOE proposed amending the definition of ''circulating water heaters'' to re-classify these products as storage-type water heaters. *Id.* After considering the comments on the December 2023 SNOPR, DOE is adopting its proposal to amend the definition for ''circulating water heater'' as it appears at 10 CFR 430.2 to reclassify these products as storage-type water heaters. The SNOPR comments received from stakeholders and DOE's responses, along with the definition of a ''circulating water heater,'' are discussed in detail in section IV.A.1.a of this document. As a result of this reclassification, the scope of coverage for circulating water heaters is limited to those products which meet the statutory input rate limits for storage-type water heaters. Specifically, electric circulating water heaters must have a nameplate input rating of 12 kW or less, gas-fired circulating water heaters must have a nameplate input rating of 75,000 Btu/h or less, oil-fired circulating water heaters must have a nameplate input rating of 105,000 Btu/h or less, and heat pump circulating water heaters must have a maximum current rating of 24 amperes (''A'') at a voltage no greater than 250 volts (''V''). Circulating water heaters that have input rates greater than these specifications would be considered commercial water heaters.

In response to the December 2023 SNOPR, BWC indicated that commercial circulating water heaters are not separately defined at 10 CFR 431.102 and the recent final rule regarding energy conservation standards for commercial water heaters [22] did not establish separate standards for circulating water heaters. BWC requested that DOE clarify how the provisions in the December 2023 SNOPR will impact commercial circulating water heaters if adopted. (BWC, No. 1413 at p. 2) A.O. Smith agreed with DOE's determination that circulating water heaters with input rates surpassing those defined for consumer storage water heaters as outlined in 10 CFR 430.2, should be classified as commercial water heaters. A.O. Smith suggested that DOE formalize this categorization by establishing definitions for commercial gas-fired circulating water heaters with input rates between 75,000 Btu/h and 200,000 Btu/h at 10 CFR 431.102. (A.O. Smith, No. 1411 at p. 2)

Rheem concluded that gas-fired circulating water heaters with input rates greater than 75,000 but less than or equal to 105,000 Btu/h could be categorized as residential-duty commercial water heating equipment,[23] and therefore could be subject to the energy conservation standards recently established in the commercial water heater equipment final rule. Rheem requested DOE confirm its understanding that the proposed definitions circulating water heaters would extend to residential-duty commercial water heaters. (Rheem, No. 1408 at p. 3)

The scope of this rulemaking pertains specifically to consumer water heaters, and the amended standards and definitions addressed herein do not apply to residential-duty commercial water heaters (which are commercial water heating equipment defined at 10 CFR 431.102). The definition of circulating water heater DOE is establishing at 10 CFR 430.2 will be supplemented by additional definitions for electric, gas-fired, and oil-fired circulating water heaters that specify input rate limits consistent with consumer water heaters. Circulating water heaters that exceed these input rates will be commercial water heaters and therefore are outside the scope of standards established in this rulemaking. DOE may consider addressing standards and test procedures for commercial circulating water heaters in a future rulemaking for commercial water heaters.

In response to the July 2023 NOPR, the Joint Advocacy Groups urged DOE to clarify that electric water heaters that can operate at inputs both above and below 12 kW must meet both the relevant consumer and commercial water heater standards. (Joint Advocacy Groups, No. 1165 at p. 8)

DOE is aware of certain ''field-convertible'' electric storage water heaters which can be sold with elements rated above 12 kW (*e.g.,* 12.1 kW), but the product is designed in a way that allows the user to change the elements to a lower input rate (*e.g.,* 6 kW). Field-convertible electric storage water heaters are, therefore, sold as commercial water heaters but can be converted into consumer water heaters.[24]

[22] On October 6, 2023 the Department published a final rule amending standards for commercial water heating equipment, including commercial circulating water heaters. 88 FR 69686.

[23] DOE defines residential-duty commercial gas-fired storage water heaters as commercial gas-fired storage water heaters that are not designed to provide outlet hot water at temperatures greater than 180 °F, do not have a rated input greater than 105,000 Btu/h, and do not have a rated storage volume greater than 120 gallons. (10 CFR 431.102)

[24] For example, Rheem offers a commercial electric water heater that is marketed for light-duty commercial applications. In certain storage volumes (*i.e.,* 66, 80, and 119.9 gallon models) the input rating as shipped from the manufacturer is only available at 12.1 kW which qualifies the product as a commercial water heater. However, the product literature states that this product is factory shipped with two 6.05 kW elements that operate simultaneously, but can be easily converted in field for non-simultaneous element operation. When converted, the input rating would be effectively 6.05 kW. This causes the product to meet the definition of a consumer water heater. For more information see: *https://s3.amazonaws.com/WebPartners/ProductDocuments/9A53AD9F-75C2-*

Continued

Consistent with its determinations in other rulemakings, DOE has concluded that if a product can be configured to meet either the commercial water heater definition or the consumer water heater definition, then it must comply with the standards applicable to all types of product/equipment in which it can be configured. For example, in a recent final rule addressing convertible consumer refrigeration products, DOE specified that if a product is capable of operating with compartment temperatures as specified in multiple product category definitions (*i.e.,* a ''convertible product''), the model must be tested and certified to each applicable product category. 88 FR 7840, 7843 (Feb. 7, 2023). Also, in a recent final rule addressing the test procedure for consumer boilers (which are a space-heating appliance that can often also be configured to provide domestic water heating), DOE determined that if a combination appliance meets the definition of a consumer boiler, the product must be tested per the boiler test procedure and demonstrate compliance with those standards. 88 FR 15510, 15515 (Mar. 13, 2023). Similarly, field-convertible electric storage water heaters are subject to the appendix E test procedure and the standards adopted by this final rule to the extent that they can be configured to meet the consumer water heater definition.

Uponor stated that other countries have generated domestic hot water via a heat exchanger connected to a hydronic mechanical system to improve water quality and energy efficiencies for decades. Uponor provided product literature from its technology offerings and requested clarification about how such products would be covered under DOE's standards. (Uponor, No. 606 at p. 1)

DOE reviewed the product literature cited by the commenter and found that the technology being referenced is an unfired heat exchange device which can couple hydronic piping to domestic hot water piping far downstream of the point of heat generation so that the heat exchange can occur in commercial high-rise buildings to produce domestic hot water using heat from the building's hydronic heating system. While DOE does not disagree that these technologies could improve high-rise building system efficiencies, the heat exchangers referenced by Uponor may be better characterized as heat recovery devices that function based on diverting excess heat to the domestic hot water supply and work in conjunction with the appliance providing the heat.

In response to the July 2023 NOPR, DOE received questions from BWC asking whether space-heating products that are capable of heating domestic hot water by means of an indirect water heater tank would be considered circulating water heaters. In response to the December 2023 SNOPR, Pickering provided comments raising concerns about the potential for evaluating efficiency gains if there is overlap between these types of systems and circulating water heaters.

Pickering commented that definitions that do not account for the array of equipment that is on the market or coming on the market, and that do not recognize the efficiency gains to be had with multiple pieces of equipment operating as a system, may limit choice and stifle innovation. Specifically, Pickering commented that the proposed definitions for circulating water heaters may be incompatible with or otherwise create regulatory impediments to air-to-water heat pumps that provide domestic hot water as an ancillary function to space conditioning. Pickering added that these combined systems can increase overall system efficiency over a more typical separated system, but that the proposed definitions mean that it may be difficult to quantity the efficiency of the domestic hot water function of a combined system specifically, and that they may not account for or accommodate the combinations of equipment (assembled on site) that produce domestic hot water in such a combined system. (Pickering, No. 1399 at pp. 1–3)

Pickering recommended DOE consider removing indirect tanks from the definition of conventional electric storage water heaters, refrain from setting water heater efficiency standards for heat pumps that produce domestic hot water as an ancillary function, clarify that gas-fueled heat pumps are not considered to be electric storage water heaters, and take a systems approach to energy efficiency for domestic hot water. (Pickering, No. 1399 at p. 3)

BWC requested that DOE provide answers to the following questions: (1) Are split-system heat pump products that provide space heating, as well as domestic hot water through an indirect unfired hot water storage tank (''UFHWST'') classified as a circulating heat pump water heater, or instead as an air-to-water heat pump? (2) Would such a product need to be tested under the residential water heater test procedure, the air-to-water heat pump test procedure once such a procedure is created, or both? (3) Will such a product need to represent its efficiency using UEF or annualized fuel utilization efficiency, or both? (BWC, No. 1164 at pp. 11–12) While these questions pertain specifically to air-to-water heat pump appliances, DOE understands the need for general clarification regardless of the fuel type or technology.

Circulating water heaters circulate potable water through a heat exchanger: warm water from the stored volume of water enters the circulating water heater and exits after being heated to the setpoint temperature. By contrast, an indirect water heater uses the main furnace or boiler of a home to heat a fluid that is circulated through a heat exchanger in the storage tank.[25] An indirect water heater does not circulate the potable domestic hot water supply to and from the boiler (it is a separate heating fluid which circulates through the tank and boiler), therefore, DOE has determined that a boiler paired with an indirect water heater is not a circulating water heater.

Pickering also commented that the proposed definitions for circulating water heaters may be incompatible with or otherwise create regulatory impediments to solar thermal water heating systems. (Pickering, No. 1399 at p. 2)

DOE understands the commenter to be referring to solar water heating systems that circulate a hot heat transfer fluid between a solar heat collector and a heat exchanger inside a domestic hot water storage tank. Such a setup is parallel to an indirect-fired water heater: it is not the potable hot water that circulates between the heat source and the tank, it is an intermediate heat transfer fluid instead. As such, solar thermal water heating systems designed in this way do not constitute circulating water heaters.

This is in contrast to a boiler with a tankless coil (or a combination boiler-water heater). A tankless coil water heater provides hot water on demand without a tank, much like an instantaneous water heater. When a hot water faucet is turned on, water is heated as it flows through a heating coil or heat exchanger installed in a main furnace or boiler. In the tankless coil configuration, the domestic hot water supply does circulate through the boiler. However, these systems are typically flow-activated, and thus most do not meet the definition of a ''circulating water heater,'' either.

4E66-8967-1BAE91B17CAC.pdf (Last accessed on Dec. 20, 2023)

[25] A diagram of an indirect water heater and further description of this design configuration is provided on DOE's website at: *www.energy.gov/energysaver/tankless-coil-and-indirect-water-heaters* (Last accessed: Oct. 30, 2023).

BWC requested clarification on whether air-to-water heat pumps would be covered as both circulating water heaters and as hydronic heating system boilers, which are being discussed by the U.S. Environmental Protection Agency (''EPA'') with regards to amendments to the consumer boiler specification. Specifically, BWC called attention to the potential overlap between the definition of circulating water heater and what the EPA is considering regulating as air-to-water (hydronic) heat pumps for space-heating in a potential revision or new specification for consumer boilers. BWC stated that both heat pump circulating water heaters and hydronic heat pumps are air-to-water heat pumps, and there would be an issue if multiple product definitions overlapped, thereby encompassing the same covered product within scope and subjecting it to two separate test procedures and efficiency standards. (BWC, No. 1164 at pp. 11–12)

There is currently no codified definition for an air-to-water hydronic heat pump used for space heating purposes. However, in a March 2023 final rule amending the test procedure for consumer boilers (the ''March 2023 Boilers TP Final Rule''), DOE determined that hydronic heat pump appliances which meet the consumer boiler definition would be classified as consumer boilers. 88 FR 15510, 15516 (Mar. 13, 2023). However, the March 2023 Boilers TP Final Rule did not establish a test method for these hydronic heat pump boilers. *Id.* At this time, there is no Federal test procedure to determine the Annual Fuel Utilization Efficiency (''AFUE'') of such a product, hence, there are also no AFUE requirements for these heat pumps. In the March 2023 Boilers TP Final Rule, DOE also stated that, to the extent that a combination space and water heating product meets the definition of electric boiler or low pressure steam or hot water boiler, it is subject to the boilers test procedure and energy conservation standards for consumer boilers at 10 CFR 430.32(e)(2), and must be tested and rated accordingly. *Id.* at 15515. Therefore, per DOE's test procedure requirements, if an air-to-water heat pump meets both the definition of a consumer boiler and a consumer water heater, then it must be tested to both test procedures, should the boilers test procedure be amended at a future date to include an applicable method of test. On June 5, 2023, EPA released a Discussion Guide [26] requesting information from stakeholders about a method of test for hydronic heat pump boiler systems. DOE will monitor the development of this method of test but notes that it is a draft specification that has not been released as of this final rule.

RVIA commented that based on the plain language of the consumer product statute, appliances designed specifically for use in a recreational vehicle (''RV'') are exempted from new standards. RVIA urged DOE to continue to recognize the uniqueness of RVs and the importance of excluding specific component parts designed for RVs from new appliance standards. (RVIA, No. 1168 at p. 4)

The scope of this rulemaking excludes water heaters designed exclusively for RV applications because the definition of ''consumer product'' in EPCA excludes consumer products designed solely for use in recreational vehicles and other mobile equipment. (*See* 42 U.S.C. 6292(a)) In the market and technology assessment, DOE evaluated certification data to ensure that the model information used throughout this rulemaking analysis aligned with the scope of coverage.

Section IV.A.1 of this document contains detailed discussion of the product classes analyzed in this final rule.

C. Test Procedure

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6293) Manufacturers of covered products must use these test procedures to certify to DOE that their product complies with energy conservation standards and to quantify the efficiency of their product. DOE's current energy conservation standards for consumer water heaters are expressed in terms of UEF. (*See* 10 CFR 430.32(d).)

DOE most recently amended the test procedure for these products at appendix E in the consumer and residential-duty commercial water heater test procedure final rule published on June 21, 2023 (''June 2023 TP Final Rule'') pursuant to the 7-year review requirement as specified by EPCA. (42 U.S.C. 6293(b)(1)(A) and 42 U.S.C. 6314(a)(1)(A)) In the June 2023 TP Final Rule, DOE added definitions and, where necessary, additional test procedure provisions for circulating water heaters, low-temperature water heaters, and tabletop water heaters, as well as provisions for high-temperature testing. However, DOE deferred the implementation of high-temperature testing provisions to this energy conservation standards rulemaking. 88 FR 40406, 40448. DOE also established effective storage volume as a metric and provided additional optional ambient test conditions for heat pump water heaters. *Id.* The test procedure for consumer water heaters incorporates by reference current versions of industry standards ASHRAE 41.1, ASHRAE 41.6, ASHRAE 118.2, ASTM D2156, and ASTM E97 and harmonizes various aspects of the test procedure with industry test procedures ASHRAE 118.2–2022 and NEEA Advanced Water Heating Specification v8.0. The amended test procedure established by the June 2023 TP Final Rule is mandatory for consumer water heater testing starting December 18, 2023, 180 days after publication, with the exception of certain provisions (*i.e.,* the new high temperature test method and the circulating water heater test method). For these specific provisions, compliance is mandatory on and after the compliance date of this final rule. (*See* Note at the beginning of appendix E).

D. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. Sections 6(b)(3)(i) and 7(b)(1) of appendix A to 10 CFR part 430 subpart C (''appendix A'').

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; (3) adverse impacts on health or safety and (4) unique-pathway proprietary technologies. Section 7(b)(2)–(5) of the Appendix A. Section IV.B of this document discusses the results of the screening analysis for consumer water heaters, particularly the designs DOE considered, those it screened out, and those that are the

[26] The Boilers Discussion Guide can be found online at: *www.energystar.gov/products/residential_boilers_specification* (Last accessed: Nov. 3, 2023).

basis for the standards considered in this rulemaking. For further details on the screening analysis for this rulemaking, *see* chapter 4 of the final rule TSD.

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt a new or amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for consumer water heaters, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this rulemaking are described in section IV.C of this final rule and in chapter 5 of the final rule TSD.

E. Energy Savings

1. Determination of Savings

For each trial standard level (''TSL''), DOE projected energy savings from application of the TSL to consumer water heaters purchased in the 30-year period that begins in the first full year of compliance with the amended standards (2030–2059).[27] The savings are measured over the entire lifetime of consumer water heaters purchased in the 30-year analysis period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards.

DOE used its national impact analysis (''NIA'') spreadsheet models to estimate national energy savings (''NES'') from potential amended standards for consumer water heaters. The NIA spreadsheet model (described in section IV.H of this document) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of primary energy savings, which is the savings in the energy that is used to generate and transmit the site electricity. For natural gas, the primary energy savings are considered to be equal to the site energy savings. DOE also calculates NES in terms of full-fuel-cycle (''FFC'') energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[28] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.H.2 of this document.

2. Significance of Savings

To adopt any new or amended standards for a covered product, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B))

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[29] For example, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis, taking into account the significance of cumulative FFC national energy savings, the cumulative FFC emissions reductions, and the need to confront the global climate crisis, among other factors.

As stated, the standard levels adopted in this final rule are projected to result in national energy savings of 17.6 quads, the equivalent of the primary annual energy use of 116 million homes. Based on the amount of FFC savings, the corresponding reduction in emissions, and the need to confront the global climate crisis, DOE has determined the energy savings from the standard levels adopted in this final rule are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B).

F. Economic Justification

1. Specific Criteria

As noted previously, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I)(VII)) The following sections discuss how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of potential new or amended standards on manufacturers, DOE conducts an MIA, as discussed in section IV.J of this document. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) INPV, which values the industry on the basis of expected future cash flows; (2) cash flows by year; (3) changes in revenue and income; and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and PBP associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the consumer costs and benefits expected to result from particular standards. DOE also evaluates the impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a standard.

b. Savings in Operating Costs Compared To Increase in Price (LCC and PBP)

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the

[27] DOE also presents a sensitivity analysis that considers impacts for products shipped in a 9-year period.

[28] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

[29] The numeric threshold for determining the significance of energy savings established in a final rule published on Feb. 14, 2020 (85 FR 8626, 8670) was subsequently eliminated in a final rule published on Dec. 13, 2021 (86 FR 70892).

initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating cost (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with new or amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of new or amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F of this document.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section IV.H of this document, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing product classes, and in evaluating design options and the impact of potential standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards adopted in this document would not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) To assist the Department of Justice (''DOJ'') in making such a determination, DOE transmitted copies of its proposed rule and the NOPR TSD to the Attorney General for review, with a request that the DOJ provide its determination on this issue. In its assessment letter responding to DOE, DOJ concluded that the proposed energy conservation standards for consumer water heaters are unlikely to substantially lessen competition. DOE is publishing the Attorney General's assessment at the end of this final rule.

In response to the July 2023 NOPR, NPGA, APGA, AGA, and Rinnai asserted that the standards proposed in the July 2023 NOPR would have a significant market effect, with manufacturers likely choosing to leave the market rather than expend the millions of dollars it would take to redesign their products and production especially in requiring condensing technology in order to be in compliance with the standards proposed. (NPGA, APGA, AGA, and Rinnai, No. 441 at p. 3)

Although commenters focus primarily on condensing technologies as it relates to GIWHs, which are not amended in this final rule, DOE continued to look at the impact of competition as it relates to the other product classes for which DOE is adopting standards in this final rule. DOE does not expect that the adopted standard would significantly alter the level of concentration in the consumer water heater market. Additionally, DOJ stated, in a letter to DOE written in response to the July 2023 NOPR, that ''we do not have an evidentiary basis to conclude that the proposed energy conservation standards for consumer water heaters are likely to substantially lessen competition.'' (*See* Attorney General's assessment at the end of this final rule). For this final rule, DOE reviewed up-to-date information on the consumer water heater models available on the U.S. market to ensure a comprehensive analysis of the current manufacturer landscape. In response to stakeholders' comments, DOE carefully reviewed product offerings of original equipment manufacturers (''OEMs'') of gas-fired storage water heaters. DOE identified five OEMs of gas-fired storage water heaters that would be subject to more stringent standards under this rulemaking. Of the five OEMs identified, four OEMs currently manufacture gas-fired storage water heaters that meet the adopted TSL (EL 2 for gas-fired storage water heaters). Collectively, the four OEMs that already offer gas-fired storage water heaters that meet EL 2 account for approximately 95 percent of gas-fired storage water heater shipments.

f. Need for National Energy Conservation

DOE also considers the need for national energy and water conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the adopted standards are likely to provide improvements to the security and reliability of the Nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity, as discussed in section IV.M of this document.

DOE maintains that environmental and public health benefits associated with the more efficient use of energy are important to take into account when considering the need for national energy conservation. The adopted standards are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases (''GHGs'') associated with energy production and use. DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K of this document; the estimated emissions impacts are reported in section V.B.6 of this document. DOE also estimates the economic value of emissions reductions resulting from the considered TSLs, as discussed in section IV.L of this document.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent DOE identifies any relevant information regarding economic justification that does not fit into the other categories described previously, DOE could consider such information under ''other factors.''

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential amended energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F of this document.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this rulemaking with regard to consumer water heaters. Separate subsections address each component of DOE's analyses.

DOE used several analytical tools to estimate the impact of the standards considered in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential amended or new energy conservation standards. The national impacts analysis uses a second spreadsheet set that provides shipments projections and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (''GRIM''), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE website for this rulemaking: *www.regulations.gov/docket/EERE-2017-BT-STD-0019*. Additionally, DOE used output from the latest version of the Energy Information Administration's (''EIA's'') *Annual Energy Outlook* (''*AEO*'') for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this rulemaking include (1) a determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of consumer water heaters. The key findings of DOE's market assessment are summarized in the following sections. *See* chapter 3 of the final rule TSD for further discussion of the market and technology assessment.

1. Product Classes

When evaluating and establishing energy conservation standards for a type (or class) of covered products, DOE divides covered products into product classes by the type of energy used, or by capacity or other performance-related features which other products within such type (or class) do not have and that justify differing standards. (42 U.S.C. 6295(q)) In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE determines are appropriate. *Id.*

EPCA, as amended by the National Appliance Energy Act (NAECA; Pub. L. 100–12), established initial energy conservation standards, expressed as EF, that were based on three product classes differentiated by fuel type: (1) gas-fired, (2) oil-fired, and (3) electric. (42 U.S.C. 6295(e)(1)) These standards applied to consumer water heaters manufactured on or after January 1, 1990.

DOE subsequently amended these EF standards twice, most recently in the April 2010 Final Rule, with which compliance was required starting on April 16, 2015. 75 FR 20112. In the April 2010 Final Rule, DOE further divided consumer water heaters into product classes based on fuel type (gas-fired, oil-fired, or electric), product type (storage, instantaneous, tabletop), storage volume, and input rate.

The Energy Efficiency Improvement Act of 2015 (''EEIA 2015'') (Pub. L. 114–11), enacted on April 30, 2015, added a definition of ''grid-enabled water heater'' and a standard in terms of EF for such products to EPCA's energy conservation standards. (42 U.S.C. 6295(e)(6)(A)(ii)) DOE codified the definition for grid-enabled water heater and the associated energy conservation standards in a final rule published and effective on August 11, 2015. 80 FR 48004.

Most recently, the December 2016 Conversion Factor Final Rule, published and effective on December 29, 2016, translated the EF-based standards to UEF-based standards for certain classes of consumer water heaters, which are shown in Table IV.1. Although the classes of consumer water heaters with UEF-based standards have limitations on the stored volume, as discussed in that final rule, the standards established in EPCA do not place any limitation on the storage volume of consumer water heaters. Therefore, the original standards established by EPCA in terms of EF remain applicable to all products without UEF-based standards. 81 FR 96204, 96209–96211.

The 32 product classes covered in this final rule for which DOE has currently established UEF-based standards are summarized in Table IV.1. The product classes without UEF-based standards, for which EF-based standards from EPCA apply, are shown in Table IV.2.

BILLING CODE 6450–01–P

Table IV.1 Consumer Water Heater Product Classes with Current UEF-Based Standards

Product Type Covered in this Final Rule	Rated Storage Volume and Input Rating (if applicable)	Draw Patterns
Gas-Fired Storage Water Heater	≥ 20 gal and ≤ 55 gal	Very Small Low Medium High
Gas-Fired Storage Water Heater	> 55 gal and ≤ 100 gal	Very Small Low Medium High
Oil-Fired Storage Water Heater	≤ 50 gal	Very Small Low Medium High
Electric Storage Water Heater	≥ 20 gal and ≤ 55 gal	Very Small Low Medium High
Electric Storage Water Heater	> 55 gal and ≤ 120 gal	Very Small Low Medium High
Tabletop Water Heater	≥ 20 gal and ≤ 120 gal	Very Small Low Medium High
Instantaneous Electric Water Heater	< 2 gal	Very Small Low Medium High
Grid-Enabled Water Heater	> 75 gal	Very Small Low Medium High

Table IV.2 Consumer Water Heater Product Classes without Current UEF-Based Standards

Product Class Covered in this Final Rule	Rated storage volume and input rating (if applicable)
Gas-fired Storage	< 20 gal
	> 100 gal
Oil-fired Storage	> 50 gal
Electric Storage	< 20 gal
	> 120 gal
Tabletop	< 20 gal
	> 120 gal*
Oil-fired Instantaneous	< 2gal
	≥ 2 gal
Electric Instantaneous	≥ 2 gal

* Note: products larger than 120 gallons are not possible to fit into the design description of a tabletop water heater, as discussed in section IV.A.1.f.iv.

The CA IOUs suggested that DOE reconsider its approach to setting minimum UEF standards for the water heaters formerly subject to EF standards. Citing the provisions in EPCA (42 U.S.C. 6295(q)(1)(B)), the CA IOUs stated that DOE must consider capacity, consumer utility, and other performance-related features when establishing separate product classes for different types of water heaters. The CA IOUs questioned whether converting an EF standard to a

UEF standard should result in a new product class. The commenter urged DOE to immediately initiate a new rulemaking to address appropriate standards levels or the new product classes, if established. (CA IOUs, No. 1175 at p. 5)

In response to the CA IOUs, DOE originally established these product classes in the 2016 Conversion Factor Final Rule. 81 FR 96204, 96210. At this time, DOE does not have sufficient data to perform an analysis of costs versus benefits of subjecting these products to standards of the same stringency as the amended standards proposed in the July 2023 NOPR. While these products may not have performance-related ''features'' distinguishing them from currently covered products, these models come in different capacities than the products for which DOE has already established UEF-based standards. As has been observed in DOE's teardown analyses and has been indicated by comments from manufacturers, the applicability of efficiency-improving design options is often predicated upon the size or capacity of the water heater; therefore, at this time, the capacities of these products do appear to justify separate standards. However, should future product designs demonstrate that the same efficiency-improving design options are equally as applicable for these capacities, DOE would consider the need for distinguishing these product classes by evaluating whether separate standards are justified for these capacities in a future standards rulemaking (*see* 42 U.S.C. 6295(q)(1)(B)).

a. Circulating Water Heaters

In the June 2023 TP Final Rule, DOE established a definition for ''circulating water heater'' in 10 CFR 430.2, and also established test procedures to determine the UEF of these types of water heaters. 88 FR 40406. In the July 2023 NOPR, DOE identified three potential classes of circulating water heater based on fuel type and input ratings derived from instantaneous water heater definitions in EPCA at 42 U.S.C. 6291(27), which are shown in 88 FR 49058, 49077.

Table IV.3, and proposed their addition to the definitions found at 10 CFR 430.2. 88 FR 49058, 49077.

Table IV.3 Proposed Classes of Circulating Water Heaters from July 2023 NOPR

Product Class	Characteristics
Gas-fired Circulating Water Heater	A circulating water heater with a nominal input of 200,000 Btu/h or less; contains no more than one gallon of water per 4,000 Btu/h of input
Oil-fired Circulating Water Heater	A circulating water heater with a nominal input of 210,000 Btu/h or less; contains no more than one gallon of water per 4,000 Btu/h of input
Electric Circulating Water Heater	A circulating water heater with an input of 12 kW or less; contains no more than one gallon of water per 4,000 Btu/h of input (including heat pump-only units with power inputs of no more than 24 A at 250 V)

BILLING CODE 6450–01–C

As discussed in the June 2023 TP Final Rule, DOE had at that time determined that circulating water heaters with input ratings below 200,000 Btu/h (for gas-fired), 210,000 Btu/h (for oil-fired), or 12 kW (for electric) met the definitional criteria for instantaneous consumer water heaters. As such, these products were to be subject to the applicable energy conservation standards; however, DOE previously provided an enforcement policy for circulating water heaters.[30] Because an amended test procedure that includes new provisions for testing circulating water heaters was recently finalized in the June 2023 TP Final Rule, DOE proposed in the July 2023 NOPR to establish updated UEF standards that reflect the new test method and requested feedback on the proposed standards. In response to the July 2023 NOPR, DOE received comments that largely suggested that circulating water heaters are storage-type water heaters. As noted in section III.B, on December 27, 2023, therefore, DOE published the December 2023 SNOPR that proposed to reclassify these products as configurations of storage-type water heaters, thus proposed that separate product classes for circulating water heaters are not required. 88 FR 89330.

A ''circulating water heater'' is currently defined at 10 CFR 430.2 as an ''instantaneous or heat pump-type water heater that does not have an operational scheme in which the burner, heating element, or compressor initiates and/or terminates heating based on sensing flow; has a water temperature sensor located at the inlet or the outlet of the water heater or in a separate storage tank that is the primary means of initiating and terminating heating; and must be used in combination with a recirculating pump and either a separate storage tank or water circulation loop in order to achieve the water flow and temperature conditions recommended in the manufacturer's installation and operation instructions.''

As described in the December 2023 SNOPR, circulating water heaters contain very little to no water on their own (*i.e.,* are ''tankless''), but, as was determined in the June 2023 TP Final Rule, require a separate volume of water in order to function properly when installed in the field. In that rulemaking, circulating water heaters were designated as instantaneous-type water heaters because of the minimal storage volume contained within the product. However, comments received in response to the July 2023 NOPR led DOE to reevaluate circulating water heaters and propose in the December 2023 SNOPR to classify them as storage-type water heaters because they necessarily operate in tandem with a stored volume of water; hence, the circulating water heater and its separate tank or recirculation loop must be

[30] Prior to the June 2023 TP Final Rule, DOE became aware of gas-fired instantaneous water heaters meeting the definition of consumer water heaters which operated differently than those DOE had previously considered in test procedure rulemakings. On September 5, 2019, DOE issued an enforcement policy for consumer water heaters meeting the definition of gas-fired ''circulating water heater'' as described in said enforcement policy in which DOE stated that it would not seek civil penalties for failing to certify these products, or if these products failed to comply with applicable standards, on or before December 31, 2021. The June 2023 TP Final Rule has since addressed this issue by establishing test procedures to determine UEF ratings for circulating water heaters.

treated as one system. When considering the entire system—the circulating water heater plus the stored water volume required for its operation in the field—these water heaters are operationally very similar to storage-type water heaters and, as a result, DOE had tentatively determined that it is appropriate to classify them as such under its regulations. 88 FR 89330, 89333. The December 2023 SNOPR proposed the following revised definition for circulating water heaters:

''Circulating water heater means a water heater that does not have an operational scheme in which the burner, heating element, or compressor initiates and/or terminates heating based on sensing flow; has a water temperature sensor located at the inlet or the outlet of the water heater or in a separate storage tank that is the primary means of initiating and terminating heating; and must be used in combination with a recirculating pump to circulate water and either a separate storage tank or water circulation loop in order to achieve the water flow and temperature conditions recommended in the manufacturer's installation and operation instructions. Paired with a separate storage tank, a circulating water heater constitutes a storage-type water heater.''

88 FR 89330, 89339.

CEC, BWC, NEEA, NYSERDA, ASAP et al., and A.O. Smith expressed support for DOE's tentative determination that circulating water heaters be considered storage-type water heaters and subject to the appropriate standards. (CEC, No. 1412 at pp. 1–2; BWC, No. 1413 at p. 1; NEEA, No. 1414 at p. 2; NYSERDA, No. 1406 at p. 2; ASAP et al., No. 1407 at pp. 1–2; A.O. Smith, No. 1411 at p. 2) NEEA and ASAP et al. noted that, compared to other storage-type water heaters, circulating water heaters do not provide any additional utility or performance-related features that would warrant a separate product class. (NEEA, No. 1414 at p. 2; ASAP et al., No. 1407 at pp. 1–2) NEEA and A.O. Smith commented that defining circulating water heaters as storage-type will address concerns regarding these products potentially being used as a circumvention pathway for more stringent storage-type standards. (NEEA, No. 1414 at p. 2; A.O. Smith, No. 1411 at p. 2) A.O. Smith added that this will provide more business certainty. (A.O. Smith, No. 1411 at p. 2)

DOE specifically requested comment and information on whether gas-fired circulating water heaters could offer the same utility as gas-fired instantaneous water heaters. 88 FR 89330, 89334. DOE sought to understand whether gas-fired circulating water heaters could be a potential loophole to gas-fired instantaneous water heater standards enforcement after receiving comments in response to the NOPR identifying such a possibility.

BWC agreed with DOE that gas-fired circulating water heaters would not be direct substitutes for gas-fired instantaneous water heaters, indicating that gas-fired circulating water heaters as defined in the December 2023 SNOPR are better suited towards providing large volumes of hot water in short periods of time and gas-fired instantaneous water heaters for lengthier periods of time. (BWC, No. 1413 at p. 3) Rheem supported DOE's tentative determination that circulating water heaters do not provide the same consumer utility as gas-fired instantaneous water heaters. Rheem added that though they do not currently exist on the market, the combination of the non-flow-activated operational scheme, storage tank or recirculation loop requirement, and input rate limits consistent with other storage-type water heaters present in DOE's definition ensures that any future gas-fired circulating water heaters would not serve as direct replacements for gas-fired instantaneous water heaters. (Rheem, No. 1408 at p. 2) A.O. Smith agreed with DOE's tentative determination that gas-fired circulating water heaters do not provide the same consumer utility as gas-fired instantaneous water heaters. (A.O. Smith, No. 1411 at p. 6) CEC noted that circulating water heaters provide different utilities from instantaneous water heaters and experience thermal standby losses more than a typical non-circulating storage water heater due to plumbing acting as a storage volume for a significant volume of hot water. (CEC, No. 1412 at p. 3) ASAP et al. agreed with DOE's tentative determination that gas-fired circulating water heaters do not provide the same consumer utility as gas-fired instantaneous water heaters due to the fact that gas-fired instantaneous water heaters utilize flow-activated control schemes and larger burners (compared to gas-fired circulating water heaters) in order to meet demand on a continuous basis, whereas gas-fired circulating water heaters must operate with a separate stored volume of hot water. (ASAP et al., No. 1407 at p. 2)

Rinnai agreed with DOE that gas-fired circulating water heaters do not provide the same utility as gas-fired instantaneous water heaters. Rinnai also stated that gas-fired circulating water heaters do not provide consumers with the same features, energy efficiency and reduced emissions benefits as gas-fired instantaneous water heaters at the proposed UEF levels. Rinnai reiterated its comments made in response to the July 2023 NOPR that UEFs of 0.80 to 0.81 result in increased energy savings and reduction of CO_2 emissions in comparison with the levels gas-fired circulating water heaters would be subject to as gas-fired storage water heaters. Thus, Rinnai arrived at a different conclusion from DOE and claimed that there is not a sufficient basis for allowing gas-fired circulating water heaters to be held to a lower UEF standard than other consumer products and requested that DOE instead establish the more stringent standards proposed in the July 2023 NOPR. (Rinnai, No. 1415 at pp. 1–2)

As discussed in section IV.A.1.c of this document, DOE has found sufficient justification in accordance with the provisions of EPCA to establish separate standards for storage-type and instantaneous-type water heaters.

Rheem, however, noted an additional concern that circulating water heaters can be paired with any size storage tank in the field, and that there is still a concern that circulating water heaters certified to a lower capacity energy conservation standard would be installed with higher capacity storage tanks where higher energy conservation standards would be required. Because of this, Rheem recommended DOE establish separate energy conservation standards for circulating water heaters, but at levels consistent with the higher capacity energy conservation standards. In its recommendation, Rheem showed that the standards equations for larger storage-type product classes (*i.e.,* gas-fired storage water heaters 55–100 gallons, and electric storage water heaters 55–120 gallons) would apply to both circulating water heaters and their analogous traditional storage-type water heaters. (Rheem, No. 1408 at pp. 2–3)

DOE understands Rheem to be suggesting that, in the case that a circulating water heater is designed and marketed to be paired with multiple volumes of storage tanks in the field, it is useful for the rating to reflect larger storage volumes. However, DOE notes that the size of the separate storage tank that the product is tested with (in accordance with section 4.10 of the test procedure) results in the effective storage volume of the circulating water heater, which, for most types of circulating water heaters will be 80 to 120 gallons. This already results in circulating water heaters being held to the same standards as larger storage water heaters. The only exception to this is electric heat pump circulating

water heaters, which are paired with smaller tanks. Separate storage tank pairings are discussed further in section V.D.2 of this document. Additionally, the commenter does not provide evidence as to how different standards for circulating water heaters would be justified under the provisions of EPCA.

After reviewing these comments DOE has concluded that circulating water heaters do not have any characteristics which justify separate standards under the provisions of EPCA at 42 U.S.C. 6295(q)(1). DOE has determined not to create separate product classes for circulating water heaters.

To accomplish this, in the December 2023 SNOPR DOE had proposed an addition to the definition that stated, ''Paired with a separate storage tank, a circulating water heater constitutes a storage-type water heater.'' 88 FR 89330, 89335.

Multiple stakeholders raised concern that DOE's proposed revised definition for ''circulating water heater'' seemingly implies that circulating water heaters are only storage-type water heaters if they are paired with a separate storage tank. These commenters—NEEA, ASAP et al., the CA IOUs, CEC, A.O. Smith and NYSERDA—all indicated that circulating water heaters paired with a circulating loop also constitute storage-type water heaters. (NEEA, No. 1414 at p. 3; ASAP et al., No. 1407 at p. 2; CA IOUs, No. 1409 at pp. 1–2; CEC, No. 1412 at p. 2; A.O. Smith, No. 1411 at pp. 4–5; NYSERDA, No. 1406 at p. 2)

NEEA requested that DOE define circulating water heaters as constituting storage-type water heaters regardless of the configuration in which they are sold or installed. (NEEA, No. 1414 at p. 3) ASAP et al. encouraged DOE to clarify the proposed definition for circulating water heaters so that it is clear all circulating water heaters, whether paired with a separate storage tank or recirculation loop, would be considered storage-type water heaters. (ASAP et al., No. 1407 at p. 2)

The CA IOUs also stated that excluding mention of circulation loops would be inconsistent with the earlier definitional requirements indicating that they must be paired with either a separate storage tank or a water circulation loop and recommend that DOE modify the definition as ''Paired with a separate storage tank or circulation loop, a circulating water heater constitutes a storage-type water heater.'' (CA IOUs, No. 1409 at pp. 1–2)

CEC provided similar statements, adding that the exclusion of pairings with water circulation loops may become a loophole exploited by manufacturers. CEC recommended that DOE modify the definition to simply state that ''a circulating water heater constitutes a storage-type water heater'' to avoid potential misreading. (CEC, No. 1412 at p. 2)

A.O. Smith recommended DOE remove the phrase ''paired with'' from the statement ''paired with a separate storage tank a circulating water heater constitutes a storage-type water heater'' in the definition for circulating water heater to avoid implying that only circulating water heaters that come with a manufacturer-specified or supplied tank would be considered circulating water heaters. In place of this phrasing, A.O. Smith suggested DOE incorporate the definition for a ''water heater requiring a storage tank'' currently outlined in section 1.9 of appendix E to subpart B into § 430.2 and reference this definition in the circulating water heater definition to ensure clarity. A.O. Smith commented that, given the input capacity limits placed on circulating water heaters in their respective definitions, a recirculation loop without the use of a storage tank is unlikely to be an applicable configuration in the residential context. Therefore, A.O. Smith recommended DOE remove the term ''either'' and the phrase ''or water recirculation loop'' from the circulating water heater definition proposed in the December 2023 SNOPR. (A.O. Smith, No. 1411 at pp. 4–5)

NYSERDA recommended that DOE update the definition for circulating water heater to read as follows: ''When paired with a separate storage tank or as part of a water circulation loop, a circulating water heater constitutes a storage-type water heater''. (NYSERDA, No. 1406 at p. 2)

In response to these requests for further clarification, DOE agrees with most commenters that circulating water heaters would constitute storage water heaters whether they are paired with a tank or a recirculation loop. The loop serves to store hot water in pipes instead of in a tank. In both cases, the product does not function properly unless the hot water can be maintained outside of the water heater prior to delivery at a fixture.

While A.O. Smith suggested that a circulating water heater be defined as a ''water heater requiring a storage tank,'' this is not necessarily reflective of field usage to the extent that it can be used to define the product at 10 CFR 430.2. Numerous other comments indicate that a circulating water heater can also function with a recirculation loop. DOE has found examples of gas-fired instantaneous water heaters with input rates that modulate as low as 15,000 Btu/h and can be outfitted with recirculation loops in residential homes. While these specific products are *not* circulating water heaters because they have flow-activated control schemes and do not explicitly require a separate volume of stored hot water to function, they do demonstrate that it is possible for gas-fired products with input rates lower than 75,000 Btu/h to be used in conjunction with a recirculation loop and no tank.

Circulating water heaters are treated as ''water heaters requiring a storage tank'' in appendix E for the purpose of conducting the test procedure because they are not sold with a tank. The appendix E test procedure refers to ''water heaters requiring a storage tank'' in section 1.19 order to provide instruction on how to set up such a water heater with a representative volume of stored water. Therefore, DOE is not amending 10 CFR 430.2 to define a ''water heater requiring a storage tank'' because this terminology has limited application to the test setup instructions in appendix E only. DOE is also not incorporating this terminology in the definition of ''circulating water heater'' so as not to contradict how these products can be designed, marketed, and used in the field.

After considering the suggestions provided by interested parties, DOE is amending the definition of ''circulating water heater'' at 10 CFR 430.2 to read as:

Circulating water heater means a water heater that does not have an operational scheme in which the burner, heating element, or compressor initiates and/or terminates heating based on sensing flow; has a water temperature sensor located at the inlet or the outlet of the water heater or in a separate storage tank that is the primary means of initiating and terminating heating; and must be used in combination with a recirculating pump to circulate water and either a separate storage tank or water circulation loop in order to achieve the water flow and temperature conditions recommended in the manufacturer's installation and operation instructions. A circulating water heater constitutes a storage-type water heater.

The December 2023 SNOPR had also proposed to amend the definitions of the three different fuel types of circulating water heater to align with the re-classification of these products as storage water heaters. 88 FR 89330, 89339.

CA IOUs stated that specifying the volume of stored water per 4,000 Btu/h of input in these definitions is unnecessary because circulating water

heaters are already defined as storage-type water heaters and recommended that DOE remove this requirement from the definitions of electric, gas-fired and oil-fired circulating water heaters as proposed in the December 2023 SNOPR. (CA IOUs, No. 1409 at p. 2)

DOE also agrees with the CA IOUs' suggestion to revise the definitions for the different types of circulating water heaters. As discussed in section III.B, these additional definitions serve mainly to clarify the input rate cutoffs to distinguish these products from commercial water heaters. DOE is amending these definitions to read as:

Electric circulating water heater means a circulating water heater with an input of 12 kW or less (including heat pump-only units with power inputs of no more than 24 A at 250 V).

Gas-fired circulating water heater means a circulating water heater with a nominal input of 75,000 Btu/h or less.

Oil-fired circulating water heater means a circulating water heater with a nominal input of 105,000 Btu/h or less.

In the December 2023 SNOPR DOE requested comment on what the implications to industry might be if circulating water heaters were to be treated as storage water heaters. 88 FR 89330, 89335. In response, several commenters agreed that DOE's analysis for amended standards of storage-type water heaters is still representative if circulating water heaters are included in these product classes.

CEC agreed with DOE that the definition of circulating water heater as proposed in the December 2023 SNOPR would not change the results of the life-cycle cost, national impact, and other downstream analyses, stating that the proposed changes would not cause DOE's analysis to become unrepresentative and agreeing that no additional analysis is necessary. (CEC, No. 1412 at p. 2) The CA IOUs stated that there are few to no shipments of consumer water heaters meeting the definition of ''circulating water heater'' as proposed in the December 2023 SNOPR. CA IOUs stated that DOE may therefore maintain its July 2023 NOPR analyses with respect to storage-type water heaters and apply the associated proposed standards to circulating water heaters. (CA IOUs, No. 1409 at p. 1) NYSERDA and ASAP et al. stated their agreement with DOE's assessment that, because DOE has not identified consumer water heaters on the U.S. market that qualify as circulating water heaters, analytical results from the July 2023 NOPR remain representative and do not need to be updated due to changes proposed in the December 2023 SNOPR. (NYSERDA, No. 1406 at p. 2; ASAP et al., No. 1407 at p. 3) ASAP et al. added that, if introduced, circulating water heaters would likely have similar cost and usage characteristics to existing storage-type consumer water heaters. (ASAP et al., No. 1407 at p. 3)

Rinnai, however, requested that DOE clarify the justification for amending the definition of products that do not currently exist on the market. (Rinnai, No. 1415 at p. 1) BWC agreed with DOE that circulating water heaters as defined in the June 2023 TP Final Rule are not deployed in residential applications. (BWC, No. 1413 at p. 1) BWC agreed with DOE that there are no consumer products that meet the definition of ''circulating water heater'' as proposed in the December 2023 SNOPR and requested that DOE clarify how it determined that these products would have similar cost and use profiles as storage-type water heaters. (BWC, No. 1413 at p. 2)

In the December 2023 SNOPR the Department had erroneously stated that there are no longer heat pump circulating water heaters available on the market (*see* 88 FR 89330, 89333) due to changes in a manufacturer's website. Product literature for these models exists and has been added to the docket for this rulemaking. In addition to stakeholder comments, this literature demonstrates the use of these products in a manner similar to storage-type water heaters. Shipments of these products, though they are fewer than those of traditional storage-type water heaters, are not zero. These products are included in historical data on heat pump water heater shipments as they would meet efficiency level 1 for small electric storage water heaters. Hence DOE's analysis does include circulating heat pump water heaters as storage-type water heaters.

b. Low-Temperature Water Heaters

As stated previously in section III.B of this document, in the June 2023 TP Final Rule, DOE established the following definition for ''low-temperature water heater'' in 10 CFR 430.2:

''Low-temperature water heater'' means an electric instantaneous water heater that is not a circulating water heater and cannot deliver water at a temperature greater than or equal to the set point temperature specified in section 2.5 of appendix E to subpart B of this part when supplied with water at the supply water temperature specified in section 2.3 of appendix E to subpart B of part 430 and the flow rate specified in section 5.2.2.1 of appendix E to subpart B of part 430.

DOE also established test procedures to determine the UEF of these types of water heaters. 88 FR 40406. Regarding low-temperature water heaters, DOE notes that they are covered as electric instantaneous water heaters. As discussed in section IV.C of this document, DOE is not considering updated standards for electric instantaneous water heaters in this rulemaking because it was unable to determine technologies associated with increased efficiencies in these products. Therefore, although low-temperature water heaters are tested in a slightly different manner from other electric instantaneous water heaters, DOE is maintaining low-temperature water heaters within the broader electric instantaneous water heater product class as proposed in the July 2023 NOPR and is not establishing a separate class for them.

c. Storage-Type and Instantaneous-Type Product Classes

In the March 2022 Preliminary Analysis, DOE addressed comments received in response to the May 2020 RFI that suggested that DOE should consider eliminating the separate product classes for instantaneous water heaters. For the preliminary analysis, DOE analyzed separate classes for instantaneous water heaters, but sought feedback from stakeholders on whether storage-type and instantaneous-type water heater product classes should be combined. (See section 2.3 of the preliminary TSD.)

In response to the March 2022 Preliminary Analysis, DOE received comments indicating that storage and instantaneous product classes should not be combined because each type of product provides unique utility to consumers and combining their product classes would lead to UEF standards that are not technologically feasible. DOE tentatively agreed with these comments, which were addressed in the July 2023 NOPR, and maintained separate product classes for storage and instantaneous water heaters for its analyses and proposed standards. 88 FR 49058, 49078.

In response to the July 2023 NOPR, BWC agreed with DOE's tentative determination to maintain separate product classes for instantaneous-type and storage-type water heaters because they offer distinct utilities to consumers in both their designs and capabilities. (BWC, No. 1164 at p. 14) Rheem also agreed with DOE's tentative determination to maintain separate product classes for storage-type and instantaneous-type water heaters given that these water heaters have different

utilities and operational characteristics which necessitate separate consideration. (Rheem, No. 1177 at p. 11) However, Rheem noted that the proposed standards for electric instantaneous water heaters with 2 or more gallons of rated storage volume are significantly higher than the standards proposed for very small electric storage water heaters despite these products all having similar under-sink or commercial applications. (Rheem, No. 1177 at pp. 13–14) Rheem also requested clarification on whether rated or effective storage volume should be used when determining the storage-type and instantaneous-type water heater classification. (Rheem, No. 1177 at p. 2)

NEEA stated that, while it does not disagree with DOE's conclusion to create separate standards for gas-fired storage and gas-fired instantaneous water heaters, standby energy losses should not be considered in a determination of product class as they do not constitute a performance-related feature. NEEA noted that in DOE's decision to set separate product classes for storage and tankless water heaters, DOE stated that ''storage water heaters have associated standby energy losses that instantaneous water heaters do not.'' (NEEA, No. 1199 at p. 10)

AWHI, however, urged DOE to investigate combining gas-fired instantaneous and gas-fired storage water heater categories in a future rulemaking such that the same minimum UEF requirements would apply to both product classes. (AWHI, No. 1036 at pp. 3–4)

After reviewing the comments received on the July 2023 NOPR, DOE has determined that different product classes and standards for storage and instantaneous water heaters remain necessary at this time, and DOE is not combining them in this rulemaking. As stated in the July 2023 NOPR, storage and instantaneous water heaters offer distinct utilities to a consumer. For example, instantaneous water heaters provide a continuous supply of hot water, up to the maximum flow rate, while storage water heaters are often better suited to handle large initial demands for hot water as opposed to continuous draws. 88 FR 49058, 49078. These products are, therefore, designed differently to suit these different needs. As a result of the design differences (*i.e.,* the storage of hot water in storage-type water heaters), storage-type water heaters incur standby losses to the surrounding ambient air.

In response to Rheem, DOE notes that although electric instantaneous water heaters with 2 or more gallons of rated storage volume and very small electric storage water heaters may be used for many of the same under-sink-type applications, each still offers distinct utility to the consumer. Per their definitions at 10 CFR 430.2, electric instantaneous water heaters will necessarily have a higher input rate to volume ratio, and thus will be capable of operating on a more continuous basis than very small electric storage water heaters within the flow rate expectations of these applications. DOE expects these products to have design differences because the scope of coverage is limited to products with electric input rates no greater than 12 kW (*see* section III.B of this document); therefore, electric instantaneous water heaters cannot contain more than approximately 10 gallons of hot water,[31] whereas very small electric storage water heaters can contain up to 20 gallons.

In response to NEEA, DOE does not consider standby losses to be a performance-related feature; rather, the performance-related features are as previously described and the standby losses create the difference in energy consumption between storage-type and instantaneous-type water heaters that justifies different standard levels for the two types of products. In accordance with 42 U.S.C. 6295(q), DOE has concluded that separate standards for storage-type and instantaneous-type water heaters are justified not only because these types offer distinct utilities to the consumer, but also because the design necessary to provide this utility (*i.e.,* a stored volume of water for storage-type water heaters) affects the UEF rating.

EPCA defines instantaneous-type water heaters as units which heat water but contain no more than one gallon of water per 4,000 Btu per hour of input. (42 U.S.C. 6291(27)(B)) Based on the specific use of the term ''contain,'' the rated storage volume, which reflects the amount of water that can be contained, should be used when determining the storage-type and instantaneous-type water heater classification. For circulating water heaters, which operate in a system that contains a stored volume of hot water, this is the rated storage volume of the separate storage tank (*see* section IV.A.1.a of this document).

[31] 12 kW is approximately 41,000 Btu/h. Instantaneous-type water heaters contain no more than one gallon of water per 4,000 Btu/h of input, resulting in a maximum of about 10 gallons for an electric instantaneous water heater with 12 kW of input.

d. Gas-Fired Water Heaters

Gas-fired water heaters operate by burning fuel to generate heat, which is then transferred from the products of combustion (*i.e.,* flue gases) to the water using a heat exchanger before the flue gases are expelled through venting to the outside. Regardless of efficiency, gas-fired water heaters operate in the same manner, by transferring heat to potable water for use within residences. Any combustion heat not transferred to the water is lost to the environment as waste heat, primarily through the exhaust venting. The difference between high-efficiency water heaters and low-efficiency water heaters is the amount of heat that is lost to the environment. Condensing gas-fired water heaters are able to transfer more heat from the flue gases to the water, which results in less heat being lost to the environment. As a result, flue gases exhausted from a condensing gas-fired water heater are typically less than 130 °F, while flue gases exhausted to the environment from a non-condensing gas-fired storage water heater may be in the 300–400 °F range or even higher. Condensing gas-fired water heaters are able to extract more heat due to improved heat exchanger designs.

For example, A.O. Smith notes that their high-efficiency condensing gas storage water heaters ''are built similarly to standard [non-condensing] gas tank water heaters with some modifications for higher efficiency and performance.'' [32] More specifically, A.O. Smith notes that their condensing models ''are built with [a] helical internal heat exchanger that keeps combustion gasses in the tank longer to transfer more heat into the water, increasing efficiency and reducing operating cost.'' [33]

On December 29, 2021, DOE published a final interpretive rule (''December 2021 Venting Interpretive Final Rule'') reinstating its long-standing interpretation that the heat exchanger technology and associated venting used to supply heated air or hot water is not a performance-related ''feature'' that provides a distinct consumer utility under EPCA. 86 FR 73947. Throughout this rulemaking, some commenters have urged DOE to reconsider the conclusions reached in the December 2021 Venting Interpretive Final Rule, and in the July 2023 NOPR, DOE considered these comments but

[32] *See* A.O. Smith's Info Center on Gas Tank High Efficiency Water Heaters, available at *www.hotwater.com/info-center/gas-water-heaters/gas-tank-high-efficiency.html* (last accessed Apr. 3, 2024).

[33] *Id.*

again concluded that heat exchanger technology and venting do not constitute any of the characteristics upon which DOE has the authority to establish separate product classes under EPCA. 88 FR 49058, 49079.

i. General Comments

Earthjustice supported DOE's tentative determination in the NOPR that separate product classes for condensing and non-condensing products are not warranted, and stated that this is consistent with DOE's determinations in the December 2021 Venting Interpretive Rule. (Earthjustice, No. 1189 at pp. 2–3)

In response to comments that DOE should establish separate product classes for condensing and non-condensing gas-fired water heaters, DOE notes that when evaluating and establishing energy conservation standards, DOE is required to establish product classes based on: (1) the type of energy used; and (2) capacity or other performance-related feature which other products within such type (or class) do not have and that DOE determines justify a different standard. In making a determination of whether a performance-related feature justifies a different standard, DOE must consider factors such as the utility to the consumer of the feature and other factors DOE determines are appropriate. (42 U.S.C. 6295(q))

ii. Performance-Related Feature Under 42 U.S.C. 6295(q)(1)(B)

DOE received several comments on whether non-condensing technology should be considered a performance-related feature for the purpose of establishing a separate product class under 42 U.S.C. 6295(q). For example, Rinnai stated that, pursuant to section 6295(q) of EPCA, DOE is required to issue higher or lower energy conservation standards for non-condensing and condensing gas-fired instantaneous water heaters because the products have distinct capacities and performance-related features that provide consumer utility and justify separate standards. (Rinnai, No. 1186 at p. 15) Rinnai asserted that DOE's finding in the July 2023 NOPR that non-condensing technology does not constitute a performance-related feature as prescribed by EPCA at 42 U.S.C. 6295(q)(1) exceeds DOE's authority because it errs in limiting the analysis to non-condensing technology, ignoring features associated with non-condensing technology such as ease of installation and reduced installation cost, and because it interprets ''utility'' too narrowly by only considering the impact the technology has on consumer's operation of or interaction with the appliance. (Rinnai, No. 1186 at pp. 12–14) Similarly, TPPF commented that DOE should set a separate standard for condensing water heaters because, according to TPPF, a non-condensing water heater serves a separate consumer utility because it is more compact, easier to install, and requires less maintenance. TPPF asserted that the consumer utility of a design is not limited to that which is accessible to the layperson or based upon the consumer's operation of or interaction with the product, even the ease of installation of a non-condensing gas-fired instantaneous water heater should be considered a consumer utility. (TPPF, No. 1153 at pp. 3–4)

ONE Gas asserted that minimizing installed cost is a distinct product utility. (ONE Gas, No. 1200 at p. 5) ONE Gas asserted that the availability of products that can serve as a ''drop-in'' replacement for consumers who already have non-condensing products without modifications to the installation space is a consumer utility. ONE Gas also asserted that the ability of ''drop-in'' replacements to restore water heating ability without delays associated with switching to other products is a consumer utility. (ONE Gas, No. 1200 at p. 5) ONE Gas stated that the December 2021 Venting Interpretive Final Rule did not consider the technical and economic burdens of installation when it concluded that product classes based on combustion system types (*i.e.,* non-condensing and condensing) did not provide distinct customer utility among combustion appliances. (ONE Gas, No. 1200 at p. 6) ONE Gas reiterated its comments that DOE's determination that condensing/non-condensing combustion and power/atmospheric venting do not provide unique customer utility is unreasonable and that DOE is required to separately consider minimum energy standards for ''covered products that [have] two or more subcategories'' under EPCA at 42 U.S.C. 6295(q)(1). (ONE Gas, No. 1200 at p. 8)

With respect to commenters' statements that venting associated with non-condensing technology itself is a performance-related feature that justifies a separate product class, DOE first notes that venting, like a gas burner or heat exchanger, is one of the basic components found in every gas-fired water heater (whether condensing or noncondensing). As such, assuming venting is a performance-related feature, it is a feature that all gas-fired water heaters possess. As a result, it cannot be the basis for a product class. *See* 42 U.S.C. 6295(q)(1)(B). Thus, in order to meet the product class requirements in 42 U.S.C. 6295(q)(1)(B), these commenters are requesting DOE determine that a specific type of venting is a capacity or other performance-related feature.

A specific venting technology—including non-condensing venting—is not a ''capacity or other performance related feature'' under 42 U.S.C. 6295(q)((1)(B). As discussed in the December 2021 final interpretive rule, DOE has concluded that performance-related features are those that a consumer would be aware of and would recognize as providing additional benefits during operation of the covered product or equipment. 86 FR 73947, 73955.

DOE also notes that almost every component of a covered product could be broken down further by any of a number of factors. For example, heat exchangers, which are used in a variety of covered products, could be divided further by geometry or material; refrigerator compressors could be further divided by single-speed or variable-speed; and air-conditioning refrigerants could be further divided by global warming potential. As a general matter, energy conservation standards save energy by removing the least-efficient technologies and designs from the market. For example, DOE set energy conservation standards for furnace fans at a level that effectively eliminated permanent split capacitor (PSC) motors from several product classes, but which could be met by brushless permanent magnet (BPM) motors, which are more efficient. 79 FR 38130 (July 3, 2014). As another example, DOE set energy conservation standards for microwave oven standby mode and off mode at a level that effectively eliminated the use of linear power supplies, but which could be met by switch-mode power supplies, which exhibit significantly lower standby mode and off mode power consumption. 78 FR 36316 (June 17, 2013). The energy-saving purposes of EPCA would be completely frustrated if DOE were required to set standards that maintain less-energy-efficient covered products and equipment in the market based simply on the fact that they use a specific type of less efficient heat exchanger, motor, power supply, *etc.*

In this rule and many others, DOE has considered whether the purported ''feature'' provides additional performance benefits to the consumer during operation. Using the previous example of furnace fan motors, if an interested person had wanted to preserve furnace fans with PSC motors in the market, they would have had to

show that furnace fans with PSC motors offered some additional performance benefit during operation as compared to furnace fans with BPM motors. Refrigerator-freezers, on the other hand, are an example of where DOE determined that a specific type of performance-related feature offered additional performance benefit during operation. Some refrigerator-freezers have automatic icemakers. Additionally, some automatic icemakers offer through-the-door ice service, which provides consumers with an additional benefit during operation. As such, DOE further divided refrigerator-freezers into product classes based on the specific type of automatic icemaker (*i.e.,* whether the automatic icemaker offers through-the-door ice service). *See* 10 CFR 430.32(a).

After reviewing comments from stakeholders provided in this rulemaking, DOE has concluded that commenters have not pointed to any additional performance benefits during operation offered by non-condensing water heaters that use non-condensing venting as compared to water heaters that use other types of venting. Instead, these commenters generally cite compatibility with existing venting (*i.e.,* convenience of installation) and other economic considerations as reasons why non-condensing venting should be considered a performance-related feature for the purposes of EPCA's unavailability provision. To be sure, DOE considers installation costs in determining whether a standard is economically justified. The costs of installing condensing venting may, in certain installations, be substantial, and DOE accounts for such costs in its analysis. See section IV.F.2 of this document. But such installation costs are not a ''capacity or other performance-related feature'' for purposes of section 6295(q).

DOE has determined, based on its own research as well as information presented in stakeholder comments, that differences in cost or complexity of installation between different methods of venting (*e.g.,* a condensing water heater versus a non-condensing water heater) do not make specific methods of venting a performance-related feature under 42 U.S.C. 6295(o)(4), so as to justify separating the products/equipment into different product/equipment classes under 42 U.S.C. 6295(q)(1). 86 FR 73947, 73951 (Dec. 29, 2021).

iii. Whether Stakeholders Have Shown by a Preponderance of Evidence That Standards Would Result in Unavailability

DOE received public comments in reference to the ''unavailability provision'' found in EPCA, 42 U.S.C. 6295(o)(4), contending that if the proposed amended standard for GIWH were adopted, it would eliminate non-condensing GIWH from the market. DOE is not summarizing or responding to these comments in this notice, as DOE continues to consider these comments in informing DOE's decision on amended energy conservation standards for GIWH.

iv. Proper Treatment of Economic Considerations

According to NPGA, APGA, AGA, and Rinnai, the proposed UEF requirements for gas-fired storage water heaters would require new venting requirements and other additional equipment even if the adopted standards did not require condensing gas-fired storage water heaters. Based on these proposed UEF requirements, NPGA, APGA, AGA, and Rinnai asserted that DOE failed to understand the market for water heaters and what differentiates consumer decisions, apparent in its discussion of product classes in the July 2023 NOPR. NPGA, APGA, AGA, and Rinnai further asserted that DOE's failure to separate product classes based on relevant features preferred by consumers shows a fundamental market misunderstanding, questioning DOE's capacity to regulate the market. According to NPGA, APGA, and Rinnai, DOE continues to strain to show that the consumer gains no utility from features associated with condensing and non-condensing products, insisting that the design and operation of the unit ''does not provide any utility to the consumer that is accessible to the layperson, which is based upon the consumer's operation of or interaction with the appliance;'' however, these commenters stated, these design and installation issues are certainly accessible to the consumer when choosing the appliance. (NPGA, APGA, AGA, and Rinnai, No. 441 at pp. 2–3)

NPGA, APGA, AGA, Rinnai, and TPPF commented that DOE does not capture what differentiates consumer decisions to purchase non-condensing over condensing water heaters. DOE recognizes, however, that purchase price, installation cost, and maintenance cost—factors which some commenters suggested could be ''features'' of non-condensing models that lead some consumer to pick these models over condensing models—are relevant to consumer decision-making. Accordingly, DOE has treated those variables as inputs to evaluate the costs and benefits to consumers of standards requiring differing technologies. But as stated previously, those factors, while relevant to consumer decision-making and DOE's standard setting, are not ''features'' for purpose of sections 6295(o)(4) or (q)(1)(B). As stated in the December 2021 Venting Interpretive Final Rule, the ''features'' DOE considers separately pertain to those aspects of the appliance with which the consumer interacts during the operation of the product (*i.e.,* when the product is providing its ''useful output'') and the utility derived from those features during normal operation. 86 FR 73947, 73955. The installation and purchase decision factors mentioned by commenters do not affect the performance of the water heater and how a consumer uses it, but instead impact the cost of owning and operating one.

Because DOE views the issues discussed here to be matters of cost, the Department finds it appropriate under the statute to address these issues through the rulemaking's economic analysis. 86 FR 73947, 73951 (Dec. 29, 2021). This interpretation is consistent with EPCA's requirement for a separate analysis of economic justification for the adoption of any new or amended energy conservation standard (*see* 42 U.S.C. 6295(o)(2)–(3); 42 U.S.C. 6313(a)(6)(A)–(C); 42 U.S.C. 6316(a)). These costs are addressed in the LCC in section IV.F of this document.

v. Comparison to Ventless Clothes Dryers

Rinnai noted that, in the case of ventless clothes dryers, DOE recognized consumer costs associated with venting as a basis for establishing separate product classes. (Rinnai, No. 1186 at p. 11)

In response to Rinnai's discussion of ventless clothes dryers, DOE notes that venting in the case of clothes dryers is different from venting of gas-fired appliances, where combustion gases must be exhausted outside of the home, and these differences are outlined in the December 2021 Venting Interpretative Final Rule.

Venting for clothes dryers refers to the method of removal of evaporated moisture from the cabinet space. Vented clothes dryers exhaust this evaporated moisture from the cabinet outside of the home whereas ventless clothes dryers instead use a closed-loop system with an internal condenser to remove the evaporated moisture from the heated air.

In the TSD accompanying a 2011 direct final rule pertaining to residential clothes dryers, DOE explained that ventless clothes dryers can be installed where vented dryers would be precluded due to restrictions preventing any sort of vent from being installed, and thus the Department noted that how a clothes dryer is vented is not simply an issue of initial costs or a consumer choosing one product over another.[34] As discussed in the December 2021 Venting Interpretive Final Rule, unlike consumers of ventless dryers, consumers facing the prospect of replacing a non-condensing water heater with a condensing water heater do have options available to either modify existing venting or install a new venting system to accommodate a condensing product, or to install a feasible alternative to have heated air or water provided (*i.e.,* an electric appliance); but in all cases, the consumer would not be precluded from having access to heated water, a result which is distinctly different from the one at issue in the ventless clothes dryers example. 86 FR 73947, 73957. Condensing gas-fired water heaters can still be installed in buildings where non-condensing gas-fired water heaters currently are. This is because, unlike the case of clothes dryers, both non-condensing and condensing gas-fired water heaters use a vent—the difference in installation is in the type of venting material and its cost.

vi. Conclusion

For the reasons discussed in this section and in the December 2021 Final Interpretive Rule, DOE continues to find that there is no basis for altering the Department's approach regarding the establishment of product classes for gas-fired water heaters for this rulemaking.

e. Very Large Gas-Fired Storage Water Heaters

A.O. Smith identified that a product class for > 100 gallon gas-fired storage water heaters with a non-condensing efficiency level is likely to incentivize the circumvention of current condensing standards for 55–100 gallon gas-fired storage water heaters and residential-duty commercial gas-fired storage water heaters. (A.O. Smith, No. 1182 at p. 14) NYSERDA commented that a non-condensing-level standard for gas-fired storage water heaters > 100 gallons would result in market confusion and the possibility of circumventing residential-duty commercial water heater standards, because residential-duty commercial gas-fired storage water heaters may typically only be just over the 75,000 Btu/h input rate limit and could easily be converted to consumer water heaters. (NYSERDA, No. 1192 at p. 6)

DOE notes that the non-condensing level for >100 gallon gas-fired storage water heaters is simply a crosswalk of existing standards, and, as discussed in section IV.C.2 of this document, DOE did not evaluate more stringent standards for this product class in this rulemaking.

However, DOE understands the concerns from these stakeholders and may consider evaluating amended standards for these product classes in a future rulemaking.

f. Electric Storage Water Heaters

In response to the March 2022 Preliminary Analysis, DOE received comments requesting that DOE establish separate product classes for heat pump electric storage water heaters and electric resistance storage water heaters, citing concern with expanding heat pump-level standards for electric storage water heaters. DOE responded to these comments in the July 2023 NOPR, tentatively determining that the conclusions reached in the April 2010 Final Rule that separate classes are not justified (*see* 75 FR 20112, 20135) remain valid and that heat pump electric storage water heaters and electric resistance storage water heaters do not warrant separate product classes as they do not exhibit any unique performance-related features. 88 FR 49058, 49079–49080.

In response to the July 2023 NOPR, DOE received additional comments regarding the creation of separate product classes for heat pump electric storage water heaters and electric resistance storage water heaters. EEI asserted that DOE should create separate product classes or require lower efficiency levels for electric resistance storage water heaters rather than maintaining these technologies in the same classes with heat pump water heaters, as this would allow newer technologies at more economic price points a chance to meaningfully compete in the marketplace and would, in turn, support the Administration's climate and clean energy goals. EEI stated that the proposed standards would cause a significant increase in efficiency for existing electric resistance storage water heaters. (EEI, No. 1198 at pp. 2–3) Earthjustice, however, stated that separate product classes for heat pump and electric resistance storage water heaters are not warranted, as the NOPR correctly determines. Earthjustice added, specifically, that separate product classes would not be justifiable under EPCA because heat pump and electric resistance water heaters provide equivalent service to the end-user. (Earthjustice, No. 1189 at pp. 1–2)

DOE agrees with EarthJustice and maintains its longstanding position, outlined most recently in the July 2023 NOPR, that separate product classes for heat pump and electric resistance water heaters are not warranted under EPCA. DOE establishes separate product classes based on two criteria: (1) fuel source; and (2) whether a type of product offers a unique capacity or other performance-related feature that justifies a different standard. (*See* 42 U.S.C. 6295(q)(1))

Heat pump electric storage water heaters and electric resistance water heaters both use electricity as the fuel source. 88 FR 49058, 49079–49080. They both offer similar delivery capacities, and DOE has not identified any unique performance-related features offered by either heat pump electric storage water heaters or electric resistance storage water heaters. *Id.* DOE considers performance-related features to be those aspects of the appliance with which the consumer interacts during operation of the product. The technology used to heat the water, heat pump or electric resistance, is not something a consumer would interact with during operation of the water heater. Therefore, DOE has maintained both heat pump and electric resistance technologies within the electric storage water heater classes in this rulemaking analysis, consistent with its approach in the April 2010 Final Rule.

i. Configurations of Electric Water Heaters

In response to the December 2023 SNOPR, A.O. Smith requested clarification as to what test procedure provisions apply to electric resistance booster water heaters that meet the definition of a ''water heater requiring a storage tank'' but not of a ''circulating water heater''. A.O. Smith added that the June 2023 TP Final Rule preamble seems to indicate that electric resistance booster water heaters are to be tested to section 4.10 of appendix E, but that the heading for section 4.10 indicates the section is intended for circulating water heaters and does not include provisions for electric resistance booster water heaters. A.O. Smith commented that electric resistance booster water heaters and circulating water heaters both should be considered as ''water heater requiring a storage tank'' and

[34] Technical Support Document: Energy Efficiency Program for Consumer Products and Commercial and Industrial Equipment: Residential Clothes Dryers and Room Air Conditioners, pp. 3–6 (Available at: *www.regulations.gov/document?D=EERE-2007-BT-STD-0010-0053*).

recommended that the same test procedure apply to both. A.O. Smith recommended DOE implement this approach by establishing a definition for electric resistance booster water heaters and updating section 4.10 of appendix E to include provisions for testing electric resistance booster water heaters. (A.O. Smith, No. 1411 at p. 6)

In response to A.O. Smith, DOE notes that this section provides a description of electric water heater design examples and how they should be tested and classified for the applicable standards. An electric instantaneous water heater product that is designed to operate in tandem with a storage tank but not circulate the water between itself and the tank is not a circulating water heater because it does not meet the definitional criteria ''must be used in combination with a recirculating pump to circulate water.'' A.O. Smith suggested that this type of add-on product might qualify as a ''water heater requiring a storage tank'' per section 1.19 of appendix E; however, DOE does not find this to necessarily be true. Appendix E defines a ''Water Heater Requiring a Storage Tank'' in part as a water heater without a storage tank that cannot meet the requirements of sections 2 and 5 of this appendix without the use of a storage water heater or unfired hot water storage tank. However, section 5.2.2.1 specifies that, for flow-activated water heaters, if the water heater is not capable of providing the discharge temperature specified in section 2.5 of appendix E when the flow rate is 1.7 gallons ± 0.25 gallons per minute, then adjust the flow rate as necessary to achieve the specified discharge water temperature. Based on these requirements, electric resistance booster water heaters would indeed be able to be tested in accordance with appendix E without the use of a storage water heater or separate storage tank.

A.O. Smith said that it agreed with DOE's clarifications in the December 2023 SNOPR which classify all split-system heat pump water heaters, regardless of whether or not they include a tank, as electric storage water heaters. (A.O. Smith, No. 1411 at p. 3–4)

To offer additional clarity on how different electric water heaters would be regulated as a result of this final rule, Table IV.4 shows the distinguishing characteristics of circulating water heaters, split-system heat pump water heaters, and other water heaters that operate in tandem with a separate tank but are instantaneous-type.

A split-system heat pump water heater is defined in section 1.13 of appendix E and reads, ''Split-system heat pump water heater means a heat pump-type water heater in which at least the compressor, which may be installed outdoors, is separate from the storage tank'' (therefore, a split-system heat pump water heater is supplied with a storage tank). These designs are discussed more in the following subsection of this document. The definition of a circulating water heater is provided in section IV.A.1.a of this document, and the key distinction between a heat pump circulating water heater and a split-system heat pump water heater is that a circulating water heater is not sold with a tank (but must be paired with a tank or other stored volume of water in the field to operate), whereas a split system heat pump water heater is sold with a tank. Although heat pump circulating water heaters and split system heat pump water heaters are functionally very similar when installed in the field, they are differentiated in DOE's regulations due to differences in the test methods, which are outlined in Table IV.4. The definition of a low-temperature water heater is provided in section IV.A.1.b of this document, and these units are instantaneous-type (they do not include circulating water heaters).

BILLING CODE 6450–01–P

Table IV.4 Electric Water Heater Design Examples and Classifications

No.	Design Example	Product Category	Test Method	Determining Applicable Standard
1	A heat pump module that is not sold with a hot water storage tank or auxiliary electric storage water heater, but must be paired with one in the field to operate. The heat pump intakes water and outputs it at an elevated temperature using a recirculation pump. The heat pump only activates when a temperature sensor indicates that a separately stored quantity of water cools below an activation temperature.	*Electric storage water heater.* This design meets the definition of a *circulating water heater*, which is a storage-type water heater. It heats a remotely-stored quantity of water and returns the hot water to that stored water, but is sold without a storage tank.	Test with a separate storage tank per section 4.10 of appendix E. Because this is a heat pump, the tank pairing would be a 30 ± 5 gallon small electric storage water heater. Test conditions for the tank and heat pump are to be in accordance with section 2.2.2 of appendix E.	Per section 6.3.1.1 of appendix E, the effective storage volume is the volume of the tank (30 ± 5 gallons). If the first-hour rating is below 51 gallons, the product is a small electric storage water heater.
2	A heat pump module sold with a storage tank (which may or may not include backup heating elements). The system is designed to circulate water between the heat pump and the tank and could contain the temperature sensors for the heat pump in the stored water in the tank.	*Electric storage water heater.* This design meets the definition of a *split-system heat pump water heater*, which is a storage-type water heater because it contains more than one gallon of water per 4,000 Btu per hour of input.	Test with the tank that is sold with the heat pump. Test conditions for the tank and heat pump are to be in accordance with section 2.2.2 of appendix E.	The effective storage volume is determined based on the provisions of section 6.3.1.1 of appendix E.
3	A heat pump module sold with a storage tank (which may or may not include backup heating elements) having a specific design to accommodate the temperature sensor for the heat pump and the refrigerant lines. The system is designed with refrigerant lines connecting the heat pump to the tank and provide the heat transfer (rather than circulating water between the heat pump and tank as in design example #2 in this table).	*Electric storage water heater.* This design meets the definition of *a split-system heat pump water heater*, which is a storage-type water heater because it contains more than one gallon of water per 4,000 Btu per hour of input.	Test with the tank that is sold with the heat pump. Test conditions for the tank and heat pump are to be in accordance with section 2.2.2 of appendix E.	The effective storage volume is determined based on the provisions of section 6.3.1.1 of appendix E.
4	An electric resistance heating module that is not sold with a hot water storage tank, but must be paired with one in the field to operate. The electric resistance module intakes	*Electric storage water heater.* This design meets the definition of a *circulating water heater*, which is a	Test with a separate storage tank per section 4.10 of appendix E. Because this is an electric resistance heater, the tank pairing	Per section 6.3.1.1 of appendix E, the effective storage volume is the volume of the tank (80-120 gallons).*

	water and outputs it at an elevated temperature using a recirculation pump. The electric resistance element(s) only activate when a temperature sensor indicates that a separately stored quantity of water cools below an activation temperature.	storage-type water heater. It heats a remotely-stored quantity of water and returns the hot water to that stored water, but is sold without a storage tank.	would be an 80-120 gallon unfired hot water storage tank.	
5	An electric resistance heating module that identical to design example # 4 in this table, but is sold with a storage tank.	*Electric storage water heater.* This design contains more than one gallon of water per 4,000 Btu per hour of input.	Test with the tank that is sold with the heater.	The effective storage volume is determined based on the provisions of section 6.3.1.1 of appendix E.
6	An electric resistance heater that operates in tandem with a separate storage tank, but is not sold with a tank. It activates during draws if the temperature of the water delivered by the tank falls below an activation temperature. The heater intakes water from the tank and outputs it at an elevated temperature directly to the distribution system and not back to the tank.	*Electric instantaneous water heater.* This design contains less than one gallon of water per 4,000 Btu per hour of input. While it is typically installed with a separate tank that it is not sold with, it does not circulate hot water with the tank and does not need to a recirculation pump to operate. The design is flow-activated by the draw and not thermostatically activated by the temperature inside the tank to replenish the hot water storage.	Test as a stand-alone water heater (*i.e.*, without a storage tank). If it cannot raise water from the required supply temperature to a nominal delivery temperature of 125 °F (*i.e.*, meets the definition of a *low-temperature water heater*), test per the instructions in section 5.2.2.1 of appendix E.	The draw pattern is determined based on maximum GPM determined by testing the design per section 5.2.2.1 of appendix E.

* Note that, because the standards for 55 to 120 gallon electric storage water heaters correspond to heat pump efficiencies, such a product would not be compliant with current or amended standards.

BILLING CODE 6450–01–C

The same concepts would apply for any other fuel type (*e.g.,* gas or oil).

ii. Plug-In and Split-System Heat Pump Electric Storage Water Heaters

DOE received comments in response to the March 2022 Preliminary Analysis recommending that DOE create a separate product class for split-system and plug-in (120-volt) heat pump water heaters. Commenters cited their utility in installation scenarios unable to be met by other heat pump water heaters. DOE responded to these comments in the July 2023 NOPR stating that, while plug-in heat pump water heaters were not considered in the March 2022 Preliminary Analysis because they were not commercially available in the United States at the time, DOE did not have enough information to determine whether a higher or lower efficiency standard would be justified. DOE also stated that it had not identified any unique performance-related features that would warrant a separate product class for split-system heat pump water heaters or plug-in heat pump water heaters. 88 FR 49058, 49080.

Responding to the July 2023 NOPR, Rheem supported DOE's tentative determination not to assign separate product classes to 120-volt heat pump water heaters, noting that its 120-volt design configurations are able to meet the proposed standards. Rheem also stated that there is no need to amend the test procedure for 120-volt heat pump water heaters at this time. (Rheem, No. 1177 at p. 8) A.O. Smith, however, recommended that DOE separate 120-volt heat pump water heaters into their own product class and align the efficiency levels for this product class to ENERGY STAR® Version 5.0. A.O. Smith added that 120-volt heat pump water heaters are relatively new designs and are limited in capacity due to the absence of backup electric resistance elements (because the product must operate at a lower voltage of 120 volts as opposed to conventional 240-volt products). To ensure consumer satisfaction, A.O. Smith stated, these products will tend to favor maintaining higher FHRs at the detriment of UEF. (A.O. Smith, No. 1182, pp. 15–16)

BWC also supported DOE's tentative determination not to create a separate product class for 120-volt heat pump water heaters. BWC stated it does not believe that otherwise identical electric products differentiated only by their operating voltage meet the criteria for establishing separate product classes; the commenter asserted that the voltage

of the product does not cause the consumer to interact with the product differently; not does it enhance the utility being provided directly to the consumer by the product. (BWC, No. 1164 at p. 14)

Based on its review of the few models of 120-volt heat pump water heaters that have been released at the time of this final rule, DOE agrees with BWC in that it has not identified any unique consumer utility provided by the 120-volt plug-in configuration. As discussed in the assessment of benefits and burdens of each TSL (section V.C.1 of this document), DOE has determined that the amended standards adopted in this final rule will not significantly inhibit the future development of 120-volt heat pump water heaters. Further details of 120-volt heat pump water heaters are provided in DOE's market and technology assessment in chapter 3 of the final rule TSD.

In addition to 120-volt plug-in heat pump water heaters, split-system heat pump water heaters are another possible configuration of electric storage water heater.

A.O. Smith stated that commercially available split-system heat pump water heaters fall under two main categories: refrigerant-split systems (for electric storage water heaters) and water-split or ''monoblock'' systems (for electric circulating water heaters). (A.O. Smith, No. 1182 at p. 16)

As discussed in section IV.A.1.a of this document, DOE has determined that circulating water heaters are a configuration of storage-type water heater. Therefore, refrigerant-split systems and water-split systems must meet the same the standards adopted under this final rule. As was tentatively determined in the July 2023 NOPR, DOE has determined not to create a separate product class for split-system heat pump water heaters. Split-system heat pump water heaters use the same fuel source—electricity—as other electric storage water heaters. DOE also has not identified any unique performance-related features offered by split-system heat pump water heaters that would warrant a separate product class consideration at this time. And, as DOE stated previously, the type of technology used to heat the water, in this case a split-system heat pump, is not something a consumer would interact with during operation of the water heater.

In the December 2023 SNOPR DOE explained that treating circulating water heaters as storage water heaters was parallel to how split-system heat pump water heaters are treated: a heat pump module and a separate storage tank, which, altogether, are treated as a storage-type water heater. 88 FR 89330, 89333. Specifically, DOE wrote that these products ''have long been considered to be electric storage water heaters.'' *Id.*

Pickering noted that while most air-to-water heat pumps are electric, systems using natural gas or propane as the fuel source are emerging. Pickering added that the emergence of such technologies is not in agreement with DOE's statement that heat pump water heaters ''have long been considered to be electric storage water heaters''. (Pickering, No. 1399 at p. 2)

DOE agrees with Pickering that the statement in the December 2023 SNOPR implicitly was only referring to electric heat pumps. Split-system heat pump water heaters that do not rely on electricity as the main fuel source would not be electric storage water heaters. For example, split-system heat pump water heaters that are gas-fired would be considered gas-fired storage water heaters. Gas-fired heat pump water heaters are addressed in section IV.B.1 of this document.

iii. Grid-Enabled Water Heaters

Grid-enabled water heaters are a specific type of electric storage water heater with separate standards established by EPCA. (*See* 42 U.S.C. 6295I(6)(A)(ii), also discussed in section III.B of this document). The statutory definition of a grid-enabled water heater describes its characteristics as a product which must be activated when enrolled with a utility, but it does not specifically define what connected features the product must have once enrolled. In the July 2023 NOPR, DOE did not propose to define the connected features because DOE had not found it necessary at the time to further define connectivity.

SkyCentrics and TVA requested that DOE include a requirement for an open standard communication port such as EcoPort (CTA–2045) or equivalent to be added to the product requirements for all electric storage water heaters with a storage volume larger than or equal to 32 gallons. (TVA, No. 978 at pp. 1–2; SkyCentrics, No. 1191 at p. 1) TVA added that there are many water heater models with the port currently on or soon to be on the market, and stated that DOE can help promote this port as a national standard, helping OEMs benefit from volume production and reducing the cost of production by reducing SKUs with models that can be sold nationally. (TVA, No. 978 at pp. 1–2) AWHI also urged DOE to require CTA–2045 EcoPort in new electric storage water heaters, stating that industry partners would be ready for compliance with CTA 2045–B Level 2 as of July 1, 2025. (AWHI, No. 1036 at pp. 4–6)

DOE is maintaining its determination from the July 2023 NOPR not to adopt any specific requirements to define connectivity in this rulemaking. With respect to grid-enabled water heaters, the scope of this product class is defined by EPCA, which does not posit any specific design requirements for the demand-response communication protocol. While DOE recognizes that industry may benefit from standardization of the communication protocols, demand-response technology is not known to be a design option to improve efficiency of the product over an average use cycle (*see* chapter 3 of the final rule TSD, which discusses DOE's technology assessment); hence, it was not considered in the design pathway for compliance with more stringent standards. While EPCA establishes the authority for DOE to amend energy conservation standards for consumer water heaters, it does not directly grant DOE the authority to establish prescriptive design requirements for consumer water heaters, particularly as it relates to a requirement that would not directly impact the measured energy efficiency as measured by the DOE test procedure. Instead, the ongoing work by the EPA's ENERGY STAR program is expected to promote the standardization of demand-response technology. Specifically, ENERGY STAR's version 5.0 specification contains criteria for meeting the connected product designation, which references the CTA–2045 and OpenADR protocols.

Additionally, in the July 2023 NOPR, DOE did not propose to amend standards for grid-enabled water heaters because there remains uncertainty as to whether these products can achieve higher UEF values with added insulation (reduced standby losses being the main pathway towards higher efficiency because grid-enabled water heaters are statutorily defined as having electric resistance heating). 88 FR 49058, 49086.

NRECA and ECSC supported DOE's proposed retention of existing standards for grid-enabled water heaters, adding that these larger water heaters remain an important load-control tool for their member electric cooperatives. (NRECA, No. 1127 at pp. 2, 10; ECSC, No. 1185 at p. 2) NYSERDA also supported DOE's proposals regarding grid-enabled water heaters and stated that there is additional opportunity to address demand-response functionality in a future rulemaking. (NYSERDA, No. 1192 at p. 4)

CEC, however, urged DOE to reevaluate its conclusion that heat pump technology is not applicable as a technology option for grid-enabled water heaters, adding that although they are statutorily defined as ''electric resistance water heaters'' (*see* 42 U.S.C. 6295(e)(6)(A)(ii)), this definition does not preclude additional technologies, such as heat pumps. Therefore, CEC stated, the vast majority of hybrid grid-enabled water heaters employing both heat pump and electric resistance technologies would meet the statutory definition of grid-enabled water heater. (CEC, No. 1173 at pp. 11–12) The CA IOUs recommended that DOE amend standards for grid-enabled water heaters to be equivalent in stringency to those of other electric storage water heaters in a future rulemaking because these products directly compete with heat pump water heaters between 55 and 120 gallons. The CA IOUs also requested that DOE comply with the terms of the 2015 legislation creating the grid-enabled water heater product type and release the two market data reports described in 42 U.S.C. 6295(e)(6)(D)(i). (CA IOUs, No. 1175 at p. 5)

At this time, DOE is not aware of any commercially available heat pump water heaters that also meet the statutory definition of a grid-enabled water heater. Grid-enabled water heaters constitute an entirely separate product class, defined at 42 U.S.C. 6295(e)(6)(A)(ii) and must have a rated storage volume of more than 75 gallons. Not all demand-response water heaters meet the definition of a grid-enabled water heater. While DOE agrees that it is technologically feasible for grid-enabled water heaters to employ heat pumps to increase efficiency, such a product does not exist on the market. Manufacturers of certain models of heat pump water heaters in the electric storage water heater category, however, have certified these units' demand-response capabilities (which can be incorporated in water heaters outside of the grid-enabled product class) to ENERGY STAR, which indicates that heat pump innovation for grid-connected products can continue to occur in the absence of heat pump-level standards for grid-enabled water heaters; thus, it is unclear whether heat pump-level standards for grid-enabled water heaters would result in significant energy savings considering that shipments of electric storage water heaters dwarf those of grid-enabled water heaters today.[35] In other words, consumers seeking demand-response capabilities with heat pump technology could be more likely to seek an electric storage water heater with a communication module than a grid-enabled water heater. DOE may further evaluate the potential for more stringent standards for grid-enabled water heaters in a future rulemaking addressing energy conservation standards for consumer water heaters.

Rheem noted that EPCA (42 U.S.C. 6295(e)(6)(A)(ii)(I)) specifically defines grid-enabled water heaters on the basis that such a product ''has a rated storage tank volume of more than 75 gallons,'' and that DOE would be misaligning the scope of coverage of the grid-enabled water heater product classes if it were to define these classes as being greater than 75 gallons of effective storage volume. (Rheem, No. 1177 at p. 3)

DOE agrees with Rheem and will maintain the current product class definition for grid-enabled water heaters, which is based on rated storage volume rather than effective storage volume. However, as discussed in section V.D.1.f of this document, DOE is adopting amendments to the appendix E test procedure that will effectively exempt grid-enabled water heaters from the high temperature test method such that there is not likely to be any appreciable difference between the two volume metrics as they pertain to standards for grid-enabled water heaters. Therefore, the standards for grid-enabled water heaters will apply to products with rated storage volume greater than 75 gallons instead of an effective storage volume greater than 75 gallons, and this change from the July 2023 NOPR proposal is not expected to have any impact on the results of DOE's analysis or the scope of applicability of standards.

AHRI indicated that there is an additional backsliding concern for grid-enabled water heaters but did not elaborate on details of the concern. The commenter claimed that grid-enabled water heaters will not work correctly unless they are enrolled in a utility program and noted that DOE is collecting information to determine if these products are used properly in the field. (AHRI, No. 1167 at p. 5)

DOE has not identified any backsliding concerns for grid-enabled water heaters. Furthermore, maintaining the definition of this product class in terms of rated storage volume will mean no change to the standards for grid-enabled water heaters and therefore, no backsliding will occur. Regarding the functionality of grid-enabled water heaters, DOE agrees that grid-enabled water heaters will not function correctly unless enrolled in a utility program. Specifically, per 42 U.S.C. 6295(e)(6)(A)(i), grid-enabled water heaters must possess an activation lock that requires a key to enable the product to operate at its designed specifications and capabilities and without which activation the product will provide not greater than 50 percent of the rated first hour delivery of hot water certified by the manufacturer. This requirement sets these products apart from other large electric storage water heaters with grid connectivity.

iv. Small Electric Storage Water Heaters and Tabletop Water Heaters

Current product classes for electric storage water heaters are based on rated storage volume (capacity) and draw pattern. *See* 10 CFR 430.32(d). There are product classes for electric storage water heaters with storage volumes greater than 20 gallons and less than or equal to 55 gallons, and product classes for electric storage water heaters with storage volumes greater than 55 gallons and less than or equal to 120 gallons. As discussed in section II.B.2 of this document, DOE received a Joint Stakeholder Recommendation for amended water heater standards that included recommended standard levels for electric storage water heaters. In particular, the Joint Stakeholder Recommendation suggested setting different standards for smaller electric storage water heaters. In the July 2023 NOPR, DOE tentatively concluded that separate product classes for smaller electric storage water heaters are warranted. 88 FR 49058, 49080–49081. Specifically, DOE noted that market data for electric storage water heaters suggest there is a certain category of electric storage water heaters that are limited in their physical size due to the places they are typically installed, which are commonly referred to as ''lowboy'' water heaters. The physical size limitation of these water heaters restricts the amount of hot water that can be provided to the household. *Id.*

In reviewing the market for these water heaters, DOE found that most ''small electric storage water heaters'' offer an effective storage volume greater than or equal to 20 gallons and less than or equal to 35 gallons and deliver FHRs less than 51 gallons. Due to their low capacities, ''small electric storage water

[35] DOE included an assessment of grid-enabled water heaters in the March 2022 Preliminary Analysis. In shipments estimates, it was approximated that there were about 15 thousand shipments of grid-enabled water heaters in 2021, compared to 3.8 million shipments of other electric storage water heaters. See the NIA spreadsheet to the March 2022 Preliminary Analysis, docketed as Document No. EERE–2017–BT–STD–0019–0024 and available online at *www.regulations.gov/document/EERE-2017-BT-STD-0019-0024.*

heaters'' fall into the very small or low usage draw patterns. Thus, DOE tentatively concluded that this physical limitation is a performance-related feature affecting energy efficiency that would warrant a separate product class. DOE also explained that the physical size limitation constrains the technology options that can be considered to increase the efficiency of these water heaters. DOE, therefore, analyzed splitting the existing 20–55-gallon product classes for electric storage water heaters by establishing new ''small electric storage water heater'' product classes. *Id.*

In the July 2023 NOPR, DOE identified the following proposed product classes for electric storage water heaters: (1) electric storage water heaters with an effective storage volume greater than or equal to 20 gallons and less than or equal to 35 gallons, with FHRs less than 51 gallons (*i.e.,* very small and low draw patterns) (''small electric storage water heaters''); and (2) electric storage water heaters with an effective storage volume greater than or equal to 20 gallons and less than or equal to 55 gallons (excluding small electric storage water heaters).

Responding to the July 2023 NOPR, NEEA supported DOE's proposed creation of the small electric storage water heater product class, and noted that heat pump water heaters are sometimes too large to physically fit in the spaces currently occupied by these types of water heaters. (NEEA, No. 1199 at p. 8) The CA IOUs also supported DOE's proposal to create a new product class and separate electric resistance-level standards for small electric storage water heaters with effective storage volumes of ≥ 20 and ≤ 35 gallons limited to very small and low draw patterns. The CA IOUs agreed with DOE that there is a specific practicality provided by small electric resistance water heaters (also referred to as ''lowboys''), and that it is impractical to install currently available heat pump water heater in some spaces where lowboy water heaters are commonly installed. (CA IOUs, No. 1175 at p. 3)

Rheem asserted that a large portion of 35–40-gallon heat pump water heater sales would be at risk with the structure of the product classes proposed in the July 2023 NOPR. Rheem stated that either the threshold for small electric storage water heaters should be lowered to 30 gallons or the small electric storage water heater category be additionally restricted to products less than 36 inches in height (*i.e.,* lowboys). (Rheem, No. 1177 at p. 7)

PHCC stated that if DOE wished to limit certain products based on effective storage volume, the height is not a significant factor. The commenter asked DOE about the relevance of establishing the small electric storage water heater class based on a 36-inch height limitation while asserting that removing a height consideration would take pressure off the industry and streamline available models. PHCC also suggested DOE adjust the current heat pump-level standard for >55-gal electric storage water heaters to apply to those >40 gallons as well. (PHCC, No. 1151 at p. 2)

DOE is aware that certain 20–55-gallon heat pump water heaters may be interchangeable for some of the larger electric resistance water heaters in the small electric storage water heater product class and agrees with Rheem that some small electric storage water heaters may be substituted for larger products that would be subject to more stringent standards. As discussed in section IV.G.1 of this document, DOE has accounted for this in its analysis. Although the current limitation could lead to more substitution than if the volume threshold were lowered, DOE believes the small electric storage water heater product class, as proposed in the July 2023 NOPR, strikes the balance between preserving consumer utility at smaller storage volumes and ensuring heat pump water heaters are utilized where practicable to install. As such, DOE is adopting the small electric storage water heater product class, as proposed in the July 2023 NOPR. In response to PHCC, DOE notes that although a height restriction was included in the Joint Stakeholder Recommendation, DOE did not propose a height restriction on the small electric storage water heater product class in the July 2023 NOPR. As shown in Table IV.4 of the July 2023 NOPR, small electric storage water heaters are defined by volume and delivery capacity only. 88 FR 49058,49081. Additionally, DOE notes that PHCC's suggestion for expanding the applicability of heat pump-level standards is essentially what was proposed and is being adopted in this final rule. DOE is using a 35-gallon effective storage volume cutoff combined with a draw pattern requirement for small electric storage water heaters to be in the very small or low draw patterns. In its market assessment, DOE found that many products with nominal volumes of 40 gallons have rated storage volumes from 35 to 36 gallons because manufacturers may nominally report volumes that are within 10 percent of the actual storage volume. With respect to Rheem's suggestion that a height requirement be implemented, DOE notes that although most products on the market that fit into this category are ''lowboy'' products with limited overhead space, there are also products on the market that are physically constrained by their width or diameter. These tall, small-diameter water heaters also have smaller storage capacities and delivery capacities. They also have the same energy consumption characteristics as lowboy water heaters based on certification data. In the April 2010 Final Rule, when DOE had first declined to establish a separate product class for lowboy water heaters, DOE stated that it does not believe each different combination of physical dimensions currently available on the market warrants a separate product class. 75 FR 20112, 20131–20132. Consistent with the approach taken in the previous rulemaking, DOE has determined that separate standards for lowboy water heaters and these other shapes of small electric storage water heaters are not justified and, as a result, the product class definition should not specify a height restriction.

Tabletop water heaters, which typically have rated storage volumes of around 35 gallons, also have very particular dimensions in order to be used in a kitchen workspace. DOE is not amending the standards for tabletop water heaters in this final rule based on the market assessment for these products (*see* section IV.C.2 of this document for details). There are only two basic models of tabletop water heaters on the market currently. Because of the similarities between tabletop water heaters and small electric storage water heaters, DOE proposed, in the July 2023 NOPR, to create alignment between the standards for these types of products. Specifically, DOE proposed to amend the definition of ''tabletop water heater'' to specify that the tabletop designation of electric storage water heaters is only applicable to products in the very small or low draw pattern, and any tabletop water heaters in the medium and high draw patterns would henceforth be considered in the broader electric storage water heater product classes. 88 FR 49058, 49081. In the July 2023 NOPR, DOE requested comment on its proposal to limit the tabletop water heater designation to products in the very small and low draw patterns.

In response, AHRI supported the proposal to limit the tabletop water heater designation to the products in the very small and low draw patterns as it will prevent the use of tabletop water heaters as an avenue to bypass the current limitations on small electric storage water heaters. (AHRI, No. 1167

at p. 10) The Joint Advocacy Groups also supported DOE's proposal to limit the tabletop water heater designation to products in the very small and low draw patterns, as it would align the standards for tabletop water heaters with those for small electric storage water heaters and help ensure tabletop water heaters are not used as a less efficient substitute for conventional electric storage water heaters. (Joint Advocacy Groups, No. 1165 at pp. 6–7) Rheem supported DOE's proposed amendments to the tabletop water heater definition, indicating that this otherwise low-sales-volume product has the potential to be installed in place of heat pump water heaters. (Rheem, No. 1177 at p. 8) A.O. Smith supported the changes proposed to the tabletop water heater standards even though it asserted that this may cause some issues for existing products. (A.O. Smith, No. 1182 at p. 15)

BWC stated that re-defining tabletop water heaters as products that only meet either the very small or low draw pattern would remove half of the products from the market, even though this is a very small number of models. As a result, BWC stated, there would be a drastic reduction in model availability for consumers who rely on tabletop water heaters, many of which may be in densely populated, low-income households that have higher household occupancies and therefore require products with delivery capacities in the medium draw pattern. (BWC, No. 1164 at pp. 15–16)

In response to BWC, DOE notes that, in its market assessment of tabletop water heaters, there are only two basic models found to be certified and commercially available. One is in the low draw pattern, and the other has an FHR of 55 gallons, putting it into the medium draw pattern. Water heaters with FHRs less than 51 gallons can remain categorized as tabletop water heaters. Because the medium draw pattern tabletop water heater on the market today is very close to this FHR cutoff, in the July 2023 NOPR, DOE surmised that, with minimal design changes, a modified version of this model may remain on the market and be certified in the tabletop water heater category (*see* 88 FR 49058, 49081). This would avoid limitations to consumer choice. In written comments in response to the NOPR, the two manufacturers that produce tabletop water heaters both supported the proposed updates to the tabletop water heater definition. Additionally, DOE is not aware of, nor did BWC provide, information to support BWC's assertion that many tabletop water heaters are used in households with higher occupancies that require the medium draw pattern. Therefore, DOE is finalizing the definition for tabletop water heaters as proposed.

Additionally, given these insights regarding the market for tabletop water heaters, DOE is amending the product classes for tabletop water heaters to remove the storage volume-based product class boundary at 120 gallons. Comments indicate that the market for these products is limited and requires the specific use of the rectangular casing configuration with typical dimensions of 36 inches high, 25 inches deep, and 24 inches wide. The maximum possible volume contained in these dimensions is approximately 94 gallons, hence DOE does not expect there to exist a market for tabletop water heaters larger than 120 gallons. The amended product class structure for tabletop water heaters results in two volume-based categories: products less than 20 gallons, and products greater than or equal to 20 gallons.

v. Very Large Electric Storage Water Heaters

Responding to the July 2023 NOPR, Bosch, the Joint Advocacy Groups, the CA IOUs, Rheem, A.O. Smith, and AHRI all expressed concern that defining the >120-gallon electric storage water heater product class in terms of effective storage volume (rather than rated storage volume) could pose backsliding concerns given that it would be possible for electric resistance storage water heaters between 55 and 120 gallons to increase their effective storage volume to over 120 gallons by elevating tank temperatures, such that these products could circumvent the existing heat pump-level standards for electric storage water heaters which apply to rated storage volumes between 55 and 120 gallons. (Bosch, No. 1204 at pp. 2–3; Joint Advocacy Groups, No. 1165 at p. 8; CA IOUs, No. 1175 at pp. 3–4; Rheem, No. 1177 at p. 3; A.O. Smith, No. 1182 at p. 14; AHRI, No. 1167, pp. 5–6) Bosch and the CA IOUs also suggested that defining the greater than 120-gallon electric storage water heater product class in terms of effective storage volume could encourage a market shift towards larger electric resistance storage water heaters in place of smaller, <55-gallon heat pump water heaters. (Bosch, No. 1204 at pp. 2–3; CA IOUs, No. 1175 at pp. 3–4) Rheem noted that a product with a rated storage volume of 75 gallons could achieve an effective storage volume of 120 gallons at a storage tank temperature of 160 °F. (Rheem, No. 1177 at p. 3)

Multiple stakeholders suggested remedies to this potential problem. Bosch recommended that all electric storage water heaters (apart from very small electric storage water heaters) be required to utilize heat pump technology. (Bosch, No. 1204 at pp. 2–3) The CA IOUs suggested that DOE amend the calculations for effective storage volume such that products with rated storage volumes less than or equal to 120 gallons would be capped at an effective storage volume of 120 gallons. (CA IOUs, No. 1175 at pp. 3–4) Rheem suggested that DOE exempt products with rated storage volumes greater than 120 gallons from the high temperature test method because a >120-gallon product can already provide the same or more hot water than a heat pump water heater and thus does not rely on increasing its temperature to have a large effective storage volume. (Rheem, No. 1177 at p. 3) NYSERDA suggested that, rather than creating a separate product class for electric storage water heaters >120 gallons, DOE could instead remove the 120-gallon cap and apply the same standards for electric storage water heaters >55 gallons to those >120 gallons. (NYSERDA, No. 1192 at p. 5)

DOE agrees with stakeholders that defining the >120-gallon electric storage water heater product class in terms of effective storage volume, rather than rated storage volume, would pose a backsliding risk. However, as discussed in V.D.1 of this document, the high-temperature test method does not apply to water heaters that are larger than 55 gallons in rated storage volume. Therefore, the scenarios described above of an electric resistance water heater having a rated volume less than 120 gallons and an effective storage volume greater than 120 gallons is not likely to occur without the use of the high temperature test method. As a result, there would be no risk of backsliding for these standards.

2. Technology Options

DOE conducts a technology assessment to identify a complete list of technologies for consumer water heaters (''technology options'') with the potential to improve the UEF ratings of products. Section IV.B of this document describes the process by which technology options are screened in a separate screening analysis that aims to determine which technology options could feasibly be adopted based on five screening criteria. In the engineering analysis (section IV.C of this document), DOE selects the technology options that are most likely to constitute the design pathway to higher efficiency levels in a standards-case scenario (thereafter referred to as ''design options''). Thus, after DOE identifies a comprehensive

list of technologies for the technology assessment, the subsequent analysis focuses only on those technologies that are the most likely to be implemented in response to amended standards. In the July 2023 NOPR, DOE presented a list of technologies that it identified for initial consideration in the NOPR analysis. 88 FR 49058, 49082–49083.

In the technology assessment for the July 2023 NOPR, DOE examined 120-volt heat pump water heater technology and noted that there were very few models of 120-volt heat pump water heater available on the market at the time. DOE therefore requested comment on the outlook for the emergence of 120-volt heat pump water heaters, information regarding how their design and operation could differ from 240-volt heat pump water heaters, and data on performance characteristics and efficiencies. 88 FR 49058, 49082.

In response, AWHI commented that NEEA's Advanced Water Heating Specification version 8.01 contains a technical specification for a load shifting-capable 120-volt heat pump water heater, and that there are now three manufacturers that offer commercially available 120-volt heat pump water heaters ranging from 50 to 80 gallons. AWHI cited a preliminary market assessment conducted by New Buildings Institute stating that 22 to 30 percent of existing California homes could transition from fossil fuel-based water heaters to 120-volt heat pump water heaters without substantial site upgrades, and that the installation cost of 120-volt heat pump water heaters is significantly less that for 240-volt units due to minimal electrical interventions. AWHI stated that 120-volt heat pump water heaters do not need a dedicated circuit to be installed and can instead share a circuit with other appliances, reducing the impact of installation on the existing electrical infrastructure of the home. AWHI also stated that 120-volt heat pump water heaters do not have electric resistance elements, which results in slower recovery than 240-volt heat pump water heaters and are therefore more sensitive to environmental factors that impact compressor performance, such as input water temperature and ambient air temperature. AWHI stated that 120-volt heat pump water heaters incorporate integrated mixing valves and store water at temperatures above the delivery temperature to increase hot water capacity, which allows for easier participation in load shifting and demand-response programs. Lastly, AWHI stated that a 120-volt heat pump water heater performed at an overall average UEF of 2.90 and varied by season and use characteristics in a field study conducted in California by New Buildings Institute. (AWHI, No. 1036 at pp. 1–3)

BWC supported DOE's tentative determination not to include 120-volt heat pump water heaters in its analysis because these products are relatively new and do not have significant market share at the present time. BWC stated a belief that it is appropriate for DOE, and the industry, to take more time to better understand these products before establishing regulations. (BWC, No. 1164 at p. 14)

DOE appreciates the insight into 120-volt heat pump water heaters and continues to evaluate this technology. While DOE considers 120-volt heat pump water heaters to be a technology for improving the efficiency of electric water heaters, due to the nascent status of 120-volt heat pump water heaters, DOE did not consider 120-volt designs to constitute the main pathway towards higher efficiency for electric storage water heaters. However, as discussed in section V.C.1 of this document, the Department assessed TSLs with consideration of these designs. Specifically, when evaluating TSLs, DOE considered whether the potential standards levels would likely prevent new 120-volt designs from emerging onto the market.

Responding to the July 2023 NOPR, NEEA supported DOE's inclusion of the gas pressure-actuated non-powered damper as a technology option, stating that it is likely the lowest cost pathway to achieving EL 2. (NEEA, No. 1199 at p. 9) DOE has maintained non-powered dampers as a technology option for the final rule.

Additionally, while DOE identified modulating burners as a technology option for all gas-fired water heaters in the July 2023 NOPR technology analysis, DOE tentatively determined that modulating burners were used to increase UEF only in instantaneous gas-fired water heaters. 88 FR 49058, 49082. DOE did not receive any comments on that tentative determination. As discussed in section II.B.3 of this document, gas-fired instantaneous water heaters are no longer within the scope of this rulemaking. However, modulating burners could still be used in circulating gas-fired water heaters, which are a type of gas-fired storage water heater. Hence, in light of the classification of circulating water heaters as storage-type water heaters (*see* section IV.A.1.a of this document), DOE is retaining modulating burners in its list of technology options investigated for this final rule; however, as shown in chapter 5 of the TSD, modulating burners are not expected to be part of the representative, cost-effective design pathway to increasing efficiency for gas-fired storage water heaters. The technology options for Improving UEF in consumer water heaters are listed in Table IV.5 and described in chapter 3 of the final rule TSD.

BILLING CODE 6450–01–P

Table IV.5 Potential Technologies for Increasing Consumer Water Heater Efficiency

Technology Option		
Heat traps		
Improved insulation	Increased thickness	
	Insulation on tank bottom	
	Less conductive tank materials (*e.g.*, plastic)	
	Foam insulation	
	Pipe and fitting insulation	
	Advanced insulation types	Aerogel
		Vacuum panels
		Inert gas-filled panels
Electronic ignition systems	Direct spark ignition	
	Intermittent pilot ignition	
	Hot surface ignition	
Improved burners	Pulse combustion	
	Pressurized combustion	
	Side-arm heating	
	Two-phase thermosiphon technology	
	Modulating burners	Step Modulating Burners
		Fully Modulating Burners
	Reduced burner size (slow recovery)	
Heat exchanger improvements	Increased heat exchanger surface area	
	Enhanced flue baffle	
	Submerged combustion chamber	
	Multiple flues	
	Alternative flue geometry (Helical)	
	U-Tube	
	Condensing technology	
	Induced-draft (negative vent pressure) heat exchanger	
	Direct-fired heat exchange	
Improved venting	Flue damper	Externally-powered
		Thermopile-operated (non-powered)
		Gas-actuated (non-powered)
		Buoyancy-operated (non-powered)
	Concentric direct venting	
	Power vent	
Improved heat pump water heater	Compressor improvements	Increased capacity

Technology Option		
components		Increased efficiency
		Variable-speed drive
	Fan improvements	High-efficiency fan motors
		High-efficiency fan blades
	Expansion device improvements	
	Increased evaporator surface area	
	Increased condenser surface area	
Gas-fired absorption heat pump water heaters		
Gas-fired adsorption heat pump water heaters		
Carbon dioxide heat pump water heaters		
Thermophotovoltaic and thermoelectric generators		
Improved controls	Modulating controls	

BILLING CODE 6450–01–C

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in commercially viable, existing prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility.* If a technology is determined to have a significant adverse impact on the utility of the product to subgroups of consumers, or result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Safety of technologies.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5)*Unique-pathway proprietary technologies.* If a technology has proprietary protection and represents a unique pathway to achieving a given efficiency level, it will not be considered further, due to the potential for monopolistic concerns.

10 CFR part 430, subpart C, appendix A, sections 6(b)(3) and 7(b).

In sum, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis. The reasons for eliminating any technology are discussed in the following sections.

The subsequent sections include comments from interested parties pertinent to the screening criteria, DOE's evaluation of each technology option against the screening analysis criteria, and whether DOE determined that a technology option should be excluded (''screened out'') based on the screening criteria.

1. Screened-Out Technologies

The following subsections describe the technologies that DOE eliminated for failure to meet one of the following five factors: (1) technological feasibility; (2) practicability to manufacture, install, and service; (3) impacts on equipment utility or equipment availability; (4) adverse impacts on health or safety; and (5) unique-pathway proprietary technologies.

In the July 2023 NOPR, DOE screened out the following technology options based on the above criteria: absorption and adsorption heat pump water heaters, advanced insulation types, condensing pulse combustion, direct-fired heat exchange, dual-fuel heat pumps, buoyancy-operated flue dampers, thermopile-operated flue dampers, reduced burner size (slow recovery), side-arm heating, two-phase thermosiphon technology, and U-tube flues. 88 FR 49058, 49083. Each of these technology options and the reasons for which they were screened out are discussed in detail in chapter 4 of the final rule TSD.

BWC stated that it is aware of exclusive intellectual property protections that it asserted may inhibit manufacturers from utilizing certain technologies that are assumed by DOE to be available in the market to increase energy efficiency on certain consumer water heater products, and that BWC would be able to provide information in a confidential interview with DOE's consultants. (BWC, No. 1164 at p. 16)

In selecting design options to improve efficiency in the engineering analysis, DOE performed teardowns of models manufactured by multiple companies to ensure that each efficiency level is achievable using non-proprietary designs.

BWC supported DOE's tentative determination not to consider thermopile-powered flue dampers for gas-fired storage water heaters. (BWC, No. 1164 at p. 16)

BWC stated that direct-vent and power-direct-vent gas-fired water heaters are not necessarily unsafe, but that their construction imposes limits on how these products can vent and operate; a major consideration for these products would be restrictions on the maximum allowable vent length that safety standards would permit. BWC requested that DOE consider these venting factors for gas-fired water heaters to avoid unintentionally encouraging installations that conflict with the requirements of safety standards such as ANSI Z21.10.1 and ANSI Z21.10.3. (BWC, No. 1164 at p. 16)

DOE agrees with BWC that direct-vent and power-direct-vent gas-fired water

heaters are safe to use when installed and operated in accordance with manufacturer recommendations and/or applicable safety standards. Therefore, DOE has not screened these technologies out of its analysis. In evaluating these technologies, DOE accounts for the necessary differences in venting systems installations (*see* section IV.F.2.b of this document).

2. Remaining Technologies

Through a review of each technology, DOE concludes that all of the other identified technologies listed in section IV.A.2 of this document meet all five screening criteria to be examined further as design options in DOE's final rule analysis. In summary, DOE did not screen out the following technology options listed in Table IV.6. These technology options are shown from left to right from broader categories to specific design options.

BILLING CODE 6450–01–P

Table IV.6 Remaining Technology Options

Technology Option			
Improved insulation		Increased thickness	
		Insulation on tank bottom	
		Less conductive tank materials (*e.g.*, plastic)	
		Foam insulation	
		Pipe and fitting insulation	
Electronic ignition systems		Direct spark ignition	
		Intermittent pilot ignition	
		Hot surface ignition	
Burner improvements		Pressurized combustion	
		Modulating burners	Step modulating burners
			Fully modulating burners
Gas-fired and Oil-fired Heat exchanger improvements		Increased heat exchanger surface area	
		Enhanced flue baffle	
		Submerged combustion chamber	
		Multiple flues	
		Alternative flue geometry (Helical)	
		Condensing technology	
		Induced-draft (negative vent pressure) heat exchanger	
Improved venting		Flue damper	Externally-powered
			Gas-actuated (non-powered)
		Power vent	
		Concentric direct venting	
Improved heat pump water heater components	Compressor improvements	Increased capacity	
		Increased efficiency	
		Variable-speed drive	
	Fan Improvements	High-efficiency fan motors	
		High-efficiency fan blades	
	Expansion device improvements		
	Increased evaporator surface area		
	Increased condenser surface area		
	Carbon dioxide (alternative refrigerant) heat pump water heaters		
Improved controls		Modulating controls	
Heat traps (all types)			

BILLING CODE 6450–01–C

DOE determined that these technology options are technologically feasible because they are being used or have previously been used in commercially available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.,* practicable to manufacture, install, and service and do not result in adverse impacts on consumer utility, product availability, health, or safety). For additional details, *see* chapter 4 of the final rule TSD.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of consumer water heaters. There are two elements to consider in the engineering analysis; the selection of efficiency

levels to analyze (*i.e.,* the ''efficiency analysis'') and the determination of product cost at each efficiency level (*i.e.,* the ''cost analysis''). In determining the performance of higher-efficiency products, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each product class, DOE estimates the baseline cost, as well as the incremental cost for the product at efficiency levels above the baseline. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses, the MIA, and the NIA).

As discussed in section IV.A.1 of this document, certain classes of consumer water heaters currently have UEF-based standards, while for others EPCA's EF-based standards apply. For this rulemaking, DOE analyzed amended UEF standards for the product classes that currently have standards in terms of UEF. For the product classes with EF-based standards, DOE developed translated standards in terms of UEF for use in the analysis.

In this final rule, DOE has analyzed standards with respect to the effective storage volume metric (as proposed in the July 2023 NOPR). Compared to rated storage volume and FHR, effective storage volume is a superior descriptor of the thermal energy stored in the hot water of the water heater which can be made immediately available for consumer use. As outlined in the July 2023 NOPR, there are two types of water heaters that can cause the system to store more energy than would be otherwise determined by the rated storage volume: (1) water heaters capable of operating with an elevated tank temperature, and (2) circulating water heaters. 88 FR 49058, 49086. In the June 2023 TP Final Rule, DOE established that compliance with the effective storage volume provisions (and, relatedly, the high temperature testing method and testing with separate storage tanks for circulating water heaters) would not be required until compliance with amended standards is required. For circulating water heaters, the effective storage volume of the water heater is determined by the measured storage volume of the separate storage tank used in testing because these types of water heaters are designed to operate with a volume of stored water in the field. 88 FR 40406, 40461–40462. Certain provisions for circulating water heater testing are discussed further in detail in section V.D.2 of this document. Section V.D.1 of this document discusses the proposed approach to consider efficiency determinations for water heaters tested using the high temperature testing method.

In the July 2023 NOPR, DOE tentatively determined not to propose amended standards for gas-fired storage water heaters (55 gal < V_{eff} ≤ 100 gal), tabletop water heaters (20 gal ≤ V_{eff} ≤ 120 gal), electric instantaneous water heaters (V_{eff} < 2 gal), and grid-enabled water heaters at that time based on the results of the market and technology assessment, screening analysis, interviews with manufacturers, and comments from interested parties. These assessments were discussed further in chapters 3 and 5 of the NOPR TSD. 88 FR 49058, 49086.

In this final rule, DOE has maintained the analytical approaches proposed in the July 2023 NOPR. For circulating water heaters, as discussed in section IV.A.1.a of this document, based on information from the December 2023 SNOPR, DOE has determined that these products offer the same consumer utility as storage-type water heaters, so the storage-type water heater standards would apply. In summary, Table IV.7 presents the consumer water heater product classes along with the approach to analyzing them for this final rule.

BILLING CODE 6450–01–P

Table IV.7 Analysis Approach by Product Class

Product Category Analyzed in this Final Rule	Distinguishing Characteristics (Effective Storage Volume and Input Rating)	Analysis
Gas-fired Storage Water Heater	< 20 gal	Converting EF-based standards to UEF-based standards
	≥ 20 gal and ≤ 55 gal	Amending UEF-based standards
	> 55 gal and ≤ 100 gal	No amendments
	> 100 gal	Converting EF-based standards to UEF-based standards
Oil-fired Storage Water Heater	≤ 50 gal	Amending UEF-based standards
	> 50 gal	Converting EF-based standards to UEF-based standards
Electric Storage Water Heater	< 20 gal	Converting EF-based standards to UEF-based standards
	≥ 20 gal and ≤ 35 gal, FHR < 51 gal (Small electric storage water heaters)	Amending UEF-based standards
	≥ 20 gal and ≤ 55 gal, excluding small electric storage water heaters	Amending UEF-based standards
	> 55 gal and ≤ 120 gal	Amending UEF-based standards
	> 120 gal	Converting EF-based standards to UEF-based standards
Tabletop Water Heater	< 20 gal	Converting EF-based standards to UEF-based standards
	≥ 20 gal and ≤ 120 gal	Remove boundary at 120 gal due to these sizes not being feasible within the description of a tabletop water heater
Electric Instantaneous Water Heater (including Low-Temperature Water Heaters)	< 2 gal	No amendments
	≥ 2 gal	Converting EF-based standards to UEF-based standards
Grid-enabled Water Heater	> 75 gal	No amendments
Circulating Water Heater	All Sizes	Included as storage-type water heaters

BILLING CODE 6450–01–C

Several commenters provided feedback about transitioning the energy conservation standards from a rated storage volume basis to an effective storage volume basis.

AHRI provided comments emphasizing the possibility of market confusion resulting from amended standards being prescribed in terms of effective storage volume instead of rated storage volume, noting that the previous conversion from the EF to the UEF metric itself was not without issue, leading to market disruption given that utility programs across the United States and in Canada have still not fully adopted the UEF metric. AHRI stated that the effective storage volume metric needs to be further scrutinized to evaluate the representativeness and repeatability of the metric, and that manufacturers require additional time to analyze the effective storage volume calculation to determine its accuracy, representativeness, and repeatability, as well as to conduct laboratory testing to this end. AHRI asserted that the 60-day comment period for the July 2023 NOPR was insufficient to conduct this review.

AHRI recommended using only effective storage volume in the energy conservation standards equations for products for which the metric applies to limit confusion. (AHRI, No. 1167 at p. 5) AHRI requested clarification on whether the effective storage volume metric would apply to grid-enabled water heaters, tabletop water heaters, and electric instantaneous water heaters larger than 2 gallons in rated storage volume, recommending that the effective storage volume metric not apply to grid-enabled water heaters. AHRI proposed two possible options to mitigate potential market confusion from the new effective storage volume metric: use rated storage volume for all product categories not subject to high temperature testing; or (the option AHRI stated was less preferable), include a footnote with the standards to indicate those product categories for which effective storage volume is identical to rated storage volume. (AHRI, No. 1167 at p. 6)

BWC commented that the replacement of the rated storage volume metric with effective storage volume deviates from the Joint Stakeholder Recommendation and could create situations where products may not be capable of supplying adequate hot water to the home. (BWC, No. 1164 at p. 1) BWC requested DOE not change the standards for all product classes to be in terms of effective storage volume, but instead to use the new metric only for product classes for which the rated storage volume and effective storage volume are expected to be different in order to avoid confusion. (BWC, No. 1164 at p. 9)

CEC identified a drafting error in the proposed regulatory language in the heading at 10 CFR 430.32(d)(1) and (2), where ''rated storage volume'' is used rather than ''effective storage volume.'' (CEC, No. 1173 at pp. 12–13) This was a publication error printed at 88 FR 49058, 49176. Stakeholders were notified of this typographical error in the September 13 Public Meeting. (Public Meeting Transcript, No. 1190 at p. 101).

In response, DOE maintains that effective storage volume is appropriate for use for all classes. In light of the reclassification of circulating water heaters as storage-type water heaters, defining all classes in terms of effective storage volume (rather than just electric storage classes, as was suggested by stakeholders) and delineating the standards as a function of effective storage volume is necessary to ensure the appropriate classification of these products. More specifically, because circulating water heaters will be considered part of the storage-type product classes, the same standards will apply to circulating water heaters. Where the standards for storage-type product classes are linear functions of volume, the purpose of this is to account for the additional standby loss that comes with more hot water being contained in the system. The effective storage volume of a circulating water heater is what captures the amount of hot water contained in this type of system, and therefore is most appropriate to base the standards equations on. Stakeholders correctly noted that the use of the high temperature test method (described in section V.D.1 of this document), which will apply to certain types of electric storage water heaters, is one way by which a model can have an effective storage volume different from its rated storage volume. Further, per section 6.3.1.1 of appendix E test procedure, the effective storage volume can be higher than the rated storage volume for any storage-type water heater if the mean tank temperature is more than 5 °F higher than the delivery temperature (*see* section V.D.1 of this document for details). Therefore, DOE adopts use of effective storage volume rather than storage volume in this final rule.

1. Product Classes With Current UEF-Based Standards

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). Using the efficiency-level approach, the efficiency levels established for the analysis are determined based on the market distribution of existing products (in other words, based on the range of efficiencies and efficiency-level ''clusters'' that already exist on the market). Using the design option approach, the efficiency levels established for the analysis are determined through detailed engineering calculations and/or computer simulations of the efficiency improvements from implementing specific design options that have been identified in the technology assessment. DOE may also rely on a combination of these two approaches. For example, the efficiency-level approach (based on actual products on the market) may be extended using the design-option approach to ''gap fill'' levels (to bridge large gaps between other identified efficiency levels) and/or to extrapolate to the max-tech level (particularly in cases where the max-tech level exceeds the maximum efficiency level currently available on the market).

In the July 2023 NOPR, DOE developed efficiency levels with a combination of the efficiency-level and design-option approaches. DOE conducted a market analysis of currently available models listed in DOE's CCD to determine which efficiency levels were most representative of the current distribution of consumer water heaters available on the market. DOE also completed physical teardowns of commercially available units to determine which design options manufacturers may use to achieve certain efficiency levels for each water heater category analyzed. DOE requested comments from stakeholders and conducted interviews with manufacturers concerning these initial efficiency levels, which have been updated based on the feedback DOE received.

a. Efficiency Levels

In this final rule, as noted previously, DOE has analyzed efficiency levels for UEF that are a function of effective storage volume (with the exception of certain levels which were analyzed when DOE incorporated feedback from the Joint Stakeholder Recommendation). For products with substantial storage volumes, the UEF is expected to decrease with higher volumes because standby losses (*i.e.,* energy lost from the stored water to the surroundings when the water heater is not actively heating water) are related to the temperature of the water stored and the size of the tank.[36] The efficiency levels analyzed in this rulemaking assume that the relationships between standby losses and storage volume for baseline products (*i.e.,* the slopes of the current standards equations) would remain consistent for higher efficiency levels. In other words, the higher efficiency levels are linear equations that are parallel to the current standards. The exception to this is for DOE's analysis of the Joint Stakeholder Recommendation, which included certain efficiency levels that were not specified as a function of storage volume.

In this final rule, DOE has analyzed the same efficiency levels as were considered in the July 2023 NOPR. The details of the efficiency level analysis

[36] As discussed in section III.C of this document, the effective storage volume metric accounts for both temperature and tank size, whereas rated storage volume alone only accounts for tank size.

are presented in chapter 5 of the final rule TSD, and a summary of the efficiency levels is presented in the following sections.

i. Baseline Efficiency

For each product class, DOE generally selects a baseline model as a reference point for each class and measures changes resulting from potential energy conservation standards against the baseline. The baseline model in each product class represents the characteristics of a product/equipment typical of that class (*e.g.,* capacity, physical size). Generally, a baseline model is one that just meets current energy conservation standards, or, if no standards are in place, the baseline is typically the most common or least efficient unit on the market. For this final rule, the baseline efficiency levels for product classes with current UEF-based standards are equal to the current energy conservation standards (*see* Table II.1).

ii. Higher Efficiency Levels

As part of DOE's analysis, the maximum available efficiency level is the highest efficiency unit currently available on the market. DOE also defines a ''max-tech'' efficiency level to represent the maximum possible efficiency for a given product.

In July 2023 NOPR, the max-tech efficiency levels generally corresponded to the maximum available efficiency level on the market. DOE also analyzed multiple intermediate efficiency levels between the baseline and max-tech in order to develop the cost-efficiency relationship for each product class. Intermediate efficiency levels were chosen based on the market assessment where there were clear groupings in the market's efficiency distribution. In some cases, efficiency levels were observed for one draw pattern but not the others.

DOE has constructed cost versus efficiency curves for the representative capacities and representative draw patterns which exist on the market today, as opposed to directly analyzing every possible draw pattern. However, DOE is increasing the stringency of standards for draw patterns where products do not currently exist in order to match the stringency of standards for draw patterns where products in the same category do exist, in the event that products become available with draw patterns not currently on the market.

For these cases, DOE estimated these max-tech levels using existing relationships between efficiency levels observed in other draw patterns where products do exist. Products in different draw patterns are typically differentiated by rated storage volume and heating capacity (burner input rate, compressor capacity, or element wattage), and the design options used to improve UEF in one draw pattern can generally also be applied to water heaters of the same type in a different draw pattern. For the cases where products at additional intermediate efficiency levels were observed in the market at one draw pattern but not the others, DOE estimated efficiency levels in the other draw patterns based on what was observed for the one available draw pattern. The approach took into account how each product type's efficiency correlates to its delivery capacity (*i.e.,* either FHR or maximum GPM, the delivery capacity metrics assigned for non-flow-activated water heaters and flow-activated water heaters, respectively), recovery efficiency, and technological feasibility of design-option implementation. A detailed discussion of efficiency level selection on a product-class by product-class basis is provided in chapter 5 of the final rule TSD.

In the NOPR engineering analysis, DOE considered split-system heat pump water heaters as a representative design strategy for small electric storage water heaters because small electric storage water heaters are typically configured for applications with limited vertical clearance. Whereas integrated heat pump water heaters are typically designed with the heat pump components affixed to the top of the storage tank (significantly increasing the height of the water heater), split-system heat pump water heaters have the advantage of being able to install the heat pump in a remote location so that the storage tank height does not change. However, there are currently no models of split-system heat pumps for small electric storage water heaters on the market today, so DOE estimated the performance of a hypothetical design based on circulating heat pump water heaters and lowboy water heaters that were available at the time of the July 2023 NOPR. *See* chapter 5 of the NOPR TSD for further details. To ensure that the analysis is representative, in the July 2023 NOPR, DOE requested information about the potential design specifications, manufacturing processes, and efficiencies of split-system heat pump water heaters. 88 FR 49058, 49091.

In response to DOE's request for information regarding split-system heat pump water heaters, Rheem noted that it had identified a dual-fuel combination heat pump water heater and boiler product manufactured by its sister company in the Netherlands. (Rheem, No. 1177 at p. 8)

DOE reviewed product literature for the dual-fuel split-system heat pump water heater mentioned by Rheem, marketed in the Netherlands as the Intergas Xtend model. While dual-fuel heating is being screened out from this rulemaking analysis (*see* section IV.B.1 of this document), details about this design provide valuable information about the performance potentials for split-system heat pump water heaters (operating in heat pump-only mode). The Xtend split-system heat pump water heater has a reported coefficient of performance (''COP'') of 4.68, uses R–32 refrigerant, has a total heating capacity of 5 kW (over 17,000 Btu/h), and is designed for combination space and domestic hot water heating.[37] Based on the COP rating, DOE understands that this product identified by Rheem would likely have a UEF rating higher than the max-tech efficiency analyzed for small electric storage water heaters. However, after reviewing this design, DOE determined two main factors which lead to uncertainty as to whether this design is viable for small electric storage water heaters. First, the use of R–32 refrigerant (which has not been demonstrated in water heaters in the United States market) and the resulting total capacity of over 17,000 Btu/h is more akin to the designs of single-split space-constrained air-source heat pump air conditioners, which range between 15,200 and 23,800 Btu/h in DOE's CCD. In contrast, teardown analyses of heat pump water heaters show that these systems typically have much smaller compressors than do central (*i.e.,* whole-home) air conditioners, and therefore the Xtend water heater model as well. In addition, due to the higher capacity of the Xtend model, this product is more likely to function in the medium or high draw patterns, meaning that it does not serve the same consumer utility as a small electric storage water heater. This is because a much larger compressor would have very low run time (causing technical difficulties for refrigerant circulation), be noisier, and significantly increase the footprint of the heat pump module. As a result, it remains unclear whether split-system heat pump small electric storage water heaters are able to employ the same design options to achieve the higher efficiency of the Xtend model. DOE will continue to evaluate technologies for split-system heat pump water heaters in future

[37] Product information can be found online at: *www.intergas-verwarming.nl/consument/producten/xtend/* (Last accessed: Nov. 17, 2023).

rulemakings addressing consumer water heater standards.

In the July 2023 NOPR, DOE presented its efficiency levels for analysis and specifically requested further information on the technologies employed in 45-gallon medium draw pattern electric storage products at a UEF of 3.50 (which would potentially help with re-evaluating EL 2). 88 FR 49058, 49090. DOE did not, however, receive any comments on this particular topic.

Commenting more specifically on the electric storage water heater efficiency levels analyzed in the July 2023 NOPR, BWC noted that the Joint Stakeholder Recommendation originally suggested a minimum UEF of 2.0 for some of the smallest volumes of electric storage water heaters, and the NOPR proposes a level of 2.3 UEF. BWC asserted that a minimum UEF of 2.0 would be necessary in some products to allow manufacturers more flexibility to innovate new designs and reduce the cost of heat pump water heaters, which it stated will be critical for consumers to purchase these products because key rebates and tax incentives will expire in the early 2030s. However, BWC stated that it still supported electric resistance-level standards for small and very small electric storage water heaters, and that, generally, redesigns for these products would not be necessary to meet the proposed minimum efficiency standards. (BWC, No. 1164 at pp. 1–2)

In response to BWC, DOE notes that products exceeding 2.3 UEF are widely available across a range of capacities, indicating that this level is readily achievable, and thus analyzing an additional efficiency level at a UEF of 2.0 would be unlikely to provide additional benefit. As discussed in chapter 5 of the final rule TSD, a UEF of 2.0 is expected to correspond to split-system heat pump water heaters in the small electric storage water heater product category, which, as a result of the heat pump design, have certain limitations to achieving higher efficiencies. Electric storage water heaters that are not ''small electric storage water heaters'' do not have the same design limitations and can achieve higher efficiencies with integrated heat pump water heater designs (where the heat pump is adjoined at the top of the tank). Additionally, split-system designs are typically more expensive to manufacture compared to integrated designs, meaning that the most cost-effective pathway to achieving higher efficiencies would most likely be through integrated designs. (*See* section IV.C.1.e of this document and chapter 5 of the final rule TSD for estimated manufacturer production costs of both styles of heat pump designs.) In the selection of efficiency levels for these larger water heaters, DOE considered the certified UEF ratings of integrated heat pump water heaters on the market, the ENERGY STAR v5.0 specification, the Joint Stakeholder Recommendation, and its own test data. Based on these sources, a UEF of 2.3 was determined to be most representative of a low-cost heat pump water heater design for non-small electric storage water heaters.

Earlier in this rulemaking DOE received comments from some stakeholders who suggested that DOE consider establishing a ''heat pump-only'' level, which would exclude the use of electric resistance elements, as max tech for heat pump water heaters. In the July 2023 NOPR, DOE noted that its own test data indicate that heat pump water heaters with backup electric resistance elements typically do not use the elements during DOE's 24-hour simulated use test. Therefore, adding an efficiency level that corresponds to a ''heat-pump only'' design option as max tech would not be expected to change the UEF. 88 FR 49058, 49090.

BWC agreed with not including an efficiency level for electric storage water heaters that specifically pertained to a heat pump design that did not have backup electric resistance elements on the basis that not only would a higher efficiency standard pose significant challenges for the industry transition to heat pump water heaters, but also that the efficiency benefits of not having a backup electric resistance element would not be demonstrated by the current appendix E test procedure and UEF metric. (BWC, No. 1164 at pp. 16–17)

Essency stated it has achieved an FHR of 80 gallons and a UEF of 0.93 with electric resistance technology and suggested that max tech for electric resistance water heaters has not yet been reached. (Essency, No. 1194 at p. 1) GreenTECH stated that it is currently developing a fully electric consumer heat pump water heater with projected energy savings of 50 percent compared to current models and that utilizes peak amperage of less than 10 amps at 220 volts for a 50-gallon comparable model. (GreenTECH, No. 71 at p.1)

In response to Essency, DOE previously considered an efficiency level that corresponded to increased insulation for electric resistance storage water heaters (see the March 2022 Preliminary Analysis). However, DOE received many comments from manufacturers indicating that it may not be practical to incorporate more insulation in the manufacturing process, after which DOE had revised EL 1 to reflect a baseline heat pump efficiency instead. 88 FR 49058, 49089. In response to GreenTECH, based on its review of the components that are used in conventional 240-volt heat pump water heaters, DOE expects that there would not be any appreciable difference in technology or design between conventional 240-volt heat pump water heaters and a 220-volt heat pump water heater as described by GreenTECH. However, because GreenTECH did not provide further details regarding their design, which is currently commercially unavailable, DOE was unable to evaluate GreenTECH's suggestions as a max-tech efficiency level.

NEEA urged DOE to consider gas absorption or adsorption heat pump water heaters as max-tech, adding that statutorily, DOE is not limited to commercially available technologies. NEEA noted that multiple technology developers and manufacturers are advancing gas heat pump water heaters for the residential market, many of which are expected to be commercialized by 2025. (NEEA, No. 1199 at pp. 9–10)

In response to comments from NEEA, DOE did not consider gas-fired absorption or adsorption heat pumps for the max-tech levels because, as discussed in section IV.B of this document, these technologies were screened out for not being practicable to manufacture, install, or service on the scale necessary to serve the consumer water heater market upon the compliance date of the amended standards. For more details on the screening analysis, *see* chapter 4 of the final rule TSD.

AWHI encouraged DOE to consider efficiency levels for gas-fired storage water heaters that couple 120-volt electric-readiness with gas-fired water heater installations to minimize the burden of future electrification requirements. AWHI cited a comment from Rheem made in response to the March 2022 Preliminary Analysis recommending that DOE add a higher efficiency level for gas-fired storage water heaters that would require electricity but is achievable with a Category-I venting solution. AHWI stated that adopting such a standard level would, upon the second replacement of an existing gas-fired water heater after the compliance date of this rule, give consumers the option to install drop-in replacement 120-volt heat pump water heaters because the 120-volt electricity connection would already exist (being necessary to meet

such a standard). (AWHI, No. 1036 at p. 4)

In response to AWHI, DOE notes that it does consider an efficiency level for gas-fired storage water heaters that requires electricity and is achievable with category I venting, which is identified as EL 2B (see section IV.C.1.b of this document) and includes an electric flue damper but uses category I venting. Beyond that level, based on review of the market and technologies currently being used, DOE has concluded the most likely design pathway to improved UEF would be to increase flue baffling, which would require use of category III venting (*i.e.,* ''power venting'').

CEC requested DOE establish more stringent standards for gas-fired storage water heaters and, if necessary, proceed with a separate rule for gas-fired storage water heaters to avoid delaying the finalization of other settled portions of the proposed rule. CEC added that primary innovation needed make substantial efficiency improvements to gas-fired storage water heaters is to implement a spiral flue, which will exchange more heat from the combusted gas to the water. (CEC, No. 1173 at p. 4)

In response to CEC, DOE agrees that a ''spiral'' (helical) flue is one of the main technological improvements that allows gas-fired storage water heaters to have condensing-level efficiencies. DOE notes that the manufacture and design of these flues is a complicated and expensive process, and spiraling flues have added material costs due to the significantly longer flue length. Additionally, manufacturers must adjust designs to account for the tank volume that the flue takes up: the more space the flue takes up in the tank, the less tank volume there is left to store the hot water. These costs are reflected in the manufacturer production costs (''MPCs'') and conversion cost estimates for ELs 4 and 5 for gas-fired storage water heaters, and they eventually result in higher-priced products for consumers. DOE evaluated whether standards at condensing efficiency levels were economically justified taking into account these costs (*see* section V.C.1 of this document.)

After considering these comments, DOE has maintained the efficiency levels from the July 2023 NOPR.

iii. Efficiency Levels by Product Class

DOE's analysis for efficiency levels above baseline is discussed in more detail in chapter 5 of the final rule TSD. Efficiency levels, including baseline and higher efficiencies, across all product classes are listed in the tables that follow. The efficiency levels which correspond closely to the Joint Stakeholder Recommendation are indicated with ''JSR''.

BILLING CODE 6450–01–P

Table IV.8 Gas-fired Storage: 20 gal ≤ V_{eff} ≤ 55 gal, Standard, Low, and Ultra Low NO_X

Efficiency Level	UEF			
	Very Small*	Low	Medium	High
0 (Baseline)	0.3456 – (0.0020 × V_{eff})	0.5982 – (0.0019 × V_{eff})	0.6483 – (0.0017 × V_{eff})	0.6920 – (0.0013 × V_{eff})
1	0.3725 – (0.0020 × V_{eff})	0.6251 – (0.0019 × V_{eff})	0.6646 – (0.0017 × V_{eff})	0.7024 – (0.0013 × V_{eff})
2 (JSR)	0.3925 – (0.0020 × V_{eff})	0.6451 – (0.0019 × V_{eff})	0.7046 – (0.0017 × V_{eff})	0.7424 – (0.0013 × V_{eff})
3	0.4025 – (0.0020 × V_{eff})	0.6551 – (0.0019 × V_{eff})	0.7146 – (0.0017 × V_{eff})	0.7524 – (0.0013 × V_{eff})
4	0.5125 – (0.0020 × V_{eff})	0.7651 – (0.0019 × V_{eff})	0.8146 – (0.0017 × V_{eff})	0.8624 – (0.0013 × V_{eff})
5 (Max-Tech)	0.5725 – (0.0020 × V_{eff})	0.8251 – (0.0019 × V_{eff})	0.8746 – (0.0017 × V_{eff})	0.9224 – (0.0013 × V_{eff})
* No products exist in the very small draw pattern at the time of this analysis. DOE applied the differences in efficiency levels from the low draw pattern to define the Efficiency Levels 1 through 5 for the very small draw pattern.				

Table IV.9 Oil-fired Storage: V_{eff} ≤ 50 gal

Efficiency Level	UEF			
	Very Small*	Low*	Medium*	High
0 (Baseline)	0.2509 – (0.0012 × V_{eff})	0.5330 – (0.0016 × V_{eff})	0.6078 – (0.0016 × V_{eff})	0.6815 – (0.0014 × V_{eff})
1	0.2709 – (0.0012 × V_{eff})	0.5530 – (0.0016 × V_{eff})	0.6278 – (0.0016 × V_{eff})	0.7015 – (0.0014 × V_{eff})
2 (Max-Tech)	0.2909 – (0.0012 × V_{eff})	0.5730 – (0.0016 × V_{eff})	0.6478 – (0.0016 × V_{eff})	0.7215 – (0.0014 × V_{eff})
* No products exist in these draw patterns at the time of this analysis. DOE applied the differences in efficiency levels from the high draw pattern to define the Efficiency Levels 1 and 2 for the other draw patterns.				

Table IV.10 Small Electric Storage: 20 gal ≤ V_{eff} ≤ 35 gal, FHR < 51 gal

Efficiency Level	UEF	
	Very Small†	Low
0 (Baseline)	0.8808 – (0.0008 × V_{eff})	0.9254 – (0.0003 × V_{eff})
1 (JSR)	2.00*	2.00

* DOE applied the Joint Stakeholder Recommendation for low draw pattern units to the very small draw pattern in its analysis.
† No products exist in the very small draw pattern at the time of this analysis.

Table IV.11 Electric Storage: 20 gal ≤ V_{eff} ≤ 55 gal, excluding Small Electric Storage

Efficiency Level	UEF			
	Very Small**	Low	Medium	High
0 (Baseline)	0.8808 – (0.0008 × V_{eff})	0.9254 – (0.0003 × V_{eff})	0.9307 – (0.0002 × V_{eff})	0.9349 – (0.0001 × V_{eff})
1 (JSR)	2.30*	2.30	2.30	2.30
2	3.2602 – (0.0008 × V_{eff}) †	3.3048 – (0.0003 × V_{eff})	3.3590 – (0.0002 × V_{eff})	3.4742 – (0.0001 × V_{eff})
3 (Max-Tech)	3.6602 – (0.0008 × V_{eff}) †	3.7048 – (0.0003 × V_{eff})	3.7590 – (0.0002 × V_{eff})	3.8742 – (0.0001 × V_{eff})

* DOE applied the Joint Stakeholder Recommendation for low draw pattern units to the very small draw pattern in its analysis.
** No products exist in the very small draw pattern at the time of this analysis.
† DOE applied the differences in efficiency levels from the low draw pattern to define the Efficiency Levels 2 and 3 for the very small draw pattern.

Table IV.12IVIV Electric Storage: 55 gal < V_{eff} ≤ 120 gal

Efficiency Level	UEF			
	Very Small**	Low**	Medium	High
0 (Baseline)	1.9236 – (0.0011 × V_{eff})	2.0440 – (0.0011 × V_{eff})	2.1171 – (0.0011 × V_{eff})	2.2418 – (0.0011 × V_{eff})
1 (JSR)	2.50*	2.50	2.50	2.50
2	3.2198 – (0.0011 × V_{eff}) †	3.3402 – (0.0011 × V_{eff}) †	3.4133 – (0.0011 × V_{eff})	3.5380 – (0.0011 × V_{eff})
3 (Max-Tech)	3.7698 – (0.0011 × V_{eff}) †	3.8902 – (0.0011 × V_{eff}) †	3.9633 – (0.0011 × V_{eff})	4.0880 – (0.0011 × V_{eff})

* DOE applied the Joint Stakeholder Recommendation for low draw pattern units to the very small draw pattern in its analysis.
** Only one product exists in the low draw pattern at the time of this analysis. No products exist in the very small draw pattern at the time of this analysis.
† DOE applied the differences in efficiency levels from the medium draw pattern and high draw pattern to define the Efficiency Levels 2 and 3 for the very small draw pattern and the low draw pattern.

BILLING CODE 6450–01–C

b. Design Options

Based on its teardown analyses and feedback provided by manufacturers in confidential interviews, DOE determined the technology options that are most likely to constitute the pathway to achieving the efficiency levels assessed. These technology options are referred to as ''design options.'' While manufacturers may achieve a given efficiency level using more than one design strategy, the selected design options reflect what DOE expects to be the most likely approach for the market in general in a standards-case scenario. Further details are provided in chapter 5 of the final rule TSD.

Ravnitzky indicated that DOE acknowledges that increased tank insulation can improve the efficiency of storage-type water heaters and questioned DOE's decision not to consider increased insulation thickness as a feasible technology option for electric storage water heaters. Ravnitzky claimed that, with sufficient insulation, non-heat pump water heaters can be nearly as efficient as heat pump water heaters. (Ravnitzky, No. 73 at p. 1)

DOE agrees that increased insulation thickness can improve the efficiency of storage-type water heaters and notes that increased insulation thickness is considered as a design option for increasing the efficiency of gas-fired and oil-fired storage water heaters. In addition, as discussed in the July 2023 NOPR, DOE initially considered an efficiency level for electric storage water heaters based on increased insulation thickness in the March 2022 Preliminary Analysis. However, in the July 2023 NOPR, DOE explained that in response to stakeholder feedback [38] on the March 2022 Preliminary Analysis,

[38] Specifically, DOE explained that feedback from multiple sources indicated that increasing the thickness may not be practical in the manufacturing process because the R-value of polyurethane diminishes when the compound is blown into larger cavities, and the increase in thickness does not offset the increase in water heater surface area (which will increase standby losses).

the first efficiency level design option for electric storage water heaters was changed to include heat pump technology, which DOE noted was more representative of the next level up from baseline. 88 FR 49058, 49089. Given the insulation thicknesses DOE has observed in models currently on the market, DOE maintains its position that the most likely design path for improving heat pump water heater efficiency above the baseline level would be through use of heat pump technology. Increasing insulation thicknesses to the point required to substantially increase the UEF of electric storage water heaters beyond what is required by the current standard may not be feasible. Therefore, for this final rule DOE has maintained the efficiency levels (and associated design options) for electric storage waters from the July 2023 NOPR.

In addition, DOE disagrees with the notion that non-heat pump water heaters could be made to be as efficient as heat pump water heaters through insulation thickness increases. Even if standby losses were to be completely eliminated, the electric resistance elements used for heating non-heat pump electric storage water heaters have a maximum theoretical efficiency of 100 percent, resulting in a maximum UEF of 1.00. Heat pump water heaters achieve efficiencies greater than 1.00 by extracting more heat energy from their surroundings than is required for them to operate, which non-heat pump water heaters are incapable of.

BWC generally supported the design options DOE selected at the NOPR stage. (BWC, No. 1164 at p. 16) However, BWC reiterated its comments indicating that gas-fired storage water heaters can only use 1 inch of insulation in certain circumstances, and that it should not be considered as the baseline design option. BWC stated that 1 inch of insulation would not be capable of meeting the current standards, and only certain models designed to accommodate space constraints may come with 1 inch of insulation. The decreased insulation from 2 inches, BWC stated, has a drawback in lowering the FHR and recovery rate of the model. (BWC, No. 1164 at p. 17)

DOE believes that BWC may have misunderstood the design options that were modeled for the baseline efficiency level for gas-fired storage water heaters in the engineering analysis. Based on teardown analyses, DOE did determine that products with 1 inch of insulation can meet the existing standards, but only for the low draw pattern and the medium draw pattern.[39] At the NOPR stage, DOE took into account BWC's feedback about decreased FHRs and slower recovery rates. 88 FR 49058, 49094. These factors lead to gas-fired storage water heaters with only 1 inch of insulation also having smaller burners with lower input ratings. Products in the high draw pattern require larger burners. In the NOPR engineering analysis, DOE increased the insulation thickness for the high draw pattern designs of gas-fired storage water heaters. A thickness of 1.5 inches was used based on teardown samples of high draw pattern gas-fired storage water heaters at the representative size. *Id.* (*See* chapter 5 of the NOPR TSD.) However, this specifically pertained to side insulation. After reviewing BWC's comments and its own teardown samples, DOE has again updated the design option for high draw pattern gas-fired storage water heaters to use 1.5 inches of side insulation and 2 inches of top insulation to reflect the minimum amount of insulation necessary to meet the current standards.

Table IV.13 through Table IV.17 show the design options at each UEF level analyzed for this final rule. DOE maintained the design options as they were discussed in the July 2023 NOPR.

BILLING CODE 6450–01–P

Table IV.13 - Design Options for Gas-fired Storage: 20 gal ≤ V_{eff} ≤ 55 gal

EL	**Standard and Low NOX** Design Options	**Ultra-Low NOX** Design Options
0	Standard burner; Standing pilot 1" side, 1" top insulation*; Cat I venting (atmospheric); Straight flue	Ultra-Low NO_X premix burner; Standing pilot 1" side, 1" top insulation*; Cat I venting (atmospheric); Straight flue
1	2" side, 2" top insulation	2" side, 2" top insulation
2A	Cat I venting (gas-actuated flue damper)	Cat I venting (gas-actuated flue damper)
2B	Electronic ignition; Cat I venting (electric flue damper)	Electronic ignition; Cat I venting (electric flue damper)
3	Electronic ignition Cat III venting (power venting) Increased heat exchanger baffling	Electronic ignition Cat III venting (power venting) Increased heat exchanger baffling
4	Cat IV venting (power venting) Condensing helical flue	Cat IV venting (power venting) Condensing helical flue
5	Increased heat exchanger surface area	Increased heat exchanger surface area
* 1.5" side / 2.0" top insulation was used for the high draw pattern		

[39] There are no gas-fired storage products certified within the very small draw pattern.

Table IV.14 - Design Options for Oil-fired Storage: $V_{eff} \leq 50$ gal

EL	Design Options
0	Single flue heat exchanger; Foam Insulation 1" side, 1.5" top insulation
1	Foam Insulation 2" side, 2.5" top insulation
2	Multi-flue heat exchanger

Table IV.15 - Design Options for Small Electric Storage: 20 gal $\leq V_{eff} \leq$ 35 gal, FHR < 51 gal

EL	Design Options
0	3" side 3" top insulation; Lowboy aspect ratio (less than 36 inches in height)
1	Split-system R134A rotary compressor; Capillary expansion device; Counterflow condenser design; Tube-and-fin evaporator design; Shaded Pole Motor ("SPM") evaporator fan 2" side 2" top insulation

Table IV.16 - Design Options for Electric Storage: 20 gal $\leq V_{eff} \leq$ 55 gal, excluding Small Electric Storage

EL	Design Options
0	3" side 3" top insulation; Short aspect ratio for products ≤ 35 gal or in the low draw pattern, tall aspect ratio for products > 35 gal and in the medium or high draw patterns
1	Integrated R134A rotary compressor; Capillary expansion device; Hotwall condenser; Tube-and-fin evaporator design; SPM evaporator fan 2" side 2" top insulation
2	Electronic expansion valve; Larger condenser; Larger evaporator; ECM evaporator fan
3	Larger condenser; Larger evaporator; Insulated sealed system; High efficiency fan blades

Table IV.17 - Design Options for Electric Storage: 55 gal < V_{eff} ≤ 120 gal

EL	Design Options
0	Integrated R134A rotary compressor; Electronic expansion valve; Hotwall condenser design; Tube-and-fin evaporator design; SPM evaporator fan 2" side 2" top insulation
1	Larger evaporator
2	Higher efficiency compressor; Larger condenser; Larger evaporator; ECM evaporator fan
3	Higher efficiency compressor; Larger condenser; Larger evaporator; High efficiency fan blades

BILLING CODE 6450–01–C

c. Cost Analysis

The cost analysis portion of the engineering analysis is conducted using one or a combination of cost approaches. The selection of cost approach depends on a suite of factors, including the availability and reliability of public information, characteristics of the regulated product, the availability and timeliness of purchasing the product on the market. The cost approaches are summarized as follows:

□ *Physical teardowns:* Under this approach, DOE physically dismantles a commercially available product, component-by-component, to develop a detailed bill of materials for the product.

□ *Catalog teardowns:* In lieu of physically deconstructing a product, DOE identifies each component using parts diagrams (available from manufacturer websites or appliance repair websites, for example) to develop the bill of materials for the product.

□ *Price surveys:* If neither a physical nor catalog teardown is feasible (for example, for tightly integrated products such as fluorescent lamps, which are infeasible to disassemble and for which parts diagrams are unavailable) or cost-prohibitive and otherwise impractical (*e.g.,* large commercial boilers), DOE conducts price surveys using publicly available pricing data published on major online retailer websites and/or by soliciting prices from distributors and other commercial channels.

In this rulemaking, DOE utilizes a combination of the physical and catalog teardown approaches to develop estimates of the MPC at each UEF efficiency level analyzed. Data from the teardowns were used to create bills of materials (''BOMs'') that capture all of the materials, components, and manufacturing processes necessary to manufacture products that achieve each UEF level. DOE used the BOMs along with publicly available material and component cost data as the basis for estimating the MPCs. DOE refined its cost estimates and its material and component cost data based on feedback received during confidential manufacturer interviews.

To perform this analysis, DOE selects representative capacities for each product class. These capacities reflect the most common or average size of a water heater in that product class, and this step is important because the MPC is dependent upon the size of the water heater—larger water heaters cost more to manufacture. The representative capacities analyzed in this rulemaking are detailed in chapter 5 of the final rule TSD. With the exception of one case, DOE has determined that the representative capacities analyzed in the July 2023 NOPR remain representative at this final rule stage. In this final rule analysis, DOE determined that a capacity of 75 gallons is more representative of units within the high draw pattern for electric storage water heaters in the 55–120-gallon range than 80 gallons, based on the distribution of units currently on the market (*see* appendix 3A to the final rule TSD). DOE therefore updated its analysis accordingly for this product class to use 75 gallons as the representative capacity.

In this rulemaking, DOE selected representative capacities for storage-type water heaters based on rated storage volume.

A.O. Smith agreed that heat pump water heaters are technologically feasible alternatives to electric resistance storage water heaters; however, A.O. Smith stated that 50-gallon heat pump water heaters are not always feasible replacements for 50-gallon electric resistance storage water heaters because, even for units with the same FHR, the heat pump offers a slower recovery that may not keep up with household demand. Additionally, A.O. Smith commented, homeowners must consider factors like ambient air temperature conditions when switching to a heat pump water heater, and it is often recommended to ''upsize'' when transitioning to a heat pump water heater so that performance expectations are not diluted. (A.O. Smith, No. 1182 at pp. 7–8)

DOE understands the commenter to be suggesting that, when evaluating the cost to improve efficiency, it may be more appropriate to consider representative capacities using a metric other than rated storage volume (*e.g.,* the FHR delivery capacity metric). The FHR determines which draw pattern a water heater falls into, and the engineering analysis selects representative characteristics for each draw pattern to determine cost and efficiency. While some consumers may opt to upsize when transitioning to heat pump water heaters, because the efficiency levels analyzed do not preclude designs with backup resistance heating elements, such ''hybrid'' heat pump water heaters can still achieve faster recoveries when the backup elements are used (the recovery rate of a backup element is independent of the ambient air conditions). Hence it would

not be mandatory to upsize if installing a typical hybrid heat pump water heater. Thus, in this engineering analysis, DOE has maintained analysis points based on rated storage volume as opposed to other capacity metrics such as input rate or FHR. A separate consideration for maintaining the FHR is not necessary given the analysis is performed for each draw pattern separately. DOE did, however, perform a separate analysis to address the impact of ambient air conditions on heat pump water heater energy usage (*see* section IV.E of this document).

The results of DOE's cost-efficiency analysis for this final rule are shown in section IV.C.1.e of this document.

In response to the July 2023 NOPR, Rinnai pointed to a peer review report by the National Academy of Science, Engineering and Medicine (''NAS'')[40] and stated that DOE's teardown analyses and cost reconstructions for existing products and newer high-efficiency designs is flawed and produces systematically underestimated costs (Rinnai suggested these costs were underestimated by roughly 30–50 percent). Rinnai stated that these underestimates to MPC lead to overstated LCC savings, and that DOE should instead look to market pricing to determine product cost or use market prices to validate other estimates. (Rinnai, No. 1186 at p. 33)

The rulemaking process for standards of covered products and equipment are outlined at appendix A to subpart C of 10 CFR part 430, and DOE periodically examines and revises these provisions in separate rulemaking proceedings. The recommendations in the NASEM report, which pertain to the processes by which DOE analyzes energy conservation standards, will be considered in a separate rulemaking considering all product categories.

As described in section IV.D of this document, under a more stringent standard, the mark-ups incorporated into the sales price may also change relative to current mark-ups. Therefore, DOE has concluded that basing the engineering analysis on prices of water heaters as currently seen in the marketplace would be a less accurate method of estimating future water heater prices following an amended standard than DOE's approach of conducting an engineering analysis and mark-ups analysis. (However, as noted earlier, price surveys are sometimes required when other methods are infeasible.) When relying on retail market data, the prices will include ''premium'' (*i.e.,* non-efficiency-related) features and do not account for the likely changes in designs, market, and pricing that would occur under an amended standard. Differences between online vendors with respect to mark-up and pricing practices could lead to online prices being unrepresentative for the overall market.

In response to the July 2023 NOPR, Rheem generally agreed with DOE's manufacturer production cost estimates, stating that they appeared reasonable for electric storage water heaters when the removal of non-efficiency related features and economies of scale are accounted for. (Rheem, No. 1177 at p. 8) BWC generally agreed with the gas-fired storage water heater manufacturer production cost estimates provided in the July 2023 NOPR, but noted that the MPC estimates for electric storage water heaters were inconsistent with its experience. BWC stated that it would welcome further opportunities to discuss this specific matter confidentially with DOE for this rulemaking. (BWC No. 1164 at p. 17)

As discussed in the July 2023 NOPR, DOE's consultants routinely conduct confidential manufacturer interviews to gather feedback on various analytical inputs, which are then aggregated for use in the analysis. Cost analyses are updated based on feedback where appropriate. 88 FR 49058, 49095. In addition, due to the volatility of metal prices, DOE uses 5-year average metal prices to minimize the impact of large fluctuations in metal prices. *Id.* DOE's 5-year average metal cost data have been updated to reflect prices for the most recent 5-year period ending August 2023. For all other material and component prices, DOE used the most recent prices available at the time of the analysis (*i.e.,* August 2023). As discussed, the MPC estimates used in this rulemaking reflect what would be the market-average product cost to manufacture a model that meets the efficiency level, excluding the cost of optional features that do not affect the efficiency of the product, and these estimates take into account what the designs and component costs would be in a standards-case-scenario. Because the metal prices used may deviate from the most recent year's and because the designs modeled reflect market averages in a standards-case-scenario without optional non-efficiency-related components, the MPC estimates resulting from this analysis may not exactly reflect the designs of any one specific manufacturer today.

d. Shipping Costs

Shipping costs for storage-type consumer water heater product classes were determined based on the area of floor space occupied by the unit, including packaging, and the weight. Most consumer water heaters cannot be shipped in any orientation other than vertical and are too tall to be double-stacked in a vertical fashion, though some units analyzed by DOE can be double-stacked. For small units that can be double-stacked, including lowboy electric storage water heaters and non-lowboy electric storage water heaters less than or equal to 35 gallons in storage volume, the floor area available effectively doubles, reducing the overall shipping cost compared to taller products. DOE also accounted for electric storage water heaters sold as split-system heat pumps stacking the heat pump assembly atop the tank assembly. DOE research suggests that consumer water heaters are usually shipped together in nearly fully loaded trailers, rather than in less than truckload (''LTL'') configurations, where the consumer water heaters only occupy a portion of the trailer volume. Therefore, shipping costs have been calculated assuming fully loaded trailers; however, DOE applied an assumption that each truckload would only consist of one type of water heater, which may result in a conservative estimate of shipping costs.

To calculate the shipping costs, DOE estimated the cost per trailer based on standard trailer sizes, shipping the products between the middle of the country to the coast, using the most recent reference year for prices (*i.e.,* 2022 for the July 2023 NOPR and 2023 for this final rule). Next, DOE estimated the shipped size (including packaging) of products in each product class at each efficiency level and, for each product class and efficiency level, determined the number of units that would fit in a trailer. DOE then calculated the average shipping cost per unit by dividing the cost per trailer load by the number of units that would fit per trailer (based on a calculation of whether the quantity is limited by space or by weight), for each product class and efficiency level.

In the July 2023 NOPR, DOE requested feedback on the analysis assumptions used to estimate shipping costs for consumer water heaters.

BWC stated that the shipping cost estimates provided in the July 2023 NOPR were generally consistent with its expectations, and that it is correct to assume that water heaters typically do not ship in less-than-truckload

[40] National Academy of Science, Engineering and Medicine, ''Review of Methods Used by the U.S. Department of Energy in Setting Appliance and Equipment Standards'' (2021), ISBN 978–0–309–68545–0/DOI 10.17226/25992.

configurations; however, real-world circumstances (such as one truck delivering orders to multiple wholesalers) prevent truckloads from consisting of solely one type of water heater. (BWC, No. 1164 at p. 18) However, BWC did not agree with the Department's assumption that each truckload would only consist of one type of water heater. In their experience this rarely occurs since truckloads are scheduled to fulfill multiple orders from multiple customers who are rarely ordering identical products. (BWC No. 1164 at p. 18)

DOE agrees with BWC that manufacturers do not always ship trucks completely full of one type of water heater. The shipping costs in the real world vary with a multitude of factors that are difficult to model and predict. For storage-type water heaters that are shipped with tankless water heaters, DOE expects the shipping costs it assumed to be conservatively high, because the estimate is based on a truck full of only storage-type water heaters (which would, as a result, not be able to carry as many products due to the size of the storage-type water heaters).

After considering the feedback received on shipping costs, DOE maintained the methodology from the July 2023 NOPR for this final rule but updated the cost per trailer using the most recent data available. The shipping costs are shown in section IV.C.1.e of this document.

e. Cost-Efficiency Results

The results of the engineering analysis are reported as cost-efficiency data in the form of MPCs and shipping costs calculated for each efficiency level of each product class for which DOE is proposing amended UEF-based standards. As discussed previously, DOE determined these costs by developing BOMs based on a combination of physical and catalog teardowns and using information in the BOMs along with component and material price data to estimate MPCs.

For heat pump water heaters specifically, BWC urged the Department to consider price impacts related to the Federal American Innovation and Manufacturing (''AIM'') Act of 2020, codified at 42 U.S.C. 7675. BWC noted that this legislation calls for a gradual phasedown of refrigerant products that are currently predominant in heat pump water heater designs, and stated that the provisions in the AIM Act will compel manufacturers to pivot to more costly refrigerants when producing heat pump water heater products. (BWC No. 1164 at p. 18)

In response, DOE notes that the AIM Act authorizes EPA to address hydrofluorocarbons (''HFCs'') in three main ways: phasing down HFC production and consumption through an allowance allocation program; promulgating certain regulations for purposes of maximizing reclamation and minimizing releases of HFCs from equipment; and facilitating sector-based transitions to next-generation technologies. (*See* 42 U.S.C. 7675) Regarding the gradual phasedown of HFC refrigerants with high global warming potential (''GWP''), the AIM Act mandates the phasedown of HFCs by 85 percent over a period ending in 2036, following the schedule outlined in the AIM Act. (42 U.S.C. 7675(e)(2)(C)) DOE notes that the engineering analysis incorporates up-to-date cost estimates (including the cost of refrigerants currently used in heat pump water heaters).

For this final rule, DOE reviewed EPA rulemakings pertaining to the phasedown of HFC production and consumption and sector-based transitions to next-generation technologies. Regarding the sector-based transitions under subsection (i) of the AIM Act, EPA published a final rule restricting the use of HFCs in specific sectors or subsectors on October 24, 2023 (''October 2023 EPA Final Rule''). 88 FR 73098. In the October 2023 EPA Final Rule, EPA does not adopt provisions to restrict the use of high-GWP refrigerants in heat pump water heaters. DOE understands that manufacturers may voluntarily invest in low-GWP systems for future heat pump water heater designs, however, such systems would not be mandatory as a result of Federal regulation at this time. However, the October 2023 EPA Final Rule does restrict the use of HFCs and blends containing HFCs with a GWP of 150 or greater beginning January 1, 2025 for all foam subsectors, including rigid polyurethane for use in water heaters. 88 FR 73098, 73183–73184. As discussed in chapter 3 of the final rule TSD, DOE has found that water heater manufacturers have already begun transitioning to alternative blowing agents for insulation foam, therefore this regulation is not expected to impact manufacturer production costs for consumer water heaters.

DOE maintained the same methodology as the July 2023 NOPR to develop the cost-efficiency results for this final rule, as detailed in section IV.C.1.c of this document. The results of DOE's analysis are listed in Table IV.18 through Table IV.23.

See chapter 5 of the final rule TSD for more details concerning these results.

Table IV.18 - Engineering Analysis Results for Gas-fired Storage: 20 gal ≤ V_{eff} ≤ 55 gal, Standard and Low NO_X

EL	UEF				MPC (2022$)	Shipping (2022$)
	Very Small	Low 29 gal	Medium 38 gal	High 48 gal		
0	N/A	0.54	0.58	0.63	Low: 172.98 Med: 197.89 High: 227.72	Low: 25.67 Med: 28.43 High: 42.45
1	N/A	0.57	0.60	0.64	Low: 189.41 Med: 215.70 High: 236.99	Low: 28.43 Med: 30.61 High: 44.22
2A	N/A	0.59	0.64	0.68	Low: 243.26 Med: 269.55 High: 290.85	Low: 28.43 Med: 30.61 High: 44.22
2B	N/A	0.59	0.64	0.68	Low: 277.73 Med: 303.77 High: 324.76	Low: 28.43 Med: 30.61 High: 44.22
3	N/A	0.60	0.65	0.69	Low: 290.19 Med: 316.40 High: 338.00	Low: 28.43 Med: 30.61 High: 44.22
4	N/A	0.71	0.75	0.80	Low: 372.91 Med: 398.70 High: 426.00	Low: 28.43 Med: 30.61 High: 44.22
5	N/A	0.77	0.81	0.88	Low: 385.61 Med: 415.61 High: 447.15	Low: 30.61 Med: 44.22 High: 48.24

Table IV.19 - Engineering Analysis Results for Gas-fired Storage: 20 gal ≤ V_{eff} ≤ 55 gal, Ultra Low NO_X

EL	UEF				MPC (2022$)	Shipping (2022$)
	Very Small	Low 29 gal	Medium 38 gal	High 48 gal		
0	N/A	0.54	0.58	0.63	Low: 256.02 Med: 286.10 High: 322.46	Low: 25.67 Med: 28.43 High: 42.45
1	N/A	0.57	0.60	0.64	Low: 272.76 Med: 304.67 High: 331.85	Low: 28.43 Med: 30.61 High: 44.22
2A	N/A	0.59	0.64	0.68	Low: 326.61 Med: 358.52 High: 385.70	Low: 28.43 Med: 30.61 High: 44.22
2B	N/A	0.59	0.64	0.68	Low: 361.08 Med: 392.82 High: 419.69	Low: 28.43 Med: 30.61 High: 44.22
3	N/A	0.60	0.65	0.69	Low: 377.03 Med: 409.28 High: 436.57	Low: 28.43 Med: 30.61 High: 44.22
4	N/A	0.71	0.75	0.80	Low: 451.23 Med: 481.31 High: 513.03	Low: 28.43 Med: 30.61 High: 44.22
5	N/A	0.77	0.81	0.88	Low: 463.93 Med: 498.22 High: 534.19	Low: 30.61 Med: 44.22 High: 48.24

Table IV.20 - Engineering Analysis Results for Oil-fired Storage: V_{eff} ≤ 50 gal

EL	UEF				MPC (2022$)	Shipping (2022$)
	Very Small	Low	Medium	High 30 gal		
0	N/A	N/A	N/A	0.64	893.59	30.61
1	N/A	N/A	N/A	0.66	922.63	44.22
2	N/A	N/A	N/A	0.68	1003.56	44.22

Table IV.21 - Engineering Analysis Results for Small Electric Storage: 20 gal ≤ V_{eff} ≤ 35 gal, FHR < 51 gal

EL	UEF			MPC (2022$) Draw Pattern ($V_{eff}$)	Shipping, (2022$) Draw Pattern ($V_{eff}$)
	Very Small	Low 26 gal	Low 35 gal		
0	N/A	0.92	0.91	Low (26): 149.92 Low (35): 176.41	Low (26): 16.08 Low (35): 25.27
1	N/A	2.00	2.00	Low (26): 523.46 Low (35): 547.91	Low (26): 48.24 Low (35): 50.53

Table IV.22 - Engineering Analysis Results for Electric Storage: 20 gal ≤ V_{eff} ≤ 55 gal, excluding Small Electric Storage

EL	UEF						MPC (2022$) Draw Pattern ($V_{eff}$)	Shipping (2022$) Draw Pattern ($V_{eff}$)
	Very Small	Low 36 gal	Medium 30 gal	Medium 36 gal	Medium 45 gal	High 55 gal		
0	N/A	0.91	0.92	0.92	0.92	0.93	Low (36): 175.16 Med (30): 162.38 Med (36): 178.62 Med (45): 192.16 High (55): 207.87	Low (36): 42.45 Med (30): 22.11 Med (36): 29.48 Med (45): 30.61 High (55): 46.14
1	N/A	2.30	2.30	2.30	2.30	2.30	Low (36): 419.80 Med (30): 405.14 Med (36): 421.36 Med (45): 436.17 High (55): 446.41	Low (36): 42.45 Med (30): 44.22 Med (36): 29.48 Med (45): 30.61 High (55): 46.14
2	N/A	3.29	3.35	3.35	3.35	3.47	Low (36): 445.22 Med (30): 432.13 Med (36): 446.75 Med (45): 461.48 High (55): 479.57	Low (36): 42.45 Med (30): 44.22 Med (36): 29.48 Med (45): 30.61 High (55): 46.14
3	N/A	3.69	3.75	3.75	3.75	3.87	Low (36): 496.68 Med (30): 478.86 Med (36): 495.06 Med (45): 512.85 High (55): 526.86	Low (36): 42.45 Med (30): 44.22 Med (36): 29.48 Med (45): 30.61 High (55): 46.14

Table IV.23 Engineering Analysis Results for Electric Storage: 55 gal < V_{eff} ≤ 120 gal

EL	UEF				MPC (2022$)	Shipping (2022$)
	Very Small	Low	Medium 58 gal	High 75 gal		
0	N/A	N/A	2.05	2.15	Med: 466.55 High: 493.93	Med: 44.22 High: 48.24
1	N/A	N/A	2.50	2.50	Med: 473.18 High: 498.43	Med: 44.22 High: 48.24
2	N/A	N/A	3.35	3.45	Med: 498.33 High: 515.77	Med: 44.22 High: 48.24
3	N/A	N/A	3.90	4.00	Med: 559.99 High: 576.94	Med: 44.22 High: 48.24

2. Product Classes Without Current UEF-Based Standards

In the December 2016 Conversion Factor Final Rule, DOE established that EF-based standards as established by EPCA are applicable to consumer water heaters but would not be enforced until conversion factors and converted standards are adopted. 81 FR 96204, 96209–96211. To convert these EF-based standards to UEF-based standards, DOE first developed conversion factors that convert tested values measured under the DOE test procedure in effect prior to the July 2014 TP Final Rule (which produces the EF metric) to values found under the current DOE test procedure (which produces the UEF metric). DOE then applied these conversion factors to representative baseline models and derived the UEF-based energy conservation standards from the resulting UEF values.

For the July 2023 NOPR, DOE applied a similar methodology to translate from minimum efficiency levels denominated in EF to those in UEF for classes of covered consumer water heaters that do not yet have UEF-based standards. The translated standards are shown in Table IV.24.

Table IV.24 Translated UEF-based Energy Conservation Standards for Product Classes without established UEF-based Standards

Product Class	Nominal Input	Effective Storage Volume	Draw Pattern	Uniform Energy Factor
Gas-fired Storage Water Heater	≤ 75,000 Btu/h	< 20 gal	Very Small	0.2062 - (0.0020 x V_{eff})
			Low	0.4893 - (0.0027 x V_{eff})
			Medium	0.5758 - (0.0023 x V_{eff})
			High	0.6586 - (0.0020 x V_{eff})
		> 100 gal	Very Small	0.1482 - (0.0007 x V_{eff})
			Low	0.4342 - (0.0017 x V_{eff})
			Medium	0.5596 - (0.0020 x V_{eff})
			High	0.6658 - (0.0019 x V_{eff})
Oil-fired Storage Water Heater	≤ 105,000 Btu/h	> 50 gal	Very Small	0.1580 - (0.0009 x V_{eff})
			Low	0.4390 - (0.0020 x V_{eff})
			Medium	0.5389 - (0.0021 x V_{eff})
			High	0.6172 - (0.0018 x V_{eff})
Electric Storage Water Heaters	≤ 12 kW	< 20 gal	Very Small	0.5925 - (0.0059 x V_{eff})
			Low	0.8642 - (0.0030 x V_{eff})
			Medium	0.9096 - (0.0020 x V_{eff})
			High	0.9430 - (0.0012 x V_{eff})

Product Class	Nominal Input	Effective Storage Volume	Draw Pattern	Uniform Energy Factor
		> 120 gal	Very Small	0.3574 - (0.0012 x V_{eff})
			Low	0.7897 - (0.0019 x V_{eff})
			Medium	0.8884 - (0.0017 x V_{eff})
			High	0.9575 - (0.0013 x V_{eff})
Tabletop Water Heater	≤ 12 kW	< 20 gal	Very Small	0.5925 - (0.0059 x V_{eff})
			Low	0.8642 - (0.0030 x V_{eff})
Instantaneous Oil-fired Water Heater	≤ 210,000 Btu/h	< 2 gal	Very Small	0.61
			Low	0.61
			Medium	0.61
			High	0.61
		≥ 2 gal	Very Small	0.2780 - (0.0022 x V_{eff})
			Low	0.5151 - (0.0023 x V_{eff})
			Medium	0.5687 - (0.0021 x V_{eff})
			High	0.6147 - (0.0017 x V_{eff})
Instantaneous Electric Water Heater	≤ 12 kW	≥ 2 gal	Very Small	0.8086 - (0.0050 x V_{eff})
			Low	0.9123 - (0.0020 x V_{eff})
			Medium	0.9252 - (0.0015 x V_{eff})
			High	0.9350 - (0.0011 x V_{eff})

a. Crosswalk to Equivalent-Stringency UEF-Based Standards

In the July 2023 NOPR, DOE requested feedback regarding the appropriateness of the proposed converted UEF-based standards and whether products on the market can meet or exceed the proposed levels. 88 FR 49058, 49100.

A.O. Smith noted that DOE initially proposed UEF levels for several of these classes in the supplemental notice of proposed rulemaking published on August 30, 2016 (''August 2016 Conversion Factor SNOPR''). 81 FR 59736. DOE, however, decided to forgo adopting the proposed levels for these classes in the December 2016 Conversion Factor Final Rule. A.O. Smith stated that DOE wrote it ''Received voluminous comments regarding the technical merits of the conversion factors and the converted standards expressed in UEF for the water heaters listed in Table III.1 for which DOE is going to defer finalizing and implementing these statutory standards and further consider the comments.''[41] A.O. Smith reiterated its comments submitted in response to the August 2016 SNOPR.[42] Throughout the July 2023 NOPR TSD, DOE notes that for most of the product classes being converted, there are currently no models on the market, and therefore it did not use test data to adjust its analytical model. However, there are products on the market that comport to several of the product classes for which DOE has proposed UEF energy conservation standard levels. (A.O. Smith, No. 1182 at p. 11)

In the August 2016 Conversion Factor SNOPR, DOE explained that it had considered the applicability of standards to the products which eventually did not receive UEF-based standards because these products were not considered in DOE's rulemakings that culminated in the April 16, 2010 and January 17, 2001 final rules (75 FR 20112 and 66 FR 4474, respectively), and accordingly, the standards adopted in those final rules are not applicable to these products. 81 FR 59736, 59742. Hence, the statutory EF-based standards were deemed most applicable to these product classes. *Id.* A.O. Smith generally raised the concern of needing test data to validate the converted standards when responding to the August 2016 Conversion Factor SNOPR, but did not explicitly indicate that the conversion equations were incorrect for the products which did not get converted. Rather, A.O. Smith had iterated that it was inappropriate at the time to establish standards without the basis of a test procedure that covered the sizes of water heaters in question. (A.O. Smith, EERE–2015–BT–TP–0007–0028 at pp. 2–3) As of the June 2023 TP Final Rule, the appendix E test procedure does cover all of the

[41] *See* 81 FR 96204, 96211.

[42] Found online at: *www.regulations.gov/comment/EERE-2015-BT-TP–0007-0028.*

consumer water heaters being addressed in this analysis, and it is clearly established which EF-based standards do apply to these products.

Rheem supported DOE's methodology to conduct the EF to UEF crosswalk for electric storage water heaters and gas-fired storage water heaters that currently do not have UEF-based standards. (Rheem, No. 1177 at p. 9–11) Other commenters requested that DOE publish data to demonstrate that the crosswalk results in appropriate standards compared to how these products would be rated if tested to the UEF test procedure.

A.O. Smith emphasized that DOE must have test data to demonstrate that the crosswalked UEF standards are achievable by products on the market today, especially for very small electric storage water heaters, where there are several models on the market. A.O. Smith noted that previous experience with test procedure changeovers has shown that new test methods and test metrics impact water heaters differently and often unpredictably depending upon their specific attributes. The commenter indicated that it conducted its own testing and provided a limit set of results showing that very small electric storage water heaters could pass the crosswalked standards at a normal temperature setpoint. (A.O. Smith, No. 1182 at pp. 11–12)

NYSERDA noted that the crosswalked product classes begin with the statutory EF standards, which result in the converted standards being significantly lower than those proposed for products with current UEF standards. (NYSERDA, No. 1192 at pp. 4–5) NYSERDA commented that, when the conversion factors were developed, these equations did not apply to the products that DOE is crosswalking to UEF standards in this rulemaking. (NYSERDA, No. 1192 at p. 5) Additionally, NYSERDA stated that the conversion factors were developed using rated storage volume; therefore the converted standards should be in rated storage volume also (instead of effective storage volume). (NYSERDA, No. 1192 at p. 5) NYSERDA recommended two approaches for setting standards for the product classes where there are no current models: a first option would be to test similarly sized products that do exist on the market; otherwise, the volume thresholds can be removed. NYSERDA commented that if DOE determines that these converted standards require additional analysis, it could simply clarify in the final rule that these products are still subject to the statutory EF standards and continue to rely on the waiver process to accommodate any products introduced within these categories; however, the commenter still encouraged DOE to further examine the converted EF standards. (NYSERDA, No. 1192 at p. 5)

Bosch stated there is insufficient information to fully justify the proposed converted UEF values for the very small electric storage water heater product class, adding that the 2016 Conversion Factor Final Rule was not originally intended for this product group. Bosch requested DOE release its analysis of the efficiency testing conducted on the 17 models in this product class, as there are significant differences between tanks and element types within this product class. (Bosch, No. 1204 at pp. 3–4)

BWC expressed concerns regarding the EF-to-UEF crosswalk DOE has analyzed in this rulemaking. BWC stated that using the December 2016 Conversion Factor Final Rule equations to establish UEF-based standards for these products is not appropriate because these products were never subjected to the EF test procedure, and that DOE's approach in the March 2022 Preliminary Analysis and July 2023 NOPR could set an improper baseline. (BWC, No. 1164 at p. 10)

As discussed in the July 2023 NOPR TSD, DOE conducted its own testing to verify that products on the market, when tested to the appendix E test procedure, would comply with the crosswalked standards. In response to the numerous requests for additional test data, DOE has published the results of the testing in chapter 5 of the final rule TSD. Additionally, DOE notes that A.O. Smith's test data also indicates that the standards are achievable (so long as the high temperature test is not used, which results in lower ratings). As discussed in section V.D.1 of this document, DOE has determined not to subject very small electric storage water heaters to high temperature testing; therefore, this would not be expected to reduce their UEF to a level below the adopted standards.

DOE notes that during the 2016 Conversion Factor rulemaking, it conducted testing of 55 consumer storage water heaters and 22 consumer instantaneous water heaters to validate the conversion factors used to determine the UEF-based standards DOE is establishing in this rulemaking. In addition, AHRI provided data for 130 consumer storage water heaters and 36 consumer instantaneous water heaters using both EF and UEF test procedures.[43] 81 FR 96204, 96214–96216. DOE concluded that these conversion factors resulted in UEF-based standards that were neither more nor less stringent than the equivalent EF-based standards. 81 FR 96204, 96207.

Rheem supported the translated UEF standards for very small electric storage water heaters, but recommended that DOE remove the high draw and medium draw pattern standards for very small electric storage water heaters because these levels are generally not achievable or necessary. (Rheem, No. 1177 at p. 9)

Removing the high and medium draw pattern standards for very small electric storage water heaters would result in a gap in coverage of standards, however, should products meeting this description become available in the future. Therefore, DOE is maintaining its approach to adopt standards for each draw pattern for very small electric storage water heaters. Should more data become available after this rulemaking, DOE may consider consolidating standards for different draw patterns if it can be determined conclusively that the medium and high draw pattern standards are not justified.

Rheem added further that reducing the crosswalked electric instantaneous water heater standards to align with those for very small electric storage water heaters would reduce manufacturer burden and design costs. (Rheem, No. 1177 at pp. 13–14)

While DOE acknowledges that electric instantaneous water heaters and very small electric storage water heaters may be installed in similar applications, as discussed in section IV.A.1.c of this document, storage-type and instantaneous-type water heaters generally have differences in operation that can lead to different utilities. Hence, DOE is maintaining its approach to treat these as separate product classes and evaluate standards separately.

BWC provided that it did not believe an approach that relied on a market analysis of currently listed models, along with an efficiency level and design option (teardown) analysis, was appropriate for these product classes that did not previously have a minimum efficiency standard. BWC stated that accounting for the stored water temperature and rated storage volume largely influence a product's efficiency rating, but there are other factors that can strongly influence the UEF, such as insulation thickness (for electric-type storage water heaters) and modulating controls (for instantaneous water

[43] Data for consumer water heaters tested during the development of the 2016 Conversion Factor Final Rule were reported in an SNOPR published in the **Federal Register** on August 30, 2016. 81 FR 59736.

heaters). BWC thus requested DOE to docket the analysis conducted to establish the new minimum UEF levels for these product classes. (BWC, No. 1164 at p. 10)

For this final rule DOE maintains its approach for converting standards from EF to UEF. EPCA directed DOE to establish a uniform efficiency descriptor to be used to regulate all covered water heaters, with certain exceptions for water heaters used only in commercial applications. (42 U.S.C. 6295I(5)) Therefore, DOE has conducted this analysis in satisfaction of its statutory obligation to delineate standards for all consumer water heaters in terms of UEF. The statute provides that, in the case of a test procedure or metric change, DOE must determine what equivalent standards are on the basis of the new test procedure or metric. (42 U.S.C. 6293(e)(2)) The conversion factor calculations serve to accomplish this purpose. Because the UEF-based standards for these product classes reflect the same stringency as the statutory EF-based standards that are currently applicable—*i.e.,* these are not standards that would require higher efficiency to comply— it is not necessary for DOE to conduct an assessment of energy savings or economic justification prior to proposing such standards. The Department believes that BWC may have misinterpreted the analysis for product classes with current UEF-based standards as also applying to these product classes which have EF-based standards. To reiterate, these standards are not being established pursuant to EPCA provisions at 42 U.S.C. 6295(o)(A), but instead in accordance with those at 42 U.S.C. 6293(e)(2). Additionally, the statutory EF-based standards are provided within EPCA and do not require separate justification to adopt these stringencies.

b. Consideration of More Stringent Standards

DOE also requested information and data regarding the UEF of products within these product classes if they are found to generally exceed the proposed levels. 88 FR 49058, 49100.

BWC supported DOE's tentative determination not to propose more stringent standards for product classes that are currently covered by the statutory EF-based standards because these product classes have low market share and would present limited opportunity for energy savings. (BWC, No. 1164 at p. 3)

Rheem commented that there may be no or very few water heaters on the market in the volume ranges for which crosswalked standards were proposed for gas-fired storage water heaters and therefore did not support more stringent standards for these sizes of gas-fired storage water heaters. (Rheem, No. 1177 at p. 11)

Rheem recommended against increasing the >120-gallon standards for electric storage water heaters to a level that would require heat pump technology because ASME tank construction is required for water heaters with a measured volume >120 gallons, significantly increasing the cost of the water heater to the point where it is not a low-cost replacement for a heat pump water heater. (Rheem, No. 1177 at p. 10) However, Rheem recommended increasing the energy conservation standards for <20-gallon tabletop water heaters to the levels proposed for ≥20-gallon tabletop water heaters and simplifying the energy conservation standards table. (Rheem, No. 1177 at p. 10)

In general, while there are few (or sometimes no) models on the market that fall within these product classes, comments received in response to the July 2023 NOPR suggested that, within the 5-year compliance period of this final rule, manufacturers would be incentivized to develop new models in these product classes in lieu of developing designs for product classes with current UEF-based standards that have to comply with more stringent standards. Based on the comments, which are summarized in the following paragraphs, DOE understands that this is possible if the design changes required to transfer an existing model to a product class without current UEF-based standards are less expensive than the design changes required to increase the efficiency of that model to meet the amended standard for the product class with a current UEF-based standard. Commenters provided feedback on whether or not more stringent standards were justified based on whether or not the product class could be used to ''circumvent'' other standards for similar product classes that have higher standards.

A.O. Smith indicated that simultaneous establishment of baseline UEF levels for converted product classes while increasing the efficiency levels for existing product classes creates a scenario where new products may emerge, and shipments may shift from product classes with more stringent standards to very similar products in new product classes with less stringent standards. (A.O. Smith, No. 1182 at p. 14)

DOE does not currently possess data supporting more stringent standards than those being established as part of this rulemaking. However, DOE may conduct a separate rulemaking to determine the benefits and burdens of higher standards for these products at a later time. For example, after the compliance date of this final rule, the availability of certifications of UEF may enable DOE to consider more stringent standards in a future rulemaking.

A.O. Smith provided some test data for very small electric storage water heaters showing that these products would not pass the proposed standards when tested to the high temperature test method, and thus recommended that very small electric storage water heaters be exempt from the high temperature test method. A.O. Smith stated that this test method would not be representative of an average use cycle for very small electric storage water heaters, and the company would rather dedicate its engineering resources toward the development of future heat pump offerings rather than redesigning existing product lines for modest efficiency gains resulting from overlapping test procedure changeovers. A.O. Smith recommended DOE test baseline very small and small electric storage water heaters according to the proposed test procedure to ensure that crosswalked standards do not result in a stringency increase. (A.O. Smith, No. 1182 at pp. 11–12)

Rheem recommended against setting a standard for very small electric storage water heaters at any higher stringency because a forced redesign for these products may not be necessary and would divert manufacturers' resources away from the heat pump water heater innovation. (Rheem, No. 1177 at p. 9)

DOE understands that, if the high temperature test method were to apply to very small electric storage water heaters, then that test method would result in lower efficiency ratings for these products, and these lower ratings would not comply with the crosswalked standards. Therefore, manufacturers would have to redesign very small electric storage water heaters to be more efficient in order to comply with the standards that resulted from the EF-to-UEF crosswalk, and this would effectively constitute an increase in stringency of standards for these products. In section V.D.1.c of this document, DOE explains its determination to exempt very small electric storage water heaters from the high temperature test. As a result, there would be no increase to stringency for these products.

c. Circulating Water Heaters

Prior to the publication of the June 2023 TP Final Rule, the test procedure did not provide sufficient clarity regarding how circulating water heaters should be tested, and the June 2023 TP Final Rule established a new method of testing circulating water heaters with separate storage tanks (*see* section 4.10 of appendix E) to represent how these products are used in the field. As a result of this method of testing, the efficiency ratings for circulating water heaters will reflect the standby losses incurred by the separate storage tank. As discussed previously in section IV.A.1.a of this document, DOE is classifying circulating water heaters as storage-type water heaters subject to the storage water heaters standards. In the July 2023 NOPR, however, DOE considered circulating water heaters as instantaneous water heaters and developed proposed standards using the instantaneous water heater efficiency levels as a starting point.

In response to the levels proposed in the July 2023 NOPR, NYSERDA suggested that DOE could address more stringent, heat pump-level standards for electric circulating water heaters in a separate rulemaking to ensure that the energy savings from this rulemaking are realized. (NYSERDA, No. 1192 at p. 7)

BWC requested clarification on how DOE derived the minimum efficiency levels for electric circulating water heaters in the NOPR, noting that the efficiencies corresponded to electric resistance technology, not heat pump circulating water heaters. (BWC, No. 1164 at pp. 2–3)

As discussed in section IV.A.1.a of this document, circulating water heaters will be subject to the applicable standards for storage-type water heaters. As such, there is no separate analysis to address UEF-based standards for circulating water heaters in this final rule.

In response to the December 2023 SNOPR proposing to treat circulating water heaters as part of the storage-type water heater product classes, BWC claimed that establishing heat pump-level standards for electric circulating water heaters would be inappropriate because they would favor one design option over another, as heat pump water heaters are not considered a separate product class from electric storage water heaters, stating that EPCA requires DOE to determine standards without regards to the technologies utilized by manufacturers or preferred by consumers. BWC requested that DOE clarify its understanding of its authority under EPCA with respect to these standards. (BWC, No. 1413 at pp. 2–3)

DOE notes that the analysis conducted in this rulemaking has determined that the amended standards for electric storage water heaters (which include electric circulating water heaters) are both technologically feasible and economically justified, and result in significant savings. These conclusions are discussed in detail in section V.C.1 of this document. DOE uses the screening criteria found in sections 6(b)(3) and 7(b) of appendix A to 10 CFR part 430, subpart C to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking. Under the criteria for technological feasibility, DOE considers technologies incorporated in commercially-available products or in working prototypes to be technologically feasible. As such, EPCA does not prohibit DOE from establishing a standard that can only be met through the use of a certain technology. Heat pump technology is the only technology available to allow electric circulating water heaters to achieve higher efficiency levels. DOE is not establishing a prescriptive design requirement that electric circulating water heaters must implement heat pump technology.

3. Manufacturer Selling Price

To account for manufacturers' non-production costs and profit margin, DOE applies a multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. DOE developed an average manufacturer markup by examining the annual Securities and Exchange Commission (''SEC'') 10–K [44] reports filed by publicly traded manufacturers that produce consumer water heaters, the manufacturer markups from the April 2010 Final Rule, and feedback from confidential manufacturer interviews. 75 FR 20112. *See* chapter 12 of the final rule TSD for additional detail on the manufacturer markup.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

For consumer water heaters, the main parties in the distribution chain are (1) manufacturers, (2) wholesalers or distributors, (3) retailers, (4) plumbing contractors, (5) builders, (6) manufactured home manufacturers, and (7) manufactured home dealers/retailers. *See* chapter 6 and appendix 6A of the final rule TSD for a more detailed discussion about parties in the distribution chain.

For this final rule, DOE characterized how consumer water heater products pass from the manufacturer to residential and commercial consumers [45] by gathering data from several sources, including consultant reports (available in appendix 6A of the final rule TSD), the 2023 BRG report,[46] and the 2022 Clear Seas Research Water Heater contractor survey [47] to determine the distribution channels and fraction of shipments going through each distribution channel. The distribution channels for replacement or new owners of consumer water heaters in residential applications (not including mobile homes) are characterized as follows: [48]

Manufacturer → Wholesaler → Plumbing Contractor → Consumer
Manufacturer → Retailer → Consumer
Manufacturer → Retailer → Plumbing Contractor → Consumer

For mobile home replacement or new owner applications, there is one additional distribution channel where manufacturers sell to mobile home dealers/retail outlets that then sell to the customer.[49]

[44] U.S. Securities and Exchange Commission. Company Filings. Available at*www.sec.gov/edgar/searchedgar/companysearch.html* (last accessed December 1, 2023).

[45] DOE estimates that 2 percent of gas-fired storage heaters (''GSWHs''), 29 percent of oil-fired storage water heaters (''OSWHs''), and 9 percent of electric storage water heaters (''ESWHs'') will be shipped to commercial applications in 2030.

[46] BRG Building Solutions, The North American Heating & Cooling Product Markets (2023 Edition). Available at *www.brgbuildingsolutions.com/reports-insights* (last accessed December 1, 2023).

[47] Clear Seas Research, 2022 Mechanical System—Water Heater. Available at *clearseasresearch.com/reports/industries/mechanical-systems/* (last accessed December 1, 2023).

[48] Based on available data, DOE assumed that the consumer water heater goes through the: wholesaler/contractor 50 percent of the time for GSWHs, 90 percent of the time for OSWHs, and 45 percent of the time for ESWHs; directly form the retailer 45 percent of the time for GSWHs, 5 percent of the time for OSWHs, and 50 percent of the time for ESWHs, and retailer/contractor 5 percent of the time for GSWHs, OSWHs, and ESWHs.

[49] Based on available data, DOE assumed that the consumer water heater in mobile homes goes through the: wholesaler/contractor 5 percent of the time for GSWHs, 90 percent of the time for OSWHs, and 5 percent of the time for ESWHs; directly form

Mainly for consumer water heaters in commercial applications, DOE considers an additional distribution channel for which the manufacturer sells the equipment to the wholesaler and then to the consumer through a national account in both replacement and new construction markets.

The new construction distribution channel includes an additional link in the chain—the builder. The distribution channels for consumer water heaters in new construction [50] in residential applications (not including mobile homes) are characterized as follows: [51]

Manufacturer → Wholesaler → Plumbing Contractor → Builder → Consumer

Manufacturer → Wholesaler → Builder → Consumer

Manufacturer → Wholesaler (National Account) → Consumer

For new construction, all mobile home GSWHs and ESWHs are sold as part of mobile homes in a specific distribution chain characterized as follows:

Manufacturer → Mobile Home Manufacturer → Mobile Home Dealer → Consumer

DOE developed baseline and incremental markups for each actor in the distribution chain. Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[52]

To estimate average baseline and incremental markups, DOE relied on several sources, including: (1) form 10–K [53] from U.S. Securities and Exchange Commission (''SEC'') for Home Depot, Lowe's, Wal-Mart, and Costco (for retailers); (2) U.S. Census Bureau 2017 Annual Retail Trade Report for miscellaneous store retailers (NAICS 453) (for online retailers); [54] (3) U.S. Census Bureau 2017 Economic Census data [55] on the residential and commercial building construction industry (for builder, plumbing contractor, mobile home manufacturer, mobile home retailer/dealer); and (4) the U.S. Census Bureau 2017 Annual Wholesale Trade Report data [56] (for wholesalers). DOE assumes that the markups for national accounts is half of the value of wholesaler markups. In addition, DOE used the 2005 Air Conditioning Contractors of America's (''ACCA'') Financial Analysis on the Heating, Ventilation, Air-Conditioning, and Refrigeration (''HVACR'') contracting industry [57] to disaggregate the mechanical contractor markups into replacement and new construction markets for consumer water heaters used in commercial applications.

PHCC commented that DOE's approach of incremental markups is not representative of how contractors set markups. PHCC commented that contractors know the required profit margin and set markups accordingly, rather than determining a markup for a baseline product and deciding a lower appropriate markup based on additional costs due to increased standards. (PHCC, No. 1151 at pp. 5–6) Rheem agreed that DOE's estimates of manufacturers' production costs for electric resistance and heat pump water heaters appear reasonable and that the retail price for electric resistance water heaters is accurate but the retail price of heat pump water heaters is a little low. Rheem recommended reviewing incremental markups for heat pump water heaters. Rheem also requested clarification on whether incremental markups are current markups or estimated for the compliance date of the rulemaking. (Rheem, No. 1177 at pp. 8–9)

In response, the development of all markup values is based on the most current data available, representing current markups applied to the products. The markups analysis is intended to represent products sold and installed at higher volume, since such products become the new baseline efficiency in the standards cases. Comparisons to current retail prices are therefore not necessarily applicable if such products are not common, high-volume products. For example, heat pump water heaters currently have a small market share and have higher profit margins. In a standards case with heat pump water heaters as the new baseline efficiency, their markups will be more representative of high-volume products. DOE also acknowledges that the contractor and customer relationship is of value and hence assigns contractors as an active market participant for a major portion of its distribution channels. For contractor markups, DOE utilized the 2017 Economic Census data, the latest data source consisting of the detailed operating costs needed to derive incremental markups. DOE believes that while contractors are unlikely to directly estimate an incremental markup in response to the cost change due to efficiency standards, contractor behavior is consistent with the characterization of DOE's markup approach which results in lower overall markup than baseline markup. DOE does not mean to suggest that contractors will directly adjust their markups on equipment if the price they pay goes up as a result of appliance standards. Rather, the approach assumes that such adjustment will occur over a (relatively short) period of time as part of a business management process. In summary, DOE acknowledges that its approach to estimating distributor and contractor markup practices after amended standards take effect is an approximation of real-world practices that are both complex and varying with business conditions. However, it

---

the retailer 10 percent of the time for GSWHs, 5 percent of the time for OSWHs, and 25 percent of the time for ESWHs; retailer/contractor 5 percent of the time for GSWHs, OSWHs, and ESWHs; and directly through mobile home retailer 80 percent of the time for GSWHs, 0 percent of the time for OSWHs, and 65 percent of the time for ESWHs.

[50] DOE estimates that in the residential market 10 percent of GSWHs, 2 percent of OSWHs, and 15 percent of ESWHs will be shipped to new construction applications in 2030.

[51] DOE believes that many builders are large enough to have a master plumber and not hire a separate contractor, and assigned about half of water heater shipments to new construction to this channel. DOE estimated that in the new construction market, 90 percent of the residential (not including mobile homes) and 80 percent in commercial applications goes through a wholesalers to builders channel and the rest go through national account distribution channel.

[52] Because the projected price of standards-compliant products is typically higher than the price of baseline products, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

[53] U.S. Securities and Exchange Commission. Company Filings. Available at *www.sec.gov/edgar/searchedgar/companysearch.html* (last accessed December 1, 2023).

[54] U.S. Census Bureau, *2017 Annual Retail Trade Report,* available at *www.census.gov/programs-surveys/arts.html* (last accessed December 1, 2023). Note that the 2017 Annual Retail Trade Report is the latest version of the report that includes detailed operating expenses data.

[55] U.S. Census Bureau, *2017 Economic Census Data.* available at *www.census.gov/programs-surveys/economic-census.html* (last accessed December 1, 2023). Note that the 2017 Economic Census Data is the latest version of this data.

[56] U.S. Census Bureau, *2017 Annual Wholesale Trade Report.* available at *www.census.gov/wholesale/index.html* (last accessed December 1, 2023). Note that the 2017 AWTR Census Data is the latest version of this data.

[57] Air Conditioning Contractors of America (''ACCA''), *Financial Analysis for the HVACR Contracting Industry* (2005), available at *www.acca.org/store#/storefront* (last accessed December 1, 2023). Note that the 2005 Financial Analysis for the HVACR Contracting Industry is the latest version of the report and is only used to disaggregate the mechanical contractor markups into replacement and new construction markets.

continues to believe that its assumption that standards do not facilitate a sustainable increase in profitability is reasonable.

In addition to the markups, DOE obtained State and local taxes from data provided by the Sales Tax Clearinghouse.[58] These data represent weighted average taxes that include county and city rates. DOE derived shipment-weighted average tax values for each State considered in the analysis.

In response to the July 2023 NOPR, AHRI advised that DOE's process should include industry participation by surveying manufacturers, distributors, and consumers and DOE should conduct another round of confidential interviews with manufacturers and reevaluate based on those interviews. (AHRI, No. 1167 at p. 11)

In support of the July 2023 NOPR, DOE conducted confidential interviews with OEMs representing approximately 80 percent of domestic industry consumer water heater shipments. In those interviews, DOE requested information about a range of topics including distribution channels. *See* appendix 12–A of the final rule TSD for a copy of the manufacturer interview guide. DOE also conducted confidential interviews with consumer water heater OEMs in support of the March 2022 Preliminary Analysis. Data collected through this process was recent and sufficient to conduct the analysis given that market conditions have remained largely the same since those confidential interviews. Chapter 6 of the final rule TSD provides details on DOE's development of markups for consumer water heaters.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of consumer water heaters at different efficiencies in representative U.S. single-family homes, mobile homes, multi-family residences, and commercial buildings, and to assess the energy savings potential of increased consumer water heater efficiency. The energy use analysis estimates the range of energy use of consumer water heaters in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

DOE estimated the annual energy consumption of consumer water heaters at specific energy efficiency levels across a range of climate zones, building characteristics, and water heating applications. The annual energy consumption includes the natural gas, liquid petroleum gas (''LPG''), and electricity used by the consumer water heater.

1. Building Sample

To determine the field energy use of consumer water heaters used in homes, DOE established a sample of households using consumer water heaters from EIA's 2015 Residential Energy Consumption Survey (''RECS 2015'') in the July 2023 NOPR, which was the most recent such survey that was then fully available.[59] The RECS data provide information on the vintage of the home, as well as water heating energy use in each household. DOE used the household samples not only to determine water heater annual energy consumption, but also as the basis for conducting the LCC and PBP analyses. DOE projected household weights and household characteristics in 2030, the first year of compliance with any amended or new energy conservation standards for consumer water heaters. To characterize future new homes, DOE used a subset of homes in RECS that were built after 2000.

In response to the July 2023 NOPR, Gas Association Commenters, Essency, Rinnai, and Atmos Energy commented that RECS 2015 should not have been used for the analysis and therefore the entire analysis is flawed. Gas Association Commenters stated that DOE had plenty of time to use RECS 2020 data and chose not to make their results look better. (Gas Association Commenters, No. 1181 at p. 32; Essency, No. 1194 at p. 3; Atmos Energy, No. 1183 at pp. 5–6; Rinnai, No. 1186 at p. 33) NYSERDA supported DOE's analysis, including RECS data and the consumer choice model analysis methodology. (NYSERDA, No. 1192 at pp. 3–4)

In response, DOE notes that RECS 2020 published finalized microdata in June 2023, with further updates published in July and September 2023. When conducting the analysis for the NOPR, the full set of microdata was not available. For this final rule, however, DOE incorporated RECS 2020 as the basis of the building sample development and updated the analyses accordingly.[60] DOE agrees that incorporating RECS 2020 improves the representativeness of the residential building sample as RECS 2020 brings a threefold increase in sample size compared to RECS 2015.[61] A larger sample size generally results in smaller standard errors, especially for estimates of smaller subpopulations. In this final rule, DOE maintains a similar methodology in sample development for the analyzed product classes. The details of selection criteria and the resulting sample size for each product class are presented in the final rule TSD (*see* chapter 7 and appendix 7A).

To determine the field energy use of consumer water heaters used in commercial buildings, DOE established a sample of buildings using consumer water heaters from EIA's 2018 Commercial Building Energy Consumption Survey (''CBECS 2018''), which is the most recent such survey that is currently fully available.[62] DOE has maintained its sample development methodology used in July 2023 NOPR for consumer water heaters used in commercial applications.

2. Hot Water Use Determination

Calculating hot water use for each sample household requires assigning the water heater a specific tank size (referred to as rated volume). For each household, RECS reports the size bin of the water heater (30 gallons and less, 31 to 49 gallons, and 50 gallons and more); for each commercial building, DOE assumes that the water heater generally falls under the biggest size option applicable for each product class. For each size bin, DOE derived the fraction of models falling under each draw patterns and assigns the sampled water heater to an appropriate one (*i.e.,* low, medium, and high). A specific tank size is then assigned based on the size bin and the draw pattern from the typical water heater sizes. Typical water heater sizes are the most common sizes for each product class and have the minimum energy factor allowed by current energy conservation standards.

[58] Sales Tax Clearinghouse Inc., *State Sales Tax Rates Along with Combined Average City and County Rates* (June 14, 2023). Available at *www.thestc.com/STrates.stm*) (last accessed December 1, 2023).

[59] Energy Information Administration (''EIA''), 2015 Residential Energy Consumption Survey (''RECS''). Available at *www.eia.gov/consumption/residential/* (last accessed December 1, 2023).

[60] Energy Information Administration (''EIA''), 2020 Residential Energy Consumption Survey (''RECS''). Available at *www.eia.gov/consumption/residential/* (last accessed December 1, 2023).

[61] According to published data and EIA website, RECS 2020 is based upon responses collected from in total 18,496 households which is three times greater than 5,686 respondents in RECS 2015.

[62] U.S. Department of Energy: Energy Information Administration, Commercial Buildings Energy Consumption Survey (2018). Available at: *www.eia.gov/consumption/commercial/data/2018/index.php?view=microdata* (last accessed Dec. 1, 2023).

They are 30, 40, and 50 gallon for gas and electric storage water heaters, 30 and 50 gallon for oil, and 60 and 75 gallon for electric storage water heaters larger than 55 gallons. For the product class of ESWHs smaller than 35 gallons, DOE also assigned a fraction the tank size of 35 gallons. These sizes are referred to as ''standard'' sizes. Finally, DOE calculated the hot water use for each household and building based on the characteristics of the water heater and the reported water heating energy use.

In order to disaggregate the selected sampled water heaters into draw patterns and standard sizes, DOE used a variety of sources including RECS historical data on reported tank sizes, input from an expert consultant, and model data from DOE's public CCD [63] and AHRI certification directory [64] together with other publicly available data from manufacturers' catalogs of consumer water heaters. For all product classes, DOE used disaggregated shipments data by rated volume from BRG Building Solutions 2023 report from 2007 to 2022 [65] and data from U.S. Census Bureau data (2003–2008).[66] Finally to determine the appropriate product type and size for different applications, DOE used manufacturer-produced consumer water heater sizing guidelines and calculators.

AHRI recommended DOE explain its inputs in the energy use calculations. AHRI commented that DOE's use of nesting of various assumptions for residential water heaters leads to unlikely results that DOE does not, or cannot, explain. (AHRI, No. 1167 at p. 19) AHRI also asked why DOE has not accepted the suggestion by AHRI and others to use median, not the mean values for consumption and LCC savings to avoid the effects of these outliers and to alleviate, at least in part, the deficiencies of its base case random assignment issue. (AHRI, No. 1167 at p. 20)

In response, DOE notes that RECS data provides the information on the household size and water heating energy use. RECS is the most comprehensive, nationally-representative, and robust data source on household energy consumption available to DOE. In general, DOE has found that the weighted average energy use for water heating correlates with the size of the household, *i.e.,* the reported number of people in that household. Greater energy expenditure on water heating largely falls into the bins of households of larger sizes (4 people and above). The hot water use derived based on the water heating energy use follows similar pattern (see chapter 7 of the final rule TSD for the calculation of hot water use). When reporting the distribution of the derived hot water use, DOE takes into account both consumer water heaters in residential as well as consumer water heaters used in commercial applications and close to 40 percent of the top 5 percent of water consuming sample buildings/households are commercial applications which generally have higher upper bound of hot water use. These outlier data points therefore represent either data directly reported from RECS for larger households or commercial applications using consumer water heaters, both of which represent real-world usage. In addition, DOE evaluates each sampled building/household individually by calculating its hot water use and the corresponding cost efficiency thereafter and that DOE believes the average LCC savings as reported is a good representation of the aggregated national values. Nevertheless, the LCC spreadsheet includes a calculation of median LCC savings, as well as LCC savings at various percentiles. Even if DOE were to rely on the median LCC savings instead of the mean LCC savings, DOE's conclusion of economic justification would remain the same.

Gas Association Commenters argued that water consumption should be based on household size and that there are problems with water consumption calculations. Gas Association Commenters argue the model results in unrealistic outliers for smaller households reaching consumption levels equivalent to space heating. Gas Association Commenters argue that a potential reason for this failure is how the model calculates daily water usage. For example, Gas Association Commenters argued that in DOE's model, some single person households use 200–350 gallons a day which is far from reasonable (4–7 baths of water a day every day of the year). Gas Association Commenters argued that Draw Pattern ID is based on randomly assigned distribution. Gas Association Commenters argue that for small storage units, there is a 5 percent chance of a large draw pattern Gas Association Commenters argues that a better solution would be to use the test procedure for water heaters as a basis for modeling energy usage rather than assuming draw rates based on the size of the original equipment in RECS. (Gas Association Commenters, No. 1181 at pp. 25–31) Rinnai argued that hot water usage should be determined through less opaque methods than the current method. Rinnai stated that rather than using RECS data to determine water usage, DOE should use test procedure defined hot water usage rates for comparisons of ELs. Rinnai stated that they believe that doing so would provide clearer consistency in comparison of residential water heater technologies generally and for EL comparison for proposed efficiency thresholds. Rinnai also stated that this would make DOE's analysis more consistent with other federal rating programs such as the FTC energy guide labeling program. (Rinnai, No. 1186 at p. 26 and p. 33) Furthermore, Rinnai commented that if RECS is to be used, RECS 2015 is outdated and RECS 2020 should be used for this analysis. (Rinnai, No. 1186 at p. 33) On the contrary, NEEA supported DOE's overall method of analysis using Monte Carlo simulations informed by RECS data. NEEA commented that the Monte Carlo approach can successfully represent the true distribution of water product classes, hot water use, energy use and costs and that NEEA uses a similar approach when conducting similar analysis. NEEA commented that RECS serves as a reliable national dataset that helps account for the diversity found in the water heater market. (NEEA, No. 1199 at p. 5)

In response, for this final rule, DOE incorporated the latest RECS 2020 data for its analyses. With the increased sample size and the most recent timeline of the fielding of the survey, DOE believes that it provides a sample pool of more up to date national representation of housing characteristics and energy consumption of the home appliances. As discussed previously, the weighted average of the energy use on water heating and the derived hot water use generally correlates with the size of the household with deviations that represent the real world complexities of the use of hot water heater in households of different types. DOE continues to rely on RECS as the basis of its analyses for its incomparable scope of coverage on housing

[63] U.S. Department of Energy's Compliance Certification Database is available at *regulations.doe.gov/certification-data* (last accessed December 1, 2023).

[64] Air Conditioning Heating and Refrigeration Institute. Consumer's Directory of Certified Efficiency Ratings for Heating and Water Heating Equipment. December 1, 2023. (Available at *www.ahridirectory.org*) (last accessed December 1, 2023).

[65] BRG Building Solutions. The North American Heating & Cooling Product Markets (2023 Edition). 2023.

[66] U.S. Census Bureau. Current Industrial Reports for Major Household Appliances 2003–2008. Washington, DC Report No. MA335F.

characteristics and energy consumption and believes that it is an objective reflection of the landscape in the national water heater market. In terms of the assignment of draw pattern, DOE derived the distribution of different draw patterns based on market research of the number of models in each bin that are available on the market. The breakdown can be found in chapter 7 of the final rule TSD.

Ecotemp commented that the DOE consumer usage assumptions do not match the water use patterns of cabins, vacation homes, rental properties, or any other intermittent use dwelling. (Ecotemp, No. 1092 at p. 2) In response, RECS does not include in the survey house types like vacant, seasonal, vacation homes and group quarters and thus DOE build its analysis around regular households. However, in both residential households (sample by RECS) and commercial buildings (CBECS) DOE has observed samples with lower than usual water heating energy use. As stated previously, DOE believes that RECS and CBECS provide a nationally representative sample pool that includes a variety of housing types.

3. Energy Use Determination

To calculate the energy use of consumer water heaters, DOE determined the energy consumption associated with water heating and any auxiliary electrical use. In addition, for heat pump water heaters, DOE also accounted for the indirect effects of heat pump water heaters on heating, cooling, and dehumidification systems to compensate for the effects of the heat pump operation.[67] DOE calculated the energy use of water heaters using a simplified energy equation, the water heater analysis model (''WHAM''). WHAM accounts for a range of operating conditions and energy efficiency characteristics of water heaters. Water heater operating conditions are indicated by the daily hot water draw volume, inlet water temperature, thermostat setting, and air temperature around the water heater (ambient air temperature). To describe energy efficiency characteristics of water heaters, WHAM uses three parameters that also are used in the DOE test procedure: recovery efficiency (''*RE*''), standby heat-loss coefficient (''*UA*''), and rated input power (''P_{ON}'').

The current version of WHAM is appropriate for calculating the energy use of electric resistance storage water heaters. To account for the characteristics of other types of water heaters, energy use must be calculated using modified versions of the WHAM equation. These modified versions are further discussed in chapter 7 and appendix 7B of the final rule TSD.

The daily hot water draw volume is estimated based on the water heater energy use estimated from RECS 2020 and CBECS 2018. The inlet water temperature is based on weather station temperature data and RECS 2020 ground water temperature data for each household. The consumer water heater thermostat setting is based on multiple sources including contractor survey data and field data. To estimate the air temperature around the water heater (ambient air temperature), DOE assigned the sampled water heaters a water heater installation location including indoors (in the living space, such as an indoor closet), basement, garages, crawlspaces, outdoor closets, attics, etc. These fractions vary significantly by region and type of home, and match available survey data. Once the water heater is assigned an installation location, DOE then uses a methodology to determine the surrounding water heater ambient temperature. For example, in indoor locations the temperatures are assumed to be equal to the thermostat temperature. Other locations such as unconditioned attics or unconditioned basements/crawlspaces, outdoor closets, garages could have temperatures that are either lower than 32 deg. or above 100 deg. for a fraction of the year. *See* chapter 7 and appendix 8D (installation costs) of the final rule TSD for more details about the installation location methodology and ambient temperature methodology.

ONE Gas commented that DOE responded that it uses test procedure energy descriptor performance to determine energy use that is then ''convert[ed] . . . to field energy use using modified WHAM equations,'' but ONE Gas's review of these procedures as found in appendix 7B of the Preliminary Analysis TSD suggests that the energy consumption estimates modeled do not meet the intent of the NASEM peer review, and DOE's response is effectively incomplete. ONE Gas recommended that DOE (1) use the test procedure assumptions of hot water consumption (based on the UEF draw patterns for residential water heating products) as the basis for comparing efficiency levels and alternatives for minimum efficiency standards, and (2) use WHAM calculations or other methods for scaling up efficiency level savings for the forecasted market under the ELs analyzed. (ONE Gas, No. 1200 at p. 9) In response, the appendix 7B in Preliminary Analysis TSD was merged in chapter 7 in NOPR TSD. Cross-reference pointing to appendix 7B for the energy use methodology in the TSD in the July 2023 NOPR was a typo DOE now has corrected. Description of the use of WHAM can be found in chapter 7 of the final rule TSD. As discussed in section IV.E.2 of this document, DOE determines that calculating the hot water use based on RECS reports presents a representative distribution of real world energy consumption and the use of WHAM equation is essential for translating energy consumption into hot water use. DOE maintains its methodology in this final rule to use RECS-reported water heating energy use and WHAM equation to calculate the corresponding energy use for each efficiency level of each product classed for sampled households/buildings.

For heat pump water heaters, energy efficiency and consumption are dependent on ambient temperature. To account for this factor, DOE expanded the WHAM to include a heat pump performance adjustment factor. The equation for determining the energy consumption of heat pump water heaters is similar to the WHAM equation, but a performance adjustment factor that is a function of the average ambient temperature is applied to adjust RE. In response to the July 2023 NOPR, Essency noted that the energy consumption model used in the analysis utilizes a recovery efficiency model that is too simplified and overestimated. They stated that the recovery efficiency model is a quadratic function with a minimum temperature of roughly 45 °F–50 °F which gives it a recovery efficiency at 37 °F, which Essency commented is a temperature where most of the current heat pump water heaters are working with electric resistance only. Essency also commented that the energy removed from the air is deducted in warmer months but this energy is not considered for cold months where the energy is removed from a heated space, which Essency asserted creates a bias in the published efficiency of heat pump water heaters. Essency also commented that the surrounding air temperature was used to calculate the efficiency of the heat pump even in the ducted configuration. (Essency, No. 1194 at p. 2) Armada argued that the energy savings are only realized under specific space and climate conditions, and

[67] If the heat pump water heater is installed in a conditioned space and is un-ducted, the cooling byproduct of the heat pump operation could produce a cooling effect that could increase space heating energy use in the heating season and decrease space cooling energy use in the cooling season. In addition, heat pump operation could also produce a dehumidifying effect that could reduce dehumidifier equipment energy use.

deviations from these ideal conditions diminish the efficiency of a heat pump water heater. Armada noted that many heat pump water heaters have back up electric resistance heating, and when these space and climate conditions are not met, the water heater will utilize resistance heating—all of the cost of a heat pump with none of the anticipated benefits. (Armada, No. 1193 at pp. 5–6) NRECA commented that stakeholders in cold climates are concerned about the effectiveness of heat pump water heaters during extreme cold events. In cold climates, and particularly during extreme cold events, heat pump water heater in garages or other unconditioned spaces would operate electric resistive heating elements for a large portion of the day, resulting in high energy use and reducing LCC savings. NRECA commented that cooperatives such as Agralite Electric Cooperative in Minnesota and Iowa Lakes Electric Cooperative in Iowa expressed concerns related to the energy the heat pump water heater removes from the home if installed in the conditioned space. Because the heat pump water heater draws its energy from the air in the home, the space heating system must resupply heat taken up by the heat pump water heater. (NRECA, No. 1127 at p. 12)

In response, DOE notes that the analyses account for the energy consumption when the heat pump water heater is operating on electric resistance mode. DOE estimated that the electric resistance mode of operation is used 100 percent of the time when the monthly ambient temperature is less than 32 °F or more than 100 °F. As Essency noted, DOE adjusts the recovery efficiency in a quadratic function to account for the changes in performance of the heat pump under different conditions. DOE slightly updated the adjustment function for this final rule so that when below 32 °F and above 100 °F the electric resistance mode is considered. DOE also modified the methodology to take into account the outdoor temperature in ducted setting per Essency's comment. A heat pump water heater also operates in the electric resistance mode for part of the time even when the monthly ambient temperature (where the equipment is installed) is between 32 °F and 100 °F because this product has a slower recovery rate than an electric resistance water heater. DOE determined that, depending on household hot water consumption patterns, the electric resistance mode of operation varies significantly from household to household; on average DOE estimated that electric resistance mode accounts for 10 percent of the heat pump water heater unit's operating time. Lastly, because of the cooling effect heat pump water heater can have during heating season, DOE also estimated that two-thirds of heat extracted from the air by the heat pump water heater is replaced by the space conditioning system, which was taken in account for the heating season.

Gas Association Commenters commented that there is a bug in the LCC tool that causes it to use only a single year of weather data rather than 10-year average. (Gas Association Commenters, No. 1181 at p. 34) In response, DOE notes that the analysis uses the NOAA's 30 year average weather data for the outside air temperature for all product classes.

Chapter 7 of the final rule TSD provides details on DOE's energy use analysis for consumer water heaters.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for consumer water heaters. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

- The LCC is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.
- The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of consumer water heaters in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

For each considered efficiency level in each product class, DOE calculated the LCC and PBP for a nationally representative set of housing units and commercial buildings. As stated previously, DOE developed household samples from the RECS 2020 and CBECS 2018. For each sample household and commercial building, DOE determined the energy consumption for the consumer water heaters and the appropriate energy price. By developing a representative sample of households and commercial buildings, the analysis captured the variability in energy consumption and energy prices associated with the use of consumer water heaters.

Inputs to the calculation of total installed cost include the cost of the product—which includes MPCs, manufacturer markups, retailer and distributor markups, shipping costs, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates. DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and consumer water heater user samples. For this rulemaking, the Monte Carlo approach is implemented in MS Excel together with the Crystal Ball™ add-on.[68] The model calculated the LCC for products at each efficiency level for 10,000 water heater installations in housing and commercial building units per simulation run. The analytical results include a distribution of 10,000 data points showing the range of LCC savings for a given efficiency level relative to the no-new-standards case efficiency distribution (as shown in chapter 8 of the final rule TSD). In performing an iteration of the Monte Carlo simulation for a given consumer, product efficiency is chosen based on its probability. At

[68] Crystal Ball™ is commercially-available software tool to facilitate the creation of these types of models by generating probability distributions and summarizing results within Excel, available at *www.oracle.com/technetwork/middleware/crystalball/overview/index.html* (last accessed December 1, 2023).

the high end of the range, if the chosen product efficiency is greater than or equal to the efficiency of the standard level under consideration, the LCC calculation reveals that the hypothetical consumer represented by that data point is not impacted by the standard level because that consumer is already purchasing a more-efficient product. At the low end of the range, if the chosen product efficiency is less than the efficiency of the standard level under consideration, the LCC calculation reveals that the hypothetical consumer represented by that data point is impacted by the standard level. By accounting for consumers who already purchase more-efficient products, DOE avoids overstating the potential benefits from increasing product efficiency.

DOE calculated the LCC and PBP for consumers of consumer water heaters as if each were to purchase a new product in the first year of required compliance with new or amended standards. New and amended standards apply to consumer water heaters manufactured 5 years after the date on which any new or amended standard is published. (42 U.S.C. 6295(m)(4)(A)(ii)) Therefore, DOE used 2030 as the first full year of compliance with any amended standards for consumer water heaters.

Table IV.25 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 of the final rule TSD and its appendices.

BILLING CODE 6450–01–P

Table IV.25 Summary of Inputs and Methods for the LCC and PBP Analysis*

Inputs	Source/Method
Product Cost	Derived by multiplying MPCs by manufacturer and retailer markups and sales tax, as appropriate. Used historical data to derive a price scaling index to project product costs.
Installation Costs	Baseline installation cost determined with data from RSMeans. Assumed no change with efficiency level.
Annual Energy Use	The total annual energy use multiplied by the hours per year. Average number of hours based on field data. Variability: Based on the RECS 2020 and CBECS 2018.
Energy Prices	Natural Gas: Based on EIA's Natural Gas Navigator data for 2022. Electricity: Based on EIA's Form 861 data for 2022. Propane and Fuel Oil: Based on EIA's State Energy Data System ("SEDS") for 2021. Variability: Regional energy prices determined for 50 states and District of Columbia for residential and commercial applications. Marginal prices used for natural gas, propane, and electricity prices.
Energy Price Trends	Based on *AEO2023* price projections.
Repair and Maintenance Costs	Based on RSMeans data and other sources. Assumed variation in cost by efficiency.
Product Lifetime	Based on shipments data, multi-year RECS, American Housing Survey, American Home Comfort Survey data.
Discount Rates	Residential: approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances. Commercial: Calculated as the weighted average cost of capital. Primary data source was Damodaran Online.
Compliance Date	2030

* Not used for PBP calculation. References for the data sources mentioned in this table are provided in the sections following the table or in chapter 8 of the final rule TSD.

BILLING CODE 6450–01–C

1. Product Cost

To calculate consumer product costs, DOE multiplied the MSPs developed in the engineering analysis by the markups described previously (along with sales taxes). DOE used different markups for baseline products and higher-efficiency products, because DOE applies an incremental markup to the increase in MSP associated with higher-efficiency products.

Examination of historical price data for certain appliances and equipment that have been subject to energy conservation standards indicates that the assumption of constant real prices may, in many cases, overestimate long-term trends in appliance and equipment prices. Economic literature and historical data suggest that the real costs of these products may in fact trend downward over time according to ''learning'' or ''experience'' curves.[69]

In the experience curve method, the real cost of production is related to the cumulative production or ''experience'' with a manufactured product. This

[69] Desroches, L.-B., K. Garbesi, C. Kantner, R. Van Buskirk, and H.-C. Yang. Incorporating Experience Curves in Appliance Standards Analysis. *Energy Policy*. 2013. 52 pp. 402–416; Weiss, M., M. Junginger, M.K. Patel, and K. Blok. A Review of Experience Curve Analyses for Energy Demand Technologies. *Technological Forecasting and Social Change*. 2010. 77(3): pp. 411–428.

experience is usually measured in terms of cumulative production. As experience (production) accumulates, the cost of producing the next unit decreases. The percentage reduction in cost that occurs with each doubling of cumulative production is known as the learning rate. In typical experience curve formulations, the learning rate parameter is derived using two historical data series: cumulative production and price (or cost). DOE obtained historical PPI data for water heating equipment from 1950–1961, 1968–1973, and 1977–2022 for electric consumer water heaters and from 1967–1973 and 1977–2022 for all other consumer water heaters from the U.S. Bureau of Labor Statistics' (''BLS'').[70] The PPI data reflect nominal prices, adjusted for product quality changes. An inflation-adjusted (deflated) price index for heating equipment manufacturing was calculated by dividing the PPI series by the implicit price deflator for Gross Domestic Product Chained Price Index.

From 1950 to 2006, the deflated price index for consumer water heaters was mostly decreasing, or staying flat. Since then, the index has risen, primarily due to rising prices of copper, aluminum, and steel products which are the major raw material used in water heating equipment. The rising prices for copper and steel products were attributed to a series of global events, from strong demand from China and other emerging economies to the recent severe delay in commodity shipping due to the COVID–19 pandemic. Given the slowdown in global economic activity in recent years and the lingering impact from the global pandemic, DOE believes that the extent to which the trends of the past five years will continue is very uncertain. DOE also assumes that any current supply chain constraints are short-lived and will not persist to the first year of compliance. Given the uncertainty regarding the magnitude and direction of potential future price trends, DOE decided to use constant prices as the default price assumption to project future consumer water heater prices. Thus, projected prices for the LCC and PBP analysis are equal to the 2022 values for each efficiency level in each product class. However, DOE performed a sensitivity analysis utilizing both a decreasing and an increasing price trend (see appendix 8C). The relative comparison of potential standard levels remains the same regardless of which price trend is utilized and the conclusions of the analysis do not change.

BWC requested that DOE detail its methods in utilizing price learning curves for both heat pump water heater and condensing gas products, as was indicated in Section IV(F)(1) of the July 2023 NOPR, so that stakeholders may review them. BWC suggested the additional components required to manufacture higher efficiency products required by this proposal, in addition to their more complex manufacturing processes, will continue to compel higher product costs than is currently expected of non-condensing gas and electric resistance water heaters common in the market today, economies of scale notwithstanding. (BWC No. 1164 at p. 17) The available data only allow estimation of price trends for water heaters as a group, not for different efficiency levels of water heaters. DOE agrees that the product costs of heat pump water heater and condensing gas products will continue to be higher than non-condensing gas and electric resistance water heaters. However, it is reasonable to expect that factors affecting water heaters as a whole, such as growing experience in production or changes in commodity prices, will affect all water heaters. Thus, for this final rule, it used the same price trend projection for all water heaters.

2. Installation Cost

The installation cost is the cost to the consumer of installing the consumer water heater, in addition to the cost of the water heater itself. The cost of installation covers all labor, overhead, and material costs associated with the replacement of an existing water heater or the installation of a water heater in a new home, as well as delivery of the new water heater, removal of the existing water heater, and any applicable permit fees. Higher-efficiency water heaters may require consumers to incur additional installation costs.

DOE's analysis of installation costs estimated specific installation costs for each sample household based on building characteristics given in RECS 2020 and CBECS 2018. For this final rule, DOE used 2023 RSMeans data for the installation cost estimates, including labor costs.[71] [72] [73] [74] DOE's analysis of installation costs accounted for regional differences in labor costs by aggregating city-level labor rates from RSMeans into 50 U.S. States and the District of Columbia to match RECS 2020 data and CBECS 2018 data.

PHCC stated that the costs calculated for the installation costs are too low. PHCC commented that the data source RSMeans is intended for larger contractor businesses and the data has not been properly adjusted for small businesses. PHCC noted a discrepancy in the water heater installation time between their RSMeans source and DOE's report. (PHCC, No. 1151 at p. 4) PHCC stated that the values listed in the overhead category for costs are not correct and questioned the 10% profit, believing it to be understated. PHCC commented that the overhead category will include office utilities and rent, support staff, supervisors, estimators, advertising, truck and tool acquisition expenses, fuel and maintenance, technician non-productive time and depreciation. PHCC estimated that vehicle and tooling can be 15% to 20% of a technician's hourly rate. PHCC commented that DOE's assumption of $27 per hour overhead for 1 residential plumber is too low. (PHCC, No. 1151 at p. 5) In response, RSMeans is a reputable source for cost estimation and it provides the national average labor rate for different crew types as well as regional rates, regardless of business size. DOE acknowledges that some individual contractors may depart from cost estimates determined by RSMeans, however RSMeans remains the most comprehensive and nationally representative data source for contractor rates and costs. The RSMeans database includes tens of thousands of individual line items and cost engineers spend tens of thousands of hours validating these costs every year. Thousands of contractors rely on RSMeans to determine cost estimates.[75] DOE adjust the labor rates for different regions based on where the sample household or building is located. In regards to PHCC's concern over the labor rate and overhead, DOE notes that the $27 per hour overhead for a residential plumber is pointing to 63% markup compared to the bare hourly rate. Taking into account regional difference, the exact

[70] Series ID PCU33522033522081 and PCU33522833522083; see *www.bls.gov/ppi/*.

[71] RSMeans Company Inc., *RSMeans Mechanical Cost Data.* Kingston, MA (2023) (Available at: *www.rsmeans.com/products/books/2022-cost-data-books*) (Last accessed December 1, 2023).

[72] RSMeans Company Inc., *RSMeans Residential Repair & Remodeling Cost Data. Kingston,* MA (2023) (Available at: *www.rsmeans.com/products/books/2022-cost-data-books*) (Last accessed December 1, 2023).

[73] RSMeans Company Inc., *RSMeans Plumbing Cost Data.* Kingston, MA (2023) (Available at: *www.rsmeans.com/products/books/2022-cost-data-books*) (Last accessed December 1, 2023).

[74] RSMeans Company Inc., *RSMeans Electrical Cost Data.* Kingston, MA (2023) (Available at: *www.rsmeans.com/products/books/2022-cost-data-books*) (Last accessed December 1, 2023).

[75] See: *www.rsmeans.com/info/contact/about-us* (Last accessed March 6, 2024).

dollar value of the markup increases for regions with labor rates higher than national average. For this final rule, DOE maintained the method of calculating labor rates as used in the July 2023 NOPR.

a. Basic Installation Costs and Inputs

First, DOE estimated basic installation costs that are applicable to all consumer water heaters, in replacement, new owner, and new home or building installations. These costs include putting in place and setting up the consumer water heater, gas piping and/or electrical hookup, permits, water piping, removal of the existing consumer water heater, and removal or disposal fees.

NMHC and NAA commented that in existing or future commercial-to-residential conversions, by the nature of the building construction, historic building considerations or zero lot lines result in building facades that are frequently not available for vent terminations. They claimed that these buildings may be taller than a new residential building and existing structural frame geometries and shaft locations significantly influence dwelling unit configurations, in which cases new vent piping or condensate drains may need to traverse space outside of the affected dwelling unit to reach a building shaft with sufficient space to add piping. NMHC and NAA claimed that such piping runs will virtually always exceed the lengths cited for cost-analysis in the TSD and entail substantial additional costs unconsidered by DOE. (NMHC and NAA, No. 996 at p. 4) Gas Association Commenters argued that the installation cost did not address the breadth of existing multifamily configurations like high-rise, low-rise buildings, historic structures and adaptive reuse projects (*i.e.,* commercial to residential conversions). (Gas Association Commenters, No. 1181 at p. 4) In response, DOE notes that current shipments of consumer water heaters to commercial buildings are small, approximately 5 percent of total shipments (see chapter 9 of final rule TSD). These are typically small offices, restaurants, or smaller retailers with similar hot water demand to residential households, otherwise they would be utilizing commercial water heating equipment outside the scope of this final rule. Any existing commercial-to-residential building conversions would be present in the CBECS 2018. Any future commercial-to-residential conversions are speculative at this time. Even if vent piping for gas-fired water heaters were prohibitive for a given building, electric water heaters are available to supply hot water at lower cost to each individual unit, so there is no reason to expect substantially higher costs for these residential units. Their impacts would be very similar to those estimated for medium ESWH in new construction and/or multi-family buildings and thus captured by the analysis. Furthermore, if the existing commercial building utilizes a central commercial boiler to supply hot water, DOE expects that such building conversions will take advantage of the existing central commercial boiler system to supply hot water to the newly built residential units. Also, in order to satisfy the building codes, these conversions typically require very extensive reconstructions including building new central shafts that accommodate all of the piping and vents related to plumbing, HVAC and water heating needs. These shafts could serve the condensation withdrawal as required for the heat pump water heaters or condensing gas water heaters. In regards to the length of the piping runs, DOE's analysis includes a distribution of a wide range of piping length which covers the additional piping requirements. Regarding existing multi-family buildings, DOE clarifies that the analysis does include costs separately for multi-family buildings of various sizes (see appendix 8D), and the RECS sample includes such multi-family buildings, therefore they are captured in the LCC analysis. The majority of multi-family buildings utilize electric storage water heaters.

b. Gas-Fired and Oil-Fired Storage Water Heater Installation Costs

For gas-fired and oil-fired water heater installations, DOE included a number of additional costs (''adders'') for a fraction of the sample households. Most of these additional cost adders are associated with installing higher efficiency consumer water heater designs in replacement installations.

For replacement installations, DOE conducted a detailed analysis of installation costs when a baseline (or minimum efficiency) consumer water heater is replaced with higher efficiency design options, with particular attention to space constraint issues (associated with larger dimensions for certain higher efficiency consumer water heaters), venting issues, and condensate withdrawal (for power vented and condensing gas-fired water heaters). Due to the larger dimensions of higher efficiency storage water heaters, installation adders included removing and replacing door jambs (to be able to fit the larger sized water heater). DOE also takes into account that a fraction of installations would include adding tempering valves for water heaters with increased set-point temperatures due to the household preference. For non-condensing gas-fired and oil-fired water heaters, additional costs included updating flue vent connectors, vent resizing, and chimney relining. For non-condensing power vented and condensing gas-fired storage water heaters, additional costs included adding a new flue vent, combustion air intake for direct vent installations, concealing vent pipes for indoor installations, addressing an orphaned furnace (by updating flue vent connectors, vent resizing, or chimney relining), and condensate removal. Freeze protection is accounted for in the cost of condensate removal for a fraction of condensing gas-fired water heaters installed in non-conditioned spaces.

DOE also included installation adders for new owner and new construction installations. For non-condensing gas-fired and oil-fired storage water heaters, a new flue vent and accounting for other commonly vented heating appliances are the only adders. For power vented and condensing gas-fired water heaters, the adders include new flue vent, combustion air vent for direct vent installations, and condensate removal.

ONE Gas commented that venting costs are systematically under-estimated but did not provide more data. ONE Gas argued that the Department does not provide illustrations of the full range of site conditions covered or confirmation data for its distributional data. (ONE Gas, No. 1200 at p. 10) ONE Gas argued that the Department uses a simplistic presumption of single-family household replacement installation requirements (*e.g.,* venting into masonry chimneys, common venting with furnace) for multifamily households whose water heater vents atmospherically into a common vent shared with other households, which neglects various concerns. (ONE Gas, No. 1200 at p. 10) PHCC requested clarification on the language on page 8D–7 of the NOPR TSD surrounding masonry chimneys. PHCC commented that the language gets confusing as it discusses lined masonry chimneys but then considers metal lining systems. PHCC noted that masonry chimneys must be tile lined for gas venting and it is unclear if DOE views the use of a flexible metal liner kit as a lined chimney. Furthermore, PHCC indicated the need for more clarification on the use of flexible liners in chases, as those chases should contain metallic double wall vents. Finally, PHCC requested clarification on the discussion surrounding isolated water heaters that

are not gas-fired nor vented products, as PHCC is not clear on why they are called isolated and what their relationship is with common venting. (PHCC, No. 1151 at p. 3)

In response, DOE notes that sources and references used in the analysis for deriving the methodology are presented in chapter 8 of the TSD and its appendices. DOE is aware that in some multifamily buildings, existing non-condensing storage water heaters of more than one unit can be commonly vented with other equipment vented using a Category I vent. In some cases, replacement of one water heater may require re-assessment of the shared vent path. However, this final rule does not require a condensing level for gas storage water heaters. DOE notes that it is challenging to acquire data on how frequently water heaters are commonly vented in multifamily buildings that allow DOE to statistically account for the cost impact on its own. DOE estimates, however, certain fractions by region where chimney venting is applied and believes that, besides those typical cases where chimney venting is shared by a water heater and a furnace, those installation cases have captured to some extent the costs applicable for vent path reassessment. In regards to the PHCC's comment on appendix 8D of NOPR TSD, to clarify, DOE accounts for different types of venting used in the field; venting through a masonry chimney and venting through a metal vent going through the roof are both included. For venting in the masonry chimney, DOE takes into account the cost for relining the chimney and venting for orphaned furnace/boiler where applicable in retrofits. Specifically, when venting through the chimney, DOE accounts for the cost of chimney re-lining and resizing of the vent connector should the retrofit require that. Additionally, ''isolated'' water heaters as explained in the documentation refer to water heaters that are not commonly vented or do not require venting at all, for which there are no common venting related costs considered. See chapter 8 and appendix 8D of the final rule TSD for details.

CHPK stated that the modification associated with increasing insulation, the addition of a thermal flue damper, or an electronic ignition and an electronic flue damper would require an electric supply to gas-fired storage water heaters, and would potentially reduce vent temperatures resulting in excessive condensation developing in the vent. According to CHPK, these modifications would result in additional costs of providing an electric outlet for gas storage water heaters in a replacement situation and perhaps venting issues. (CHPK, No. 1008 at p. 1) DOE took into account in the calculation of installation costs the issues CHPK raised and applied a cost adder for an electric outlet and condensate treatment for the efficiency levels that require those.

Regarding statements from some stakeholders that significant installation barriers are associated with gas condensing water heaters, the CA IOUs referred DOE to a report docketed in 2019 titled ''Investigation of Installation Barriers and Costs for Condensing Gas Appliances.'' Key findings from this report indicate that these challenges impact less than 5 percent of condensing gas retrofit installations for residential and commercial applications, and that condensate management and chimney relining were minor concerns for installing gas condensing products. (CA IOUs, No. 1175 at p. 2) DOE agrees that installation challenges will impact only a subset of consumers, and even in those cases, DOE has included additional installation costs into the analysis.

c. Heat Pump Water Heater Installation Costs

For heat pump water heater installations, DOE included a number of adders for a fraction of the sample households. Most of these adders are associated with installing heat pump water heaters in replacement installations.

For replacement installations, DOE conducted a detailed analysis of installation costs when a baseline consumer water heater is replaced with higher efficiency designs, with particular attention to space constraint issues (associated with larger dimensions for heat pump water heaters compared to electric resistance water heaters), condensate withdrawal, and ductwork for heat pump water heaters installed in conditioned spaces. To address the larger dimensions of heat pump water heaters, installation adders included removing and replacing door jambs (to be able to fit the larger sized water heater) or relocating water heater. Freeze protection is accounted for in the cost of condensate removal for a fraction of heat pump water heaters installed in non-conditioned spaces. DOE also included condensate removal installation adders for new owner and new construction heat pump water heater installations. DOE also accounted for the airflow requirements as specified in manufacturer installation manuals in its installation cost model. The additional costs of adding louvered doors, venting, or relocating a water heater are included for a fraction of installations, mainly for heat pump water heaters installed in indoor locations. See appendix 8D of the final rule TSD for more details.

PHCC commented that DOE acknowledges that up to 40% of installations could face space constrained heat pump installations and the suggestion that DOE provides to use louvered doors may not be applicable to all installations and the use of ducted air installations should be accounted for. (PHCC, No. 1151 at p. 4) PHCC noted that on page 8D–6 of NOPR TSD there are no modifications to remove and replace door jambs for basements and garages, but plumbing, building and mechanical codes require doorways to be of sufficient size to replace equipment without future removal of doors and door frames. (PHCC, No. 1151 at p. 3) NMHC and NAA noted that DOE's suggestion that it may be possible to ignore manufacturers' specified volume of space for heat pump water heater installation based on ''current research'' is not acceptable as it conflicts with building code requirements to comply with manufacturer's instructions. NMHC and NAA also commented that DOE's suggestion for installation of heat pump water heaters by replacing utility closet doors with louvered doors is not viable as it ignores the impacts of increases in equipment noise in the smaller area of the typical apartment home. (NMHC and NAA, No. 996 at p. 4) Essency argued that the cost of moving the heat pump water heater was not calculated as there are significant additional electrical, plumbing, and other construction work that are required. (Essency, No. 1194 at p. 2) EEI commented that it is important to recognize that installing heat pump water heater units in space-constrained areas (like closets or under stairs or in crawl spaces) will require significant retrofit costs given heat pump water heaters' physical operating requirements and the potential need for additional equipment. EEI commented that non-ducted heat pump water heaters require at least 700 cu ft of space to operate properly and achieve DOE's estimated efficiency levels, as shown in manufacturer specifications. EEI noted that 10 to 40 percent of water heaters are located in closets based on a survey by Southern Company. EEI commented that DOE's analysis does not include a realistic cost estimate for replacing electric resistance water heaters with heat pump water heaters in closets where walls, ceilings, and doors must be removed and replaced or ductwork

added in space constrained areas. EEI argued that DOE's analysis does not accurately account for the replacement costs in other space-constrained environments such as crawl spaces, attics, utility rooms, or laundry rooms (EEI, No. 1198 at pp. 5–6) Armada argued that ideal efficiency conditions for heat pump water heaters require 1000 cubic feet of air. Armada argued that many homes cannot support such space demands, and use of heat pump water heaters will increase home heating costs for many consumers, diminishing any savings. Armada argued that only in very rare circumstances would consumers be able to quickly replace an electric storage water heater in an emergency, as many homes will require construction to accommodate the space and environment requirements of a heat pump water heater such as installing louvered doors or building ductwork. (Armada, No. 1193 at p. 6)

In response to the preceding comments, DOE notes that the analysis takes into account the cost of moving the water heater to a different location or adding a louvered door for some installations. In the field, plumbers would guide the customers to select a way that works for them. In the analysis, DOE acknowledges the possible occurrence of those additional costs and on top of those DOE also applied a distribution of installation cost adders that ranges from $0 to $4,000 in total for the most challenging installations, averaging $2,000 (see appendix 8D).

NRECA commented that manufactured and small homes experience greater impact from both noise and cold air exhaust than larger homes that have more space to isolate the noise of the water heater and more air volume to buffer cold air exhaust. They commented that constrained spaces may not have enough room for mitigation measures such as supply and exhaust air ducting or noise dampening equipment. NRECA added that consumers will not welcome any increase in their electricity bills resulting from their heating system needing to work harder because of the heat pump water heater drawing on the warm air as its heat source. (NRECA, No. 1127 at p. 6). NRECA commented that manufactured and small homes will face unique installation challenges with heat pump water heaters. They noted that small and manufactured homes in NRECA member territories typically use 40- to 50-gallon lowboys, tall tanks, or tanks specifically designed for manufactured home closets, and that although DOE created a small electric storage water heater product class that covers some lowboy products this does not include tank sizes and form factors that electric cooperatives typically observe in space constrained spaces. NRECA cited the La Plata Electric Association (''LPEA'') pilot study where 20 heat pump water heaters were installed in owner-occupied manufactured homes and due to the complexity of installation, concluded that a majority of manufactured homes are not good candidates for a heat pump water heater. NRECA stated that although heat pump water heaters can be installed in some constrained spaces, they are likely not the best option when they cause high installation costs, noise and cold air impacts, and potentially unsightly installations to make the heat pump water heater fit a space that was never designed to accommodate it, and there often is no other available space in a small home to relocate the water heater, and reducing tank size can cause negative user experience. (NRECA, No. 1127 at pp. 6–7) NRECA commented that because low-and-moderate income consumers disproportionately face complex installations, they are likely to disproportionately bear costs rather than savings as a result of the proposed rule and they received multiple examples from electric cooperatives illustrating that installation costs are far higher than DOE's estimates. (NRECA, No. 1127 at p. 8)

NEEA noted that its research shows that heat pump water heaters can be installed in a wide range of conditions and climates, including very cold climates, and continue to deliver significant energy savings. (NEEA, No. 1199 at pp. 3–4) NEEA commented that its research supports DOE's installation cost analysis. (NEEA, No. 1199 at p. 7). However, BWC highlighted that NEEA is a regional organization that operates its programs primarily in the Northwestern United States and only included those consumers who had already made the decision to take advantage of available heat pump water heater rebate programs. (BWC, No. 1164 at p. 20)

In response, DOE acknowledges that manufactured homes and small homes typically have greater challenges in installing a heat pump water heater. Installing a heat pump water heater in such homes may require additional installation costs, as described above, more so than an average single-family home. The LCC analysis accounts for the higher installation costs for such homes. However, in many cases, such homes can utilize a small electric storage water heater instead of a heat pump water heater, significantly reducing their total installed cost. In terms of the cooling effect of the heat pump module, DOE took that into account in its energy use analysis the additional heating it might need in compensation, as discussed in section IV.E.3 of this document. DOE acknowledges that for low income homeowners, higher installation costs would indeed need more years of energy savings to pay back or may even lead to net cost, and this is accounted for in the overall LCC results. For renters, since they won't bear the first cost, it will more likely be economically beneficial (as discussed in section IV.I.1 of this document).

In the July 2023 NOPR, DOE did extensive revisions to its installation cost model to include installations of low-boy water heaters. DOE estimated around 10 percent of the total 20 to 55 gallon electric storage water heater market to be low boy water heaters. DOE assessed that many of these installations would require significant installation costs in order to install a heat pump water heater. DOE notes that at the proposed standard, most models currently serving the small electric water heater market will remain available.

A.O. Smith argued that retrofit costs associated with space-constrained installs are under-represented, especially for the lowboy electric resistance water heater to heat pump water heater transition. A.O. Smith also argued that undersizing an electric storage water heater (''ESWH'') and raising the temperature would not be possible in scenarios where a heat pump water heater would not fit in a confined space (which represents half of the modeled outcomes). A.O. Smith stated that while the difference in size for tall ESWH replacements is accounted for with a ~3 inch diameter increase, this same change is not accounted for in a substantial way for lowboys which present an even greater size constraint challenge. (A.O. Smith, No. 1182 at pp. 8–9) A.O. Smith pointed out that they could not find the referenced ''review of studies'' mentioned in Appendix 8D of the NOPR TSD which was supposed to include a literature review and a comparison of results of studies (related to lowboy costs) in response to previously submitted comments. (A.O. Smith, No. 1182 at p. 9) AHRI commented that DOE is not adequately considering the retrofit costs associated with space constrained retrofits. Specifically, DOE did not consider the added product and installation costs that would be faced by homeowners when replacing medium draw pattern lowboy or ''short'' electric resistance water heater with a heat pump water

heater. AHRI noted that consumers would not have the option to install an over-heated tank in lieu of facing space constrained scenarios as electric resistance storage water heaters with the capability of being overheated will not be permitted under the proposed energy conservation standard. AHRI stated that replacement of a lowboy with a heat pump would require the use of a more expensive split heat pump and would have additional installation costs. (AHRI, No. 1167 at p. 7)

DOE is aware of the challenges of replacing a low boy water heater with a heat pump water heater, especially in confined space and in small homes or manufactured homes. As discussed above and in the July 2023 NOPR, DOE applied significant installation cost adders to those installations to encompass the additional labor hour and materials needed to install such water heaters.

A.O. Smith argued that DOE did not fully account for the increased product and installation costs associated with split-system heat pump water heater designs that would be used to replace lowboy installations. A.O. Smith recommended that DOE incorporate higher product and installation costs associated with split designs for 13.7 percent of shipments in the medium electric storage water heater product class. (A.O. Smith, No. 1182 at p. 9) For this final rule DOE conducted further research on installing a heat pump water heater in a split system configuration. Currently there are not many models available for split system configuration and thus there are limited installation examples. DOE maintained its main analytical approach while adding a local installation cost sensitivity analysis for installing a split system heat pump water heater. Specifically, DOE modeled the cost line items needed for the installation of a 44-gallon low boy tank with a split heat pump module, which is a commonly used lowboy tank size for medium ESWHs. Appendix 8D of the final rule TSD provides more details on this sensitivity analysis. In summary, DOE found that the installation costs of a split system heat pump water heater are not necessarily higher than an integrated heat pump in a constrained space. Since DOE already applies a significant adder to the installation of an integrated heat pump water heater in these households, the overall average LCC savings would be more positive for the adopted heat pump level had DOE included this split heat pump option for medium electric storage water heaters in the main analysis. Even though the retail price for a split system heat pump water heater may be higher than an integrated heat pump, the lower installation cost for a split system heat pump water heater compared to an integrated heat pump water heater in a confined space and in small homes or manufactured homes is likely to result in an overall lower total installed cost. Should the market include more split heat pump models in the future, the likely cost impacts will decrease for consumers with water heaters in a confined space and in small homes or manufactured homes.

A.O. Smith argued that DOE's analysis assumed that all water heaters in manufactured homes are 30 gal and therefore did not account for the costs of these units transitioning to heat pump levels. A.O. Smith also pointed out that DOE acknowledges that 40 gal are also common standards for manufactured homes. (A.O. Smith, No. 1182 at p. 10) In response, DOE notes that the statement A.O. Smith was referencing was in a consultant report, where 30 gallon was only an example made to represent the cost breakdown of water heaters typically used in mobile homes. In DOE's actual analysis, different standard sizes were considered (see section IV.E.2 for more information).

Rheem found the reported installation costs for heat pump water heater to be lower than expected, but the incremental installation costs between EL 0 and EL 3 aligned with their internal installation cost data. Rheem noted that as operation at high tank temperatures is expected to be representative of electric resistance water heater operation, the installation of a mixing valve should be included in DOE's analysis. (Rheem, No. 1177 at p. 9) DOE has found that for some applications mixing valves are currently being used in order to have higher hot water temperature for dishwashers or clothes washers, to provide more hot water capacity, and to reduce bacterial growth, while making sure the delivered water is within a safe range.[76] Some water heaters have internal mixing valves that are meant to increase available hot water. In some cases, mixing valves could be used to address the increased hot water needs when the number of people in the household increases without replacing the entire water heater. DOE's updated test procedure includes a method to test water heaters in the highest storage tank temperature mode, which would be more representative for these types of installations (this is discussed more in section V.D.1). DOE's analysis in this final rule accounts for a fraction of installations that utilize a mixing valve.

[76] See *www.geappliances.com/appliance/GE-Smart-50-Gallon-Electric-Water-Heater-with-Flexible-Capacity-GE50S10BMM.*

3. Annual Energy Consumption

For each sampled household and building, DOE determined the energy consumption for consumer water heaters at different efficiency levels using the approach described previously in section IV.E of this document.

Higher-efficiency water heaters reduce the operating costs for a consumer, which can lead to greater use of the water heater. A direct rebound effect occurs when a product that is made more efficient is used more intensively, such that the expected energy savings from the efficiency improvement may not fully materialize. At the same time, consumers benefit from increased utilization of products due to rebound. Although some households may increase their water heater use in response to increased efficiency, DOE does not include the rebound effect in the LCC analysis because the increased utilization of the water heater provides value to the consumer. DOE does include rebound in the NIA for a conservative estimate of national energy savings and the corresponding impact to consumer NPV. See chapter 10 of the FR TSD for more details.

4. Energy Prices

Because marginal energy price more accurately captures the incremental savings associated with a change in energy use from higher efficiency, it provides a better representation of incremental change in consumer costs than average electricity prices. Therefore, DOE applied average energy prices for the energy use of the product purchased in the no-new-standards case, and marginal energy prices for the incremental change in energy use associated with the other efficiency levels considered.

DOE derived average monthly marginal residential and commercial electricity, natural gas, and LPG prices for each state using data from EIA.[77] [78] [79]

[77] U.S. Department of Energy-Energy Information Administration, Form EIA–861M (formerly EIA–826) detailed data (2022) (Available at: *www.eia.gov/electricity/data/eia861m/*) (Last accessed December 1, 2023).

[78] U.S. Department of Energy-Energy Information Administration, Natural Gas Navigator (2022) (Available at: *www.eia.gov/naturalgas/data.php*) (Last accessed December 1, 2023).

[79] U.S. Department of Energy-Energy Information Administration, State Energy Data System (''SEDS'') (2021) (Available at: *www.eia.gov/state/seds/*) (Last accessed December 1, 2023).

DOE calculated marginal monthly regional energy prices by: (1) first estimating an average annual price for each region; (2) multiplying by monthly energy price factors, and (3) multiplying by seasonal marginal price factors for electricity, natural gas, and LPG. The analysis used historical data up to 2022 for residential and commercial natural gas and electricity prices and historical data up to 2021 for LPG and fuel oil prices. Further details may be found in chapter 8 of the final rule TSD.

GAAS argued that DOE has not fully responded to their previous suggestion of using the CMER (Consumer Marginal Energy Rates) method for energy prices. (GAAS, No. 1139 at p. 1)

DOE has evaluated other estimates of marginal energy prices but maintains its approach in the final rule, since the data used to develop those prices are nationally representative. Stakeholders have previously proposed alternative methods and data to estimate marginal natural gas prices. However, DOE compared its seasonal marginal price factors developed from the EIA data to marginal price factors for 23 gas tariffs provided by the Gas Technology Institute for the 2016 residential boilers energy conservation standards rulemaking. DOE found that the winter price factors used by DOE are generally comparable to those computed from the tariff data, indicating that DOE's marginal price estimates are reasonable at average usage levels. The summer price factors are also generally comparable. Of the 23 tariffs analyzed, eight have multiple tiers, and of these eight, six have ascending rates and two have descending rates. The tariff-based marginal factors use an average of the two tiers as the commodity price. A full tariff-based analysis would require information about the household's total baseline gas usage (to establish which tier the consumer is in), and a weight factor for each tariff that determines how many customers are served by that utility on that tariff. These data are generally not available in the public domain. DOE's use of EIA State-level data effectively averages overall consumer sales in each State, and so incorporates information from all utilities. DOE's approach is, therefore, more representative of a large group of consumers with diverse baseline gas usage levels than an approach that uses only tariffs. DOE notes that within a State, there could be significant variation in the marginal price factors, including differences between rural and urban rates. In order to take this to account, DOE developed marginal price factors for each individual household using RECS 2015 billing data. These data are then normalized to match the average State marginal price factors, which are equivalent to a consumption-weighted average marginal price across all households in the State. DOE's methodology allows energy prices to vary by sector, region and season. For more details on the comparative analysis and marginal price analysis, see appendix 8E of the final rule TSD.

To estimate energy prices in future years, DOE multiplied the 2022 energy prices by the projection of annual average price changes for each of the 50 U.S. states and District of Columbia from the reference case in *AEO2023,* which has an end year of 2050.[80] To estimate price trends after 2050, DOE used the average annual growth rate in prices from 2046 to 2050 based on the methods used in the 2022 Life-Cycle Costing Manual for the Federal Energy Management Program (''FEMP'').[81]

AWHI suggested that the CA IOUs outline a price forecast scenario that more accurately accounts for future changes in energy costs. (AWHI, No. 1036 at p. 4) Gas Association Commenters argued that energy price assumptions from AEO are consistently overestimated and therefore should not be used (70% of the time was an overestimate for residential and 86% of the time was an overestimate for commercial sector between the 2010 and 2023 AEO projections). They argued that a distribution of prices should be used and not a forecasted mean. (Gas Association Commenters, No. 1181 at p. 34) Rinnai stated that DOE's average and marginal consumer energy price forecasts (from EIA) for electricity and gaseous fuels have historically overstated prices (particularly for natural gas). Rinnai stated that DOE should instead use energy prices employed in the Federal Trade Commission (''FTC'') Energy Guide labels because the uncertainty of applying forecasted prices shouldn't be primary drivers of LCC costs/savings and because FTC's use of AEO energy prices is audited annually and approved as published in the **Federal Register** prior to use for the EnergyGuide program. (Rinnai, No. 1186 at pp. 26–28) ONE Gas argued that consumer energy price forecasts from the *AEO* have been shown to be notoriously unreliable from forecasting year to forecasting year, and they systematically overpredict natural gas prices over time. (ONE Gas, No. 1200 at pp. 10–11) In response, DOE relies on AEO forecast for the energy price projection across appliance standards work as a cross-cutting methodology. Current energy prices are developed using other EIA data sources as described above. DOE acknowledges that it is difficult to project the future trend for any source given the uncertainty and unpredictability. However, AEO 2023 projects relatively flat energy price trends out to 2050 (see appendix 8E). AEO as issued by EIA remains the most comprehensive and trustworthy source and DOE maintains its methodology for this final rule. The energy prices developed for FTC are consistent with DOE's development of current energy prices (although here the analysis relies on marginal energy prices).

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product. Typically, small incremental increases in product efficiency produce no, or only minor, changes in repair and maintenance costs compared to baseline efficiency products. DOE included additional maintenance and repair costs for higher efficiency consumer water heaters (including maintenance costs associated with condensate withdrawal, heat pump component filter cleaning, and deliming of the heat exchanger and repair costs associated with electronic ignition, controls, and blowers for fan-assisted designs, compressor, evaporator fan) based on 2023 RSMeans data.[82] DOE accounted for regional differences in labor costs by using RSMeans regional cost factors.

Ravnitzky stated that non-heat pump water heaters are less likely to require maintenance or repair than heat pump water heaters because they have a less complex design with fewer moving parts. (Ravnitzky, No. 73 at p. 1) Essency argued that maintenance costs are underestimated for heat pump water heaters because the lifetime of some components in heat pump water heaters will require replacements of parts once the heater is out of warranty. (Essency, No. 1194 at p. 3) Rheem voiced support

[80] EIA. *Annual Energy Outlook 2023 with Projections to 2050.* Washington, DC. Available at *www.eia.gov/forecasts/aeo/* (last accessed December 1, 2023).

[81] Lavappa, Priya D. and J.D. Kneifel. Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis—2022 Annual Supplement to NIST Handbook 135. National Institute of Standards and Technology (NIST). NISTIR 85–3273–37, available at *www.nist.gov/publications/energy-price-indices-and-discount-factors-life-cycle-cost-analysis-2022-annual* (last accessed December 1, 2023).

[82] RSMeans Company, Inc., *RS Means Facilities Repair and Maintenance* (2023), available at *www.rsmeans.com/* (last accessed December 1, 2023).

for DOE's handling of operational and maintenance costs over the life of the water heater. (Rheem, No. 1177 at p. 9)

In response to Ravnitzky, research conducted by DOE has not shown that heat pump water heaters have different lifetimes than electric resistance storage water heaters. DOE has factored any additional maintenance or repair costs into the LCC. DOE takes into account replacement of certain parts after the warranty period. For the replacement of the heating element (which Essency provided as an example in its comment), the replacement cost is accounted for the fraction where it occurs and annualized across the years of use. The repair and maintenance cost summary in the final rule TSD represents the average cost with some households experiencing more or less than the reported value.

6. Product Lifetime

Product lifetime is the age at which an appliance is retired from service. DOE conducted an analysis of water heater lifetimes based on the methodology described in a journal paper.[83] For this analysis, DOE relied on RECS 1990, 1993, 2001, 2005, 2009, 2015, and 2020.[84] DOE also used the U.S. Census's biennial American Housing Survey (''AHS''), from 1974–2021, which surveys all housing, noting the presence of a range of appliances.[85] DOE used the appliance age data from these surveys, as well as the historical water heater shipments, to generate an estimate of the survival function. The survival function provides a lifetime range from minimum to maximum, as well as an average lifetime. DOE estimates the average product lifetime to be around 15 years for storage water heaters.

Stanonik argued that increased average lifetimes for consumer storage water heaters are calculated estimates rather than based on field data thus leading to overstatements of average lifetime. Stanonik also argued that the increased complexity of newer products realistically would result in shorter lifetimes and more scenarios where ''replace'' might be a cheaper alternative than ''repair,'' and that these scenarios are not reflected well in the analysis. (Stanonik, No. 1197 at p. 2) NMHC and NAA noted that AHRI assumes a 10–13 year lifespan for water heaters, which is less than DOE's estimated lifetime. (NMHC and NAA, No. 996 at p. 6) DOE has conducted an extensive literature review, including studies and surveys and warranty information, to determine its product lifetimes, as discussed in appendix 8G. DOE also utilizes Weibull distribution for the product lifetime to capture the field variations.

Noritz disputed that condensing and non-condensing products have the same average lifespan based on their internal testing. Noritz argued that the less complex nature of the non-condensing product in their testing typically lasts between 10 and 20 percent longer than a similar condensing product. Noritz argued that the analysis conducted by DOE that proposes the average lifespan of the two products to be identical will impact the LCC and payback analysis. (Noritz, No. 1202 at p. 3). In response, DOE has not found any evidence in its research pointing to a significantly different lifespan for the two types of water heaters. As described in appendix 8G, the data sources cited did not indicate any systematic decrease in lifetime for gas-fired condensing products. For this final rule, DOE maintains its methodology of assuming the same lifetime within product classes.

BWC noticed that the 2010 rulemaking reports an average lifetime of 13 years, rather than the assumed 15 years in the current rulemaking. BWC claimed that the lower product lifetime conclusions reached by DOE in the 2010 rulemaking appear to be more consistent with the evidence presented in the NOPR TSD. Specifically, in Figure 8G.4.6 in the TSD, the inflection points of the curves in this figure more closely align with the assumed product lifetimes established as part of DOE's 2010 rulemaking, and in the case of electric storage water heaters, indicate a product lifetime that is lower still. The assumed lifetime of 13 years for heat pump water heater products is also shared by the ENERGY STAR program in its materials that promote these products. BWC requested that DOE elaborate on the reason for an increase in product lifetimes from the assumptions deployed in the 2010 rulemaking to the longer product lifetimes assumed in the July 2023 NOPR. BWC also requested that DOE explain the apparent discrepancies between the graphic demonstration of product lifetimes in 8G.4.6 and those expressed in Table 8G.4.1. (BWC, No. 1164 at pp. 3–4)

From the 2010 Final Rule to this rulemaking, DOE was able to collect more evidence from literature review on product lifetime as well as develop a more robust survival function to calculate the lifetimes. Regarding the figure in the NOPR TSD, the inflection point represents the lifetime most water heaters will live to, whereas the average takes into account those who live an unusually short or long lifetime. The lifetime distribution in this rulemaking, compared to that of the 2010 rulemaking, has an early start, taking into account those that retire starting from year two, and a longer tail, allowing some water heaters to survive much longer than average. DOE believes that it is beneficial to capture the variations in lifetime and thus maintain its methodology in this final rule.

BWC expressed support for DOE conducting a sensitivity analysis for all water heater product classes, as they claimed this is an effective way for this rulemaking to account for the reality that product lifetimes are not constant across efficiency levels and decrease with increased efficiency and complexity of a system. (BWC, No. 1164 at p. 4) In order to evaluate the impact of the lifetime on the economic analysis results, for this final rule DOE conducted a sensitivity analysis, where two additional lifetime scenarios were evaluated. The sensitivity results do not change DOE's conclusion of economic justification of the adopted standards (see appendix 8G of the final rule TSD for the comparison of results).

7. Discount Rates

In the calculation of LCC, DOE applies discount rates appropriate to households to estimate the present value of future operating cost savings. DOE estimated a distribution of discount rates for consumer water heaters based on the opportunity cost of consumer funds.

DOE applies weighted average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates.[86] The LCC

[83] Lutz, J., A. Hopkins, V. Letschert, V. Franco, and A. Sturges, Using national survey data to estimate lifetimes of residential appliances, *HVAC&R Research* (2011) 17(5): pp. 28 (Available at: *www.tandfonline.com/doi/abs/10.1080/10789669.2011.558166*) (Last accessed December 1, 2023).

[84] U.S. Department of Energy: Energy Information Administration, *Residential Energy Consumption Survey (''RECS'')*, Multiple Years (1990, 1993, 1997, 2001, 2005, 2009, 2015, and 2020) (Available at: *www.eia.gov/consumption/residential/*) (Last accessed December 1, 2023).

[85] U.S. Census Bureau: Housing and Household Economic Statistics Division, *American Housing Survey,* Multiple Years (1974, 1975, 1976, 1977, 1978, 1979, 1980, 1981, 1983, 1985, 1987, 1989, 1991, 1993, 1995, 1997, 1999, 2001, 2003, 2005, 2007, 2009, 2011, 2013, 2015, 2017, 2019, and 2021) (Available at: *www.census.gov/programs-surveys/ahs/*) (Last accessed December 1, 2023).

[86] The implicit discount rate is inferred from a consumer purchase decision between two otherwise identical goods with different first cost and operating cost. It is the interest rate that equates the increment of first cost to the difference in net present value of lifetime operating cost, incorporating the influence of several factors: transaction costs; risk premiums and response to uncertainty; time preferences; interest rates at which a consumer is able to borrow or lend. The

Continued

analysis estimates net present value over the lifetime of the product, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long time horizon modeled in the LCC analysis, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's triennial Survey of Consumer Finances [87] (''SCF'') starting in 1995 and ending in 2019. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and equity and income groups, weighted by market share of each product class, is 4.2 percent. See chapter 8 of the final rule TSD for further details on the development of consumer discount rates.

To establish commercial discount rates for the small fraction of consumer water heaters installed in commercial buildings, DOE estimated the weighted-average cost of capital using data from Damodaran Online.[88] The weighted-average cost of capital is commonly used to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so their cost of capital is the weighted average of the cost to the firm of equity and debt financing. DOE estimated the cost of equity using the capital asset pricing model, which assumes that the cost of equity for a particular company is proportional to the systematic risk faced by that company. DOE's commercial discount rate approach is based on the methodology described in a Lawrence Berkeley National Laboratory report, and the distribution varies by business activity.[89] The average rate for consumer water heaters used in commercial applications in this final rule analysis, across all business activity and weighted by the market share of each product class, is 6.9 percent.

See chapter 8 of this final rule TSD for further details on the development of consumer and commercial discount rates.

8. Energy Efficiency Distribution in the No-New-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies under the no-new-standards case (*i.e.,* the case without amended or new energy conservation standards). This approach reflects the fact that some consumers may purchase products with efficiencies greater than the baseline levels.

To estimate the energy efficiency distribution of consumer water heaters for 2030, DOE used available shipments data by efficiency including in previous AHRI submitted historical shipment data,[90] ENERGY STAR unit shipments data,[91] and data from a 2023 BRG Building Solutions report. [92] To cover gaps in the available shipments data, DOE used DOE's public CCD model database [93] and AHRI certification directory.[94]

The estimated market shares for the no-new-standards case for consumer water heaters are shown in Table IV.26. See chapter 8 of the final rule TSD for further information on the derivation of the efficiency distributions.

BILLING CODE 6450–01–P

implicit discount rate is not appropriate for the LCC analysis because it reflects a range of factors that influence consumer purchase decisions, rather than the opportunity cost of the funds that are used in purchases.

[87] The Federal Reserve Board, *Survey of Consumer Finances* (1995, 1998, 2001, 2004, 2007, 2010, 2013, 2016, and 2019) (Available at: *www.federalreserve.gov/econres/scfindex.htm*) (last accessed Dec. 1, 2023). The Federal Reserve Board is currently processing the 2022 Survey of Consumer Finances, which is expected to be fully available in late 2023.

[88] Damodaran Online, Data Page: Costs of Capital by Industry Sector (2021) (Available at: *pages.stern.nyu.edu/~adamodar/*) (Last accessed December 1, 2023).

[89] Fujita, S., Commercial, Industrial, and Institutional Discount Rate Estimation for Efficiency Standards Analysis: Sector-Level Data 1998—2018 (Available at: *ees.lbl.gov/publications/commercial-industrial-and*) (Last accessed December 1, 2023).

[90] AHRI. Gas-fired and Electric Storage Water Heater Shipments Data to DOE. March 11, 2008; AHRI. Gas-fired Storage Heater Shipments Data to DOE. March 18, 2009.

[91] ENERGY STAR. Unit Shipments data 2010–2021. multiple reports. (Available at: *www.energystar.gov/partner_resources/products_partner_resources/brand_owner_resources/unit_shipment_data*) (Last accessed December 1, 2023).

[92] BRG Building Solutions. The North American Heating & Cooling Product Markets (2023 Edition). 2023.

[93] U.S. Department of Energy's Compliance Certification Database is available at *regulations.doe.gov/certification-data* (last accessed Dec. 1, 2023).

[94] Air Conditioning Heating and Refrigeration Institute. Consumer's Directory of Certified Efficiency Ratings for Heating and Water Heating Equipment. May 16, 2023. (Available at *www.ahridirectory.org*) (Last accessed December 1, 2023).

Table IV.26 No-New-Standards Case Energy Efficiency Distributions in 2030 for Consumer Water Heaters

Efficiency Level	Draw Pattern					
	Low		Medium		High	
	UEF*	Market Share *(%)*	UEF*	Market Share *(%)*	UEF*	Market Share *(%)*
Gas-Fired Storage Water Heaters, ≥20 gal and ≤55 gal						
0	0.54	52%	0.58	57%	0.63	56%
1	0.57	25%	0.60	22%	0.64	22%
2	0.59	4%	0.64	5%	0.68	5%
3	0.60	19%	0.65	14%	0.69	15%
4	0.71	0%	0.75	1%	0.80	1%
5	0.77	0%	0.81	1%	0.88	1%
Oil-Fired Storage Water Heaters, ≤50 gal						
0					0.64	67%
1					0.66	17%
2					0.68	17%
Small Electric Storage Water Heaters, ≥20 gal and ≤35 gal and FHR < 51 gal						
0	0.91/0.92**	99.0				
1	2.00	1.0				
Electric Storage Water Heaters, ≥20 gal and ≤55 gal, excluding Small ESWHs						
0	0.91	88%	0.92	88%	0.93	84%
1	2.30	1%	2.30	1%	2.30	1%
2	3.29	8%	3.35	7%	3.47	10%
3	3.69	3%	3.75	4%	3.87	5%
Electric Storage Water Heaters, >55 gal and ≤120 gal						
0			2.05	4%	2.15	4%
1			2.50	11%	2.50	12%
2			3.35	75%	3.45	74%
3			3.90	10%	4.00	11%

* UEF at the representative rated capacity.

** 0.91 UEF at 30 gallon effective storage volume and 0.92 UEF at 35 gallon effective storage volume.

BILLING CODE 6450–01–C

The LCC Monte Carlo simulations draw from the efficiency distributions and assign an efficiency to the water heater purchased by each sample household in the no-new-standards case according to these distributions.

Finally, DOE considered the 2019 AHCS survey,[95] which includes questions to recent purchasers of HVAC equipment regarding the perceived efficiency of their equipment (Standard, High, and Super High Efficiency), as well as questions related to various household and demographic characteristics. DOE did not find similar data for consumer water heaters, but believes that the HVAC data is relevant to other larger appliances such as consumer water heaters since they similarly represent large energy end uses. From these data, DOE found that households with larger square footage exhibited a higher fraction of High- or Super-High efficiency equipment installed. The fraction of respondents with ''super high efficiency'' equipment was larger by approximately 5 percent for larger households and correspondingly smaller for smaller households. DOE therefore used the AHCS data to adjust its water heater efficiency distributions as follows: (1) the market share of higher efficiency equipment for households under 1,500 sq. ft. was decreased by 5 percentage points; and (2) the market share of condensing equipment for households above 2,500 sq. ft. was increased by 5 percentage points.

DOE acknowledges that economic factors may play a role when consumers, commercial building owners, or builders decide on what type of water heater to install. However, assignment of water heater efficiency for a given installation based solely on economic measures such as life-cycle cost or simple payback period most likely would not fully and accurately reflect actual real-world installations. There are a number of market failures discussed in the economics literature that illustrate how purchasing decisions with respect to energy efficiency are unlikely to be perfectly correlated with energy use, as described below. While this literature is not specific to water heaters, DOE finds that the method of assignment, which is in part random, simulates behavior in the water heater market, where market failures and other consumer preferences result in purchasing decisions not being perfectly aligned with economic interests, more realistically than relying only on apparent cost-effectiveness criteria derived from the limited information in CBECS or RECS. DOE further emphasizes that its approach does not assume that all purchasers of water

[95] Decision Analysts, 2019 American Home Comfort Studies (Available at: *www.decisionanalyst.com/Syndicated/HomeComfort/*) (Last accessed January 5, 2024).

heaters make economically irrational decisions (*i.e.,* the lack of a correlation is not the same as a negative correlation). As part of the random assignment, some homes or buildings with large hot water use will be assigned higher efficiency water heaters, and some homes or buildings with particularly low hot water use will be assigned baseline water heaters. By using this approach, DOE acknowledges the variety of market failures and other consumer behaviors present in the water heater market, and does not assume certain market conditions unsupported by the available evidence.

First, consumers are motivated by more than simple financial trade-offs. There are consumers who are willing to pay a premium for more energy-efficient products because they are environmentally conscious.[96] There are also several behavioral factors that can influence the purchasing decisions of complicated multi-attribute products, such as water heaters. For example, consumers (or decision makers in an organization) are highly influenced by choice architecture, defined as the framing of the decision, the surrounding circumstances of the purchase, the alternatives available, and how they're presented for any given choice scenario.[97] The same consumer or decision maker may make different choices depending on the characteristics of the decision context (*e.g.,* the timing of the purchase, competing demands for funds), which have nothing to do with the characteristics of the alternatives themselves or their prices. Consumers or decision makers also face a variety of other behavioral phenomena including loss aversion, sensitivity to information salience, and other forms of bounded rationality.[98] R.H. Thaler, who won the Nobel Prize in Economics in 2017 for his contributions to behavioral economics, and Sunstein point out that these behavioral factors are strongest when the decisions are complex and infrequent, when feedback on the decision is muted and slow, and when there is a high degree of information asymmetry.[99] These characteristics describe almost all purchasing situations of appliances and equipment, including water heaters. The installation of a new or replacement water heater is done infrequently, as evidenced by the mean lifetime for water heaters. Additionally, it would take at least one full water heating season for any impacts on operating costs to be fully apparent. Further, if the purchaser of the water heater is not the entity paying the energy costs (*e.g.,* a building owner and tenant), there may be little to no feedback on the purchase. Additionally, there are systematic market failures that are likely to contribute further complexity to how products are chosen by consumers, as explained in the following paragraphs.

The first of these market failures—the split-incentive or principal-agent problem—is likely to affect water heaters more than many other types of appliances. The principal-agent problem is a market failure that results when the consumer that purchases the equipment does not internalize all of the costs associated with operating the equipment. Instead, the user of the product, who has no control over the purchase decision, pays the operating costs. There is a high likelihood of split incentive problems in the case of rental properties where the landlord makes the choice of what water heater to install, whereas the renter is responsible for paying energy bills. In the LCC sample, a significant fraction of households with a water heater are renters. For example, for the medium electric storage water heaters LCC sample, nearly 30 percent of households are renters, whereas for the small electric storage water heater LCC sample, nearly 50 percent of households are renters. These fractions are significantly higher for low-income households (see section IV.I of this document and chapter 11 of the final rule TSD). The principle-agent problem can also impact homeowners. For example, in new construction, builders influence the type of water heater used in many homes but do not pay operating costs. Finally, contractors install a large share of water heaters in replacement situations, and they can exert a high degree of influence over the type of water heater purchased based on which products they are familiar with.

In addition to the split-incentive problem, there are other market failures that are likely to affect the choice of water heater efficiency made by consumers. For example, emergency replacements of essential equipment such as water heaters are strongly biased toward like-for-like replacement (*i.e.,* replacing the non-functioning equipment with a similar or identical product). Time is a constraining factor during emergency replacements and it may not be possible to consider the full range of available options on the market. The consideration of alternative product options is far more likely for planned replacements and installations in new construction.

Additionally, Davis and Metcalf[100] conducted an experiment demonstrating that the nature of the information available to consumers from EnergyGuide labels posted on air conditioning equipment results in an inefficient allocation of energy efficiency across households with different usage levels. Their findings indicate that households are likely to make decisions regarding the efficiency of the climate control equipment of their homes that do not result in the highest net present value for their specific usage pattern (*i.e.,* their decision is based on imperfect information and, therefore, is not necessarily optimal).

In part because of the way information is presented, and in part because of the way consumers process information, there is also a market failure consisting of a systematic bias in the perception of equipment energy usage, which can affect consumer choices. Attari, et al.[101] show that consumers tend to underestimate the energy use of large energy-intensive appliances but overestimate the energy use of small appliances. Water heaters are one of the largest energy-consuming end-uses in a home. Therefore, it is likely that consumers systematically underestimate the energy use associated with water heater, resulting in less cost-effective water heater purchases.

These market failures may affect a sizeable share of the consumer population. A study by Houde[102]

[96] Ward, D.O., Clark, C.D., Jensen, K.L., Yen, S.T., & Russell, C.S. (2011): ''Factors influencing willingness-to pay for the ENERGY STAR® label,'' *Energy Policy, 39*(3), 1450–1458. (Available at: w*ww.sciencedirect.com/science/article/abs/pii/S0301421510009171*) (Last accessed January 5, 2024).

[97] Thaler, R.H., Sunstein, C.R., and Balz, J.P. (2014). ''Choice Architecture'' in *The Behavioral Foundations of Public Policy,* Eldar Shafir (ed).

[98] Thaler, R.H., and Bernartzi, S. (2004). ''Save More Tomorrow: Using Behavioral Economics in Increase Employee Savings,'' *Journal of Political Economy* 112(1), S164–S187. *See also* Klemick, H., et al. (2015) ''Heavy-Duty Trucking and the Energy Efficiency Paradox: Evidence from Focus Groups and Interviews,'' *Transportation Research Part A: Policy & Practice,* 77, 154–166. (providing evidence that loss aversion and other market failures can affect otherwise profit-maximizing firms).

[99] Thaler, R.H., and Sunstein, C.R. (2008). Nudge: Improving Decisions on Health, Wealth, and Happiness. New Haven, CT: Yale University Press.

[100] Davis, L.W., and G.E. Metcalf (2016): ''Does better information lead to better choices? Evidence from energy-efficiency labels,'' *Journal of the Association of Environmental and Resource Economists,* 3(3), 589–625. (Available at: *www.journals.uchicago.edu/doi/full/10.1086/686252*) (Last accessed January 5, 2024).

[101] Attari, S.Z., M.L. DeKay, C.I. Davidson, and W. Bruine de Bruin (2010): ''Public perceptions of energy consumption and savings.'' *Proceedings of the National Academy of Sciences* 107(37), 16054–16059 (Available at: *www.pnas.org/content/107/37/16054*) (Last accessed January 5, 2024).

[102] Houde, S. (2018): ''How Consumers Respond to Environmental Certification and the Value of Energy Information,'' *The RAND Journal of Economics,* 49 (2), 453–477 (Available at:

indicates that there is a significant subset of consumers that appear to purchase appliances without taking into account their energy efficiency and operating costs at all, though subsequent studies using alternative methodologies have highlighted other consumer groups who are to some extent responsive to local energy prices with their appliance purchases.[103] The extent to which consumers are perceptive of energy prices and product efficiency when making appliance purchasing decisions is a topic of ongoing research.

Although consumer water heaters are predominantly installed in the residential sector, some are also installed in commercial buildings (less than 10 percent of projected shipments; see chapter 9 of the final rule TSD). There are market failures relevant to consumer water heaters installed in commercial applications as well. It is often assumed that because commercial and industrial customers are businesses that have trained or experienced individuals making decisions regarding investments in cost-saving measures, some of the commonly observed market failures present in the general population of residential customers should not be as prevalent in a commercial setting. However, there are many characteristics of organizational structure and historic circumstance in commercial settings that can lead to underinvestment in energy efficiency.

First, a recognized problem in commercial settings is the principal-agent problem, where the building owner (or building developer) selects the equipment and the tenant (or subsequent building owner) pays for energy costs.[104] [105] Indeed, more than a quarter of commercial buildings in the CBECS 2018 sample are occupied at least in part by a tenant, not the building owner (indicating that, in DOE's experience, the building owner in some cases is not responsible for paying energy costs). Additionally, some commercial buildings have multiple tenants. There are other similar misaligned incentives embedded in the organizational structure within a given firm or business that can impact the choice of a water heater. For example, if one department or individual within an organization is responsible for capital expenditures (and therefore equipment selection) while a separate department or individual is responsible for paying the energy bills, a market failure similar to the principal-agent problem can result.[106] Additionally, managers may have other responsibilities and often have other incentives besides operating cost minimization, such as satisfying shareholder expectations, which can sometimes be focused on short-term returns.[107] Decision-making related to commercial buildings is highly complex and involves gathering information from and for a variety of different market actors. It is common to see conflicting goals across various actors within the same organization as well as information asymmetries between market actors in the energy efficiency context in commercial building construction.[108]

Second, the nature of the organizational structure and design can influence priorities for capital budgeting, resulting in choices that do not necessarily maximize profitability.[109] Even factors as simple as unmotivated staff or lack of priority-setting and/or a lack of a long-term energy strategy can have a sizable effect on the likelihood that an energy efficient investment will be undertaken.[110] U.S. tax rules for commercial buildings may incentivize lower capital expenditures, since capital costs must be depreciated over many years, whereas operating costs can be fully deducted from taxable income or passed through directly to building tenants.[111]

onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12231) (Last accessed January 5, 2024).

[103] Houde, S. and Meyers, E. (2021). ''Are consumers attentive to local energy costs? Evidence from the appliance market,'' Journal of Public Economics, 2011 (Available at: *sciencedirect.com/science/article/pii/S004727272100116X*) (Last accessed March 7, 2024).

[104] Vernon, D., and Meier, A. (2012). ''Identification and quantification of principal—agent problems affecting energy efficiency investments and use decisions in the trucking industry,'' *Energy Policy,* 49, 266–273.

[105] Blum, H. and Sathaye, J. (2010). ''Quantitative Analysis of the Principal-Agent Problem in Commercial Buildings in the U.S.: Focus on Central Space Heating and Cooling,'' Lawrence Berkeley National Laboratory, LBNL–3557E. (Available at: *escholarship.org/uc/item/6p1525mg*) (Last accessed January 5, 2024).

[106] Prindle, B., Sathaye, J., Murtishaw, S., Crossley, D., Watt, G., Hughes, J., and de Visser, E. (2007). ''Quantifying the effects of market failures in the end-use of energy,'' Final Draft Report Prepared for International Energy Agency. (Available from International Energy Agency, Head of Publications Service, 9 rue de la Federation, 75739 Paris, Cedex 15 France).

[107] Bushee, B.J. (1998). ''The influence of institutional investors on myopic R&D investment behavior,'' *Accounting Review,* 305–333. DeCanio, S.J. (1993). ''Barriers Within Firms to Energy Efficient Investments,'' *Energy Policy,* 21(9), 906–914. (explaining the connection between short-termism and underinvestment in energy efficiency).

[108] International Energy Agency (IEA). (2007). Mind the Gap: Quantifying Principal-Agent Problems in Energy Efficiency. OECD Pub. (Available at: *www.iea.org/reports/mind-the-gap*) (Last accessed January 5, 2024).

[109] DeCanio, S.J. (1994). ''Agency and control problems in US corporations: the case of energy-efficient investment projects,'' *Journal of the Economics of Business,* 1(1), 105–124.

Stole, L.A., and Zwiebel, J. (1996). ''Organizational design and technology choice under intrafirm bargaining,'' *The American Economic Review,* 195–222.

[110] Rohdin, P., and Thollander, P. (2006). ''Barriers to and driving forces for energy efficiency in the non-energy intensive manufacturing industry in Sweden,'' *Energy,* 31(12), 1836–1844.

Takahashi, M and Asano, H (2007). ''Energy Use Affected by Principal-Agent Problem in Japanese Commercial Office Space Leasing,'' In *Quantifying the Effects of Market Failures in the End-Use of Energy.* American Council for an Energy-Efficient Economy. February 2007.

Visser, E and Harmelink, M (2007). ''The Case of Energy Use in Commercial Offices in the Netherlands,'' In *Quantifying the Effects of Market Failures in the End-Use of Energy.* American Council for an Energy-Efficient Economy. February 2007.

Bjorndalen, J. and Bugge, J. (2007). ''Market Barriers Related to Commercial Office Space Leasing in Norway,'' In *Quantifying the Effects of Market Failures in the End-Use of Energy.* American Council for an Energy-Efficient Economy. February 2007.

Schleich, J. (2009). ''Barriers to energy efficiency: A comparison across the German commercial and services sector,'' *Ecological Economics,* 68(7), 2150–2159.

Muthulingam, S., et al. (2013). ''Energy Efficiency in Small and Medium-Sized Manufacturing Firms,'' *Manufacturing & Service Operations Management,* 15(4), 596–612. (Finding that manager inattention contributed to the non-adoption of energy efficiency initiatives).

Boyd, G.A., Curtis, E.M. (2014). ''Evidence of an 'energy management gap' in US manufacturing: Spillovers from firm management practices to energy efficiency,'' *Journal of Environmental Economics and Management,* 68(3), 463–479.

[111] Lovins, A. (1992). Energy-Efficient Buildings: Institutional Barriers and Opportunities. (Available at: *rmi.org/insight/energy-efficient-buildings-institutional-barriers-and-opportunities/*) (Last accessed January 5, 2024).

Third, there are asymmetric information and other potential market failures in financial markets in general, which can affect decisions by firms with regard to their choice among alternative investment options, with energy efficiency being one such option.[112] Asymmetric information in financial markets is particularly pronounced with regard to energy efficiency investments.[113] There is a dearth of information about risk and volatility related to energy efficiency investments, and energy efficiency investment metrics may not be as visible to investment managers,[114] which can bias firms towards more certain or familiar options. This market failure results not because the returns from energy efficiency as an investment are inherently riskier, but because information about the risk itself tends not to be available in the same way it is for other types of investment, like stocks or bonds. In some cases energy efficiency is not a formal investment category used by financial managers, and if there is a formal category for energy efficiency within the investment portfolio options assessed by financial managers, they are seen as weakly strategic and not seen as likely to increase competitive advantage.[115] This information asymmetry extends to commercial investors, lenders, and real-estate financing, which is biased against new and perhaps unfamiliar technology (even though it may be economically beneficial).[116] Another market failure known as the first-mover disadvantage can exacerbate this bias against adopting new technologies, as the successful integration of new technology in a particular context by one actor generates information about cost-savings, and other actors in the market can then benefit from that information by following suit; yet because the first to adopt a new technology bears the risk but cannot keep to themselves all the informational benefits, firms may inefficiently underinvest in new technologies.[117]

In sum, the commercial and industrial sectors face many market failures that can result in an under-investment in energy efficiency. This means that discount rates implied by hurdle rates [118] and required payback periods of many firms are higher than the appropriate cost of capital for the investment.[119] The preceding arguments for the existence of market failures in the commercial and industrial sectors are corroborated by empirical evidence. One study in particular showed evidence of substantial gains in energy efficiency that could have been achieved without negative repercussions on profitability, but the investments had not been undertaken by firms.[120] The study found that multiple organizational and institutional factors caused firms to require shorter payback periods and higher returns than the cost of capital for alternative investments of similar risk. Another study demonstrated similar results with firms requiring very short payback periods of 1–2 years in order to adopt energy-saving projects, implying hurdle rates of 50 to 100 percent, despite the potential economic benefits.[121] A number of other case studies similarly demonstrate the existence of market failures preventing the adoption of energy-efficient technologies in a variety of commercial sectors around the world, including office buildings,[122] supermarkets,[123] and the electric motor market.[124]

The existence of market failures in the residential and commercial sectors is well supported by the economics literature and by a number of case studies. Although these studies are not specifically targeted to the water heater market, they cover decision-making generally and the impact of energy efficiency, operating costs, and future savings/expenditures on those decisions, all of which apply to the purchase of a consumer water heater. DOE is not aware of any market failure studies specifically and narrowly focused on water heaters and so relies on the available literature discussed above. If DOE developed an efficiency distribution that assigned water heater efficiency in the no-new-standards case solely according to energy use or economic considerations such as life-cycle cost or payback period, the resulting distribution of efficiencies within the building sample would not reflect any of the market failures or behavioral factors above. DOE thus concludes such a distribution would not be representative of the water heater market.

DOE further notes that, in the case of gas-fired storage, oil-fired storage, and electric storage water heaters (≤55 gal), the distribution of efficiency in the current market is heavily weighted toward baseline efficiency or efficiency at EL 1. Accordingly, in the no new-standards case, most consumers are assigned EL 0 or EL 1 in accordance with the market data. As a result, any variation to DOE's efficiency assignment methodology will not produce substantially differing results than presented in this final rule, as most consumers will continue to be assigned the same efficiency regardless of the details of the methodology. In other words, as most consumers in the storage water heater market are choosing baseline or near-baseline efficiency products, there would be no significant difference between a random

[113] Mills, E., Kromer, S., Weiss, G., and Mathew, P. A. (2006). ''From volatility to value: analysing and managing financial and performance risk in energy savings projects,'' *Energy Policy,* 34(2), 188–199.

Jollands, N., Waide, P., Ellis, M., Onoda, T., Laustsen, J., Tanaka, K., and Meier, A. (2010). ''The 25 IEA energy efficiency policy recommendations to the G8 Gleneagles Plan of Action,'' *Energy Policy,* 38(11), 6409–6418.

[114] Reed, J.H., Johnson, K., Riggert, J., and Oh, A. D. (2004). ''Who plays and who decides: The structure and operation of the commercial building market,'' U.S. Department of Energy Office of Building Technology, State and Community Programs. (Available at: *www1.eere.energy.gov/buildings/publications/pdfs/commercial_initiative/who_plays_who_decides.pdf*) (Last accessed January 5, 2024).

[115] Cooremans, C. (2012). ''Investment in energy efficiency: do the characteristics of investments matter?'' *Energy Efficiency,* 5(4), 497–518.

[116] Lovins 1992, op. cit. The Atmospheric Fund. (2017). Money on the table: Why investors miss out on the energy efficiency market. (Available at: *taf.ca/publications/money-table-investors-energy-efficiency-market/*) (Last accessed January 5, 2024).

[117] Blumstein, C. and Taylor, M. (2013). Rethinking the Energy-Efficiency Gap: Producers, Intermediaries, and Innovation. Energy Institute at Haas Working Paper 243. (Available at: *haas.berkeley.edu/wp-content/uploads/WP243.pdf*) (Last accessed January 5, 2024).

[118] A hurdle rate is the minimum rate of return on a project or investment required by an organization or investor. It is determined by assessing capital costs, operating costs, and an estimate of risks and opportunities.

[119] DeCanio 1994, op. cit.

[120] DeCanio, S.J. (1998). ''The Efficiency Paradox: Bureaucratic and Organizational Barriers to Profitable Energy-Saving Investments,'' *Energy Policy,* 26(5), 441–454.

[121] Andersen, S.T., and Newell, R.G. (2004). ''Information programs for technology adoption: the case of energy-efficiency audits,'' *Resource and Energy Economics,* 26, 27–50.

[122] Prindle 2007, op. cit. Howarth, R.B., Haddad, B.M., and Paton, B. (2000). ''The economics of energy efficiency: insights from voluntary participation programs,'' *Energy Policy,* 28, 477–486.

[123] Klemick, H., Kopits, E., Wolverton, A. (2017). ''Potential Barriers to Improving Energy Efficiency in Commercial Buildings: The Case of Supermarket Refrigeration,'' *Journal of Benefit-Cost Analysis,* 8(1), 115–145.

[124] de Almeida, E.L.F. (1998). ''Energy efficiency and the limits of market forces: The example of the electric motor market in France'', *Energy Policy,* 26(8), 643–653. Xenergy, Inc. (1998). United States Industrial Electric Motor Systems Market Opportunity Assessment. (Available at: *www.energy.gov/sites/default/files/2014/04/f15/mtrmkt.pdf*) (Last accessed January 5, 2024).

assignment of those efficiency levels to consumers as to another type of assignment methodology such as one that tried to consider consumer rationality more explicitly—in either case nearly every individual consumer would be assigned a baseline or near-baseline efficiency product. This may be in contrast to a product with a broad distribution of efficiency levels purchased in the market, where changing the assignment methodology could more significantly impact the assignment of an efficiency level to individual consumers and therefore impact the results.

Gas Association Commenters and Atmos Energy argued that random assignment methodology is unreasonable because it overstates standards-compliant outcomes in the base case by capturing decisions that consumers would naturally choose on their own for economically beneficial reasons and it understates outcomes in the rule case by disproportionately including unattractive economic outcomes. Gas Association Commenters argued that consumer economic preference is not accounted for in random assignments, and argued that consumer choice models, which were used for fuel switching scenarios in gas furnaces, should be used in water heaters. Gas Association Commenters argued that random assignment creates extreme examples of economic benefits and consequences that heavily skew averages and are the least realistic outcomes as they would be the most obvious economic consumer choice. Gas Association Commenters argued that DOE has cases in their analysis where a standards-compliant product is the cheapest option but because of random assignment, a less-efficient, more expensive option is initially assigned, skewing benefits for rule scenarios. In its comment, Gas Association Commenters proposed alternatives to random assignment. (Gas Association Commenters, No. 1181 at p. 10 and pp. 11–23; Atmos Energy, No. 1183 at pp. 6–7) Rinnai argued that DOE has not yet addressed the central criticism of the random assignment of base case efficiencies which is that DOE has not justified through either correlation or causation of random assignment to the alleged market failures it represents. Rinnai argued that there are many better alternate approaches to solving market failures beyond appliance standards. Rinnai argued that base case random assignment implies that consumers only make rational economic decisions in rulemaking scenarios. Rinnai argued many of the same points made in other comments already mentioned in this document; namely: consumers in base case choosing worse efficiency products even when doing so is more expensive; highly favorable economic outcomes that skew results; base case irrationality versus rulemaking case rational economic decision making. (Rinnai, No. 1186 at pp. 31–33)

ONE Gas argued that in its comments that past issues of random assignment of consumers to appliance purchase decisions in the base case life cycle cost analysis has been an enduringly contentious issue with the Department's TSD approach, and the Department appears to have not undertaken measures to address stakeholder concerns of that kind. ONE Gas noted that more detailed review of this issue by industry stakeholders is ongoing. ONE Gas argued that the Department has never presented analysis that justifies linkages between market failure and random purchase behavior and no evidence is provided in the Preliminary Analysis TSD document that the Department has included additional consideration of NASEM peer review recommendation that calls on the Department to improve its coverage of market failure in relation to the setting of appliance minimum efficiency standards. ONE Gas proposed to the Department that it use alternative means of defining consumer base case efficiencies based upon one of two of the following base case definition strategies for consumer simulations: correlated consumer attributes approach or rational consumer economic choice approach. (ONE Gas, No. 1200 at pp. 11–12) NPGA, APGA, AGA, and Rinnai noted that DOE's response to comments on its failing to address consumer choice and to account for consumers making choices based on rational economic terms in the July 2023 NOPR is arbitrary, capricious, and without foundation. NPGA, APGA, AGA, and Rinnai commented that instead of referencing actual interviews or studies, DOE pivoted to a ''cherry-picked'' library of behavioral economics papers that have no bearing or relevance to water heaters or the proposed rule. (NPGA, APGA, AGA, and Rinnai, No. 441 at p. 4) AHRI recommended that DOE provide a theory of market performance tailored to the specific situation for each and every rulemaking. AHRI commented that DOE should build an analytical approach that reflects some degree of market efficiency, rather than assuming complete market efficiency. AHRI acknowledges that this may necessitate a rethinking of the Monte Carlo method and the assignment of base and standard case efficiencies. (AHRI, No. 1167 at p. 17) AHRI highlighted that AHRI demonstrated there are ways to use the current Monte Carlo approach to generate results and then use alternative ranking systems to assign base and standards case efficiencies. (AHRI, No. 1167 at p. 18) AHRI commented that DOE misunderstands the role of plumbing contractors in the decision process and DOE implies that the influence of plumbing contractors on water heater type purchased in the replacement scenario is a form of market failure. AHRI claimed this is incorrect as contractors serve as the information mediators to overcome one of the key sources of possible market failure identified by DOE—the absence of knowledge from consumers who rarely purchase water heaters. (AHRI, No. 1167 at p. 18) AHRI posed the following questions for DOE related to market failure: ''Why has DOE not adopted the National Academies of Sciences (NAS) peer review recommendations and when will it do so? On what basis has DOE determined that there are significant market failures for residential water heaters, how prevalent are these failures and do standards address them? How will DOE modify its random assignment approach to be more responsive to actual market conditions? '' (AHRI, No. 1167 at p. 18) Gas Association Commenters argued the tab ''No-New Standards Case UEF'' of the analysis tool incorrectly states an equation (relative to the coded version) for how square footage of residences impacts likelihood of efficiency of products. (Gas Association Commenters, No. 1181 at p. 35) Gas Association Commenters argued that adjustment factors used based on square footage do not make sense for this analysis and instead size of household should be used. (Gas Association Commenters, No. 1181 at p. 35) Gas Association Commenters argued that estimated fractions of shipments by market shares do not exactly match the stated distributions (see specifics in comment). (Gas Association Commenters, No. 1181 at p. 35) ONE Gas commented that, unlike many other products covered by EPCA, consumers rarely have opportunity to consider other water heating options when hot water is unavailable in a residence, a premium exists to restore service, especially since water heater failure is rarely anticipated by an average consumer; when time or other circumstances allow, the consumer is likely to make a rational consumer choice based, first and foremost, on minimizing installed cost;

life cycle cost considerations and other factors play a role in decision making, provided comparative installed costs are available to the consumer. (ONE Gas, No. 1200 at p. 5)

In response, DOE notes that even for consumers who are motivated and informed, the choice of product efficiency that perfectly minimizes life-cycle cost is highly nuanced and requires access to many sources of information. To make a decision that maximizes benefits for any given consumer, that consumer would need to consider information including utility bills for at least a year (and have the ability to disaggregate the portion of the utility bill specific to the water heater), the expected lifetime of the product, knowledge of equipment and installation costs up front, knowledge of each potential product's efficiency and performance in the field, future repair and maintenance costs, the value of future operating savings and costs in the present year, *etc.* This is a time-consuming and nontrivial calculation for even the most motivated consumer and requires significant data collection to make even a decent approximation. While there is some information easily available to the consumer prior to making a purchase (*e.g.,* labels, technical specifications, price estimates, *etc.*), this information typically assumes an average household. Therefore, for a consumer wishing to make an informed decision that results in minimization of life-cycle costs in the no-new-standards case based on such a label, it would require knowing how their own situation differs from an average national household (*e.g.,* hot water usage, energy price, ambient indoor air temperature, inlet water temperature, *etc.*). This evaluation is very complex. These challenges are part of the reason why consumer perception of energy consumption of appliances is varied and the extent to which consumers choose product efficiency based on this perceived energy consumption is mixed, as discussed in some of the literature cited above. There is empirical evidence that, on average, consumers' perceived energy consumption of household appliances and equipment does not match the actual energy consumption.

Acknowledging this consumer behavior, PHCC commented that in the case of replacement due to a failed water heater, many consumers will prioritize a water heater that is readily available within their price range and will not consider energy efficiency in their decision. They further comment that most consumers never even look at the energy label, they just want hot water at the lowest cost. (PHCC, No. 1151 at p. 6)

As stated above, the use of a random assignment of water heater efficiency in the no-new-standards case of LCC model is a methodological approach that reflects the full range of consumer behaviors in this market, including consumers who make informed and economically beneficial decisions and other consumers who, due to the market failures discussed, do not or cannot make such perfectly economically beneficial decisions. The methodology is further constrained by shipments data by efficiency level; it must produce an overall distribution that matches the available data. In the simplest case, where baseline market shares are split between one lower efficiency level and one higher efficiency level, DOE's methodology results in the following groups of consumers:

(1) Consumers who, in the absence of standards, choose a lower efficiency product with a lower life-cycle cost based on their surveyed hot water usage. These consumers are making an optimal choice from the perspective of cost savings in the model in the no-new-standards case. With amended standards, they are made to purchase a more efficient product and therefore experience a net cost in the standards case. The efficiency assignment model is already assigning minimal-cost choices to this fraction of consumers in the no-new-standards case.

(2) Consumers who, in the absence of standards, choose a higher efficiency product that also lowers their life-cycle cost compared to the baseline efficiency product. These consumers are making a cost-minimizing choice in the model in the no-new-standards case. With amended standards, these consumers are not impacted because they are already purchasing a standards-compliant product. The efficiency assignment model is already assigning minimal-cost choices to this fraction of consumers in the no-new-standards case.

(3) Consumers who, in the absence of standards, choose a lower efficiency product that does not minimize their life-cycle cost. The market failures discussed above apply to these consumers, preventing them from making the choice that minimizes their costs in the no-new-standards case. With amended standards, they are made to purchase a more efficient product that ultimately results in a lower life-cycle cost. These consumers experience a net benefit as a result of the standard.

(4) Consumers who, in the absence of standards, choose a higher efficiency product that does not lower their life-cycle cost compared to the baseline or lower efficiency product. Although these consumers are choosing a higher efficiency product in the no-new-standards case, they may have incomplete knowledge of the energy consumption of the equipment or may value environmental features such as efficiency more heavily, resulting in a choice of a higher efficiency product that does not lower life-cycle cost compared to a baseline or lower efficiency product. With amended standards, these consumers are not impacted because they are already purchasing a standards-compliant product.

DOE's methodological approach is a proxy that ultimately reflects a diversity of scenarios for consumers and therefore the range of outcomes that will result from this diversity. The approach already reflects market share outcomes consistent with some degree of market efficiency and optimal decision-making among some consumers, but the approach also acknowledges a number of factors that hinder perfect decision-making for others. Furthermore, the model produces an overall distribution of efficiency that matches the available shipments data.

Although DOE's random assignment methodology does not explicitly model consumer decision making, nor does it take a stance on the rationality or irrationality of specific consumers, DOE believes that the approach would be consistent with a model in which some share of consumers make economically optimal decisions, and some consumers—in the face of market failures—do not. The use of a random assignment of water heater efficiency is a methodological approach that reflects the full range of consumer behaviors in this market, including consumers who make economically beneficial decisions and consumers who, due to market failures, do not or cannot make such economically beneficial decisions, both of which occur in reality. Within those constraints, DOE then assigns product efficiencies to consumers in the LCC, consistent with the economics literature discussed above, to reflect neither purely rational nor purely irrational decision-making.

DOE's analytical approach reflects some degree of market efficiency. An alternative approach which assumes consumer behavior is based solely on cost outcomes, for example by ranking LCCs and using those to assign efficiencies as suggested by the commenters, is not evidenced by the scientific literature surveyed above or by any data submitted in the course of this rulemaking. Such an approach would depend on the assumption, for example, that homeowners know—as a rule—the efficiency of their homes' water heater and water heating energy use, such that they always make water heating investments accordingly. Similarly, such an approach would assume that, faced with a water heater failure, homeowners will always select as a replacement the most economically beneficial available model. Given the work documenting market failures in

energy efficiency contexts described above, DOE believes that such assumptions would bias the outcome of the analysis to the least favorable results. DOE's approach, by contrast, recognizes that assumptions like these hold for some consumers some of the time—but not all consumers and not at all times.

As part of the random assignment, some households or buildings with large water heating loads will be assigned higher-efficiency water heaters in the no-new-standards case, and some households or buildings with particularly low water heating loads will be assigned baseline water heaters—*i.e.,* the lowest cost investments.

DOE ran a sensitivity to look at the base-case shipment distribution in 2030 that would be expected if every consumer made their purchasing decision based on minimizing their life-cycle costs to understand how this compares to actual consumer purchases based on the data on shipments by efficiency. If every consumer in the LCC sample chose a product that minimized their total life-cycle cost (*i.e.,* perfectly rational, cost-minimizing consumers), the resulting distribution of products by efficiency would deviate significantly from the actual efficiency distribution, as determined from market share data and shipments data by efficiency. For example, for medium ESWHs, the baseline efficiency (EL 0, representing an electric resistance water heater) results in a minimum life-cycle cost for only 36 percent of all consumers in the LCC analysis, while higher efficiency heat pump water heaters (ELs 1, 2, and 3) result in a minimum life-cycle cost for the remaining 64 percent of consumers. Therefore, in a scenario in which all consumers made cost-minimizing choices, one would expect the efficiency distribution of new shipments in 2030, without any amended standards, to be 36 percent electric resistance medium ESWHs and 64 percent heat pump medium ESWHs (at various efficiencies). However, the projected efficiency distribution in 2030, based on existing market share and actual shipments data (and even accounting for the recent growth trend of heat pump water heaters), is that only 12 percent of the market will be heat pump water heaters despite the fact that these water heaters would result in lower total life-cycle costs for 64 percent of consumers, *i.e.,* at least half of consumers will be selecting a water heater that does not minimize their costs. This significant discrepancy suggests the presence of the market failures discussed previously in the medium ESWH market, which prevents a significant portion of consumers from making purchasing decisions that would minimize their life-cycle costs.

Regarding the role of contractors, DOE notes that they can exert a high degree of influence over the type of water heater purchased. DOE acknowledges that they can serve as an information mediator. However, it is possible for a contractor to also influence the decision toward a familiar like-for-like replacement, for example, or perhaps the quickest replacement option available (*e.g.,* based on equipment availability). An individual contractor may not be familiar with every product option available on the market. Ultimately, there are multiple actors involved in the decision-making process which results in complex purchasing behavior.

As DOE has noted, there is a complex set of behavioral factors, with sometimes opposing effects, affecting the water heater market. It is impractical to model every consumer decision incorporating all of these effects at this extreme level of granularity given the limited available data. Given these myriad factors, DOE estimates the resulting distribution of such a model would be very scattered with high variability. It is for this reason DOE utilizes a random distribution (after accounting for market share constraints) to approximate these effects. This is the standard methodological approach used on all of DOE's prior rules. The methodology is not an assertion of economic irrationality, but instead, it is a methodological approximation of complex consumer behavior. The analysis is neither necessarily biased toward high or low energy savings. The methodology does not preferentially assign lower-efficiency water heaters to households in the no-new-standards case where savings from the rule would be greatest, nor does it preferentially assign lower-efficiency water heaters to households in the no-new-standards case where savings from the rule would be smallest. However, it is worth noting that energy use could be improperly estimated if preferences for energy efficiency are correlated with demand for hot water. Some consumers were assigned the water heaters that they would have chosen if they had engaged in the kind of perfect economic thinking upon which the commenters have focused. Others were assigned less-efficient water heaters even where a more-efficient water heater would eventually result in life-cycle savings, simulating scenarios where, for example, various market failures prevent consumers from realizing those savings. Still others were assigned water heaters that were more efficient than one would expect simply from life-cycle costs analysis, reflecting, say, ''green'' behavior, whereby consumers ascribe independent value to minimizing harm to the environment.

DOE cites the available economic literature of which it is aware on this subject, supporting the existence of the various market failures in other appliance markets which would give rise to such a distribution, and has requested more data or studies on this topic in the May 2020 RFI, March 2022 preliminary analysis, and July 2023 NOPR. DOE is not aware of any specific study regarding how consumer water heaters (and their efficiency) are purchased.

In summary, DOE's efficiency assignment methodology produces overall results that are consistent with the observed distribution of efficiency across products as seen in the shipments data. The methodology also results in a share of consumers being assigned product efficiencies that minimize their lifetime costs in the absence of standards. This represents consumers making informed decisions regarding the efficiency of their products, without amended standards. These consumers will be negatively impacted by the adopted standard levels and the analysis accounts for these impacts. However, the methodology also acknowledges that some consumers are unable to minimize the life-cycle costs of their products for a variety of reasons discussed in the economics literature (*e.g.,* renters with no say in the products purchased for their household). Even for motivated and informed consumers, the information and data required to ultimately make the best product choice that minimizes life-cycle cost is complex and time-consuming. As a result, there are a subset of consumers for whom adopting more stringent standard levels will result in life-cycle savings. In contrast to some commenters' characterization, DOE's methodology already reflects some degree of market efficiency in terms of consumer choice of product efficiency, but it also reflects a variety of observed effects that inhibit perfect market efficiency. This is representative of the water heater market. On the whole, when accounting for both consumers negatively impacted by, as well as those benefiting from, amended standards, DOE's analysis demonstrates that there are economically justified savings.

Finally, DOE notes that the recommendations of the NAS report, which pertain to the processes by which DOE analyzes energy conservation

standards, will be addressed as part of a separate notice-and-comment process.

9. Payback Period Analysis

The payback period is the amount of time (expressed in years) it takes the consumer to recover the additional installed cost of more-efficient products, compared to baseline products, through energy cost savings. Payback periods that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. DOE refers to this as a ''simple PBP'' because it does not consider changes over time in operating cost savings. The PBP calculation uses the same inputs as the LCC analysis when deriving first-year operating costs.

As noted previously, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price projection for the year in which compliance with the amended standards would be required.

Armada noted that the EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost is less than three times the value of the first year's energy savings, but the initial costs to switch from an electric resistance storage water heater to one with heat pump technology is greater than a three-year payback period, and that assumes the consumer's home can accommodate a heat pump water heater. (Armada, No. 1193 at pp. 5–6) In response, DOE notes that the rebuttable presumption provision is not a requirement that the average PBP of a standard must be less than three years. Rather, it establishes a presumption that a standard meeting that criteria is economically justified, which is then evaluated further using the other criteria used to evaluate economic justification. Whether the presumption is or is not met, a determination of economic justification must be based on the criteria specified by EPCA, as is the case for this final rule.

10. Accounting for Product Switching

For the preliminary analysis, DOE did not account for the product switching under potential standards. For the July 2023 NOPR and this final rule, DOE maintained the same approach and did not include any product switching in its analysis, other than consumers potentially downsizing their electric storage water heater to a small electric water heater, as discussed in more detail in section IV.G.1 of this document. DOE assumes that any product switching as a result of the proposed standards is likely to be minimal.

As discussed in the specific examples below, the costs to switch to another product class are higher than simply purchasing a standards-compliant product in the same product class. When faced with the need to replace a water heater, a consumer can either install a standards-compliant product of the same product class as they originally had, or spend even more to switch to an alternative product class. Because of this higher cost to switch, DOE concludes it is extremely unlikely that consumers would choose to spend more to switch product classes specifically in response to amended standards. In the absence of amended standards, some consumers choose to switch for reasons other than simply cost, and that is reflected in historical market trends that are incorporated into the analysis. However, for the purposes of the analysis, the issue is whether *more* consumers would switch due to the higher incremental costs of standards-compliant products. DOE concludes that this is very unlikely and therefore market trends will be unaffected.

In the hypothetical case of a consumer switching from a gas-fired storage water heater to an electric water heater (storage or instantaneous), there are likely additional installation costs necessary to add an electrical connection since both of these types of electric water heaters require high wattage. These are costs above and beyond the normal installation costs included in the LCC analysis. In some cases, it may be possible to install a 120-volt heat pump storage water heater with minimal additional installation costs, particularly if there is a standard electrical outlet nearby already. In most cases, however, a standard 240-volt electrical storage water heater would be installed. To do so, the consumer would need to add a 240-volt circuit to either an existing electrical panel or upgrade the entire panel if there is insufficient room for the additional amperage. The installation of a new 240-volt circuit by a qualified electrician will be at least several hundred dollars. Panel upgrade costs are significant and can be approximately $750—$2,000 to upgrade to a 200-amp electrical panel.[125] Older homes and homes with gas-fired space heating (*e.g.,* homes with gas furnaces) are more likely to need an electrical panel upgrade in order to install an electric storage water heater, given the relatively modest electrical needs of the home at the time of construction. Given the significant additional installation costs for nearly all homes potentially switching to an electric water heater, DOE estimates that very few consumers would switch from gas-fired storage water heaters to electric water heaters as a result of an energy conservation standard, especially at the proposed standard at TSL 2. At TSL 2, the average total installed cost of an electric storage water heater is $1,855 compared to the average total installed cost of $1,578 for a gas-fired storage water heater (see section V.B.1 of this document). Further, these costs do not include the electrical upgrade costs necessary when switching from a gas-fired to an electric water heater. When including those costs, the average total installed cost to switch to an electric water heater is significantly higher than the standards-compliant gas-fired storage water heater (electric instantaneous water heaters were not analyzed in this rule, however the electrical panel upgrade cost alone is nearly as much as a standards-compliant gas-fired storage water heater). Switching from a gas-fired to an electrical water heater is especially unlikely in the case of an emergency replacement where time is a critical factor. When a water heater fails, consumers typically have limited time to make a decision on which new water heater the consumer is going to choose to purchase and rely upon replacing the water heater with one that is similar to the one that failed. Consumers are unlikely to invest in switching fuels to a water heater that utilizes a different fuel source in the emergency replacement scenario.

In the hypothetical case of a consumer switching from an electric storage water heater to a gas-fired water heater, there are, similarly, additional installation costs necessary to add a gas connection. Based on RECS 2020, DOE estimates that only 25 percent of homes with an electric storage water heater currently

[125] For example, see: *www.homeadvisor.com/cost/electrical/upgrade-an-electrical-panel/#upgrade* (last accessed Dec. 1, 2023).

use natural gas and an additional 25 percent reported that natural gas is available in the neighborhood. Therefore, the option to switch to a gas-fired water heater is not available to half of consumers and for another 25 percent, it would require bringing in a natural gas connection from the street level to the home. Additionally, switching to a gas-fired water heater would require the installation of new gas plumbing in the home, even if the home currently uses natural gas, which would add several hundreds of dollars to the installation costs.[126] An additional 10 percent of homes use LPG, but the fuel costs are much more expensive than natural gas and requires significant gas line connection upgrades to connect the LPG tank to the water heater. Even in homes with an existing gas connection, new venting would need to be installed for either gas-fired storage water heaters or gas-fired instantaneous water heaters. Installing new venting represents a significant additional cost when switching from an electric water heater to a gas fired heater. The LCC averages presented in V.B.1 of this document for the gas-fired water heaters include some situations where vent replacement is not necessary, and none of the replacement situations require adding gas lines, therefore typical installation costs for switching from an electric water heater to a gas-fired water heater would be higher than the averages presented in section V.B.1 of this document. Therefore, the total installed costs for either gas-fired option, including all the necessary venting and additional gas lines in the home, are larger than replacing the electrical storage water heater with a standards-compliant model (at the proposed level). As a result, DOE estimates that very few consumers would switch from electric storage water heaters to gas-fired water heaters as a result of an energy conservation standard, particularly in the case of an emergency replacement.

Even if some consumers of medium ESWHs elected to switch to a non-electric water heater (*e.g.,* a GSWH), despite the additional costs of doing so and instead of simply purchasing a standards-compliant medium ESWH, the rule would still save a significant amount of energy. These consumers would still need to purchase a standards-compliant GSWH. Such switching from medium ESWHs to GSWHs or GIWHs would result in a slight increase in FFC energy consumption for these consumers, however that is more than made up for by the rest of the savings from medium ESWH consumers, even after accounting for consumers switching to small ESWHs. The energy savings for the rest of the medium ESWHs are at least an order of magnitude larger than any incremental increase in energy consumption from a small subset of consumers who might switch to GSWHs or GIWHs. Under the assumption that all such consumers who switch to gas-fired water heaters face an increase in cost, the total percentage of existing medium ESWH consumers experiencing a net cost as a result of the rule would therefore increase by a proportional amount. For example, even if 10 percent of medium ESWH consumers elected to switch to gas-fired water heaters despite the costs, the percentage of consumers experiencing a net cost would increase by at most 10 percent and the average LCC savings for medium ESWH consumers would still be positive, which would not change DOE's conclusion that the standards adopted are economically justified.

Lastly, in the hypothetical case of a consumer switching from a GSWH to a GIWH, there are additional installation costs necessary as well. The vast majority of GSWHs utilize non-condensing technology that utilizes Category I type B metal vent material, whereas switching to GIWHs would require Category III or Category IV venting material. Regarding non-condensing GIWHs, A.O. Smith noted that these utilize Category III venting (A.O. Smith, No. 1182 at p. 15). Condensing GIWHs require Category IV venting. Switching from a GSWH to a GIWH would therefore require replacing the venting in either case. Replacing the venting system would result in significant installation costs. Additionally, given the significantly higher Btu/h input required for instantaneous water heaters, it may be necessary to upgrade the gas line feeding the water heater to a larger diameter when switching from GSWH to GIWH. This is especially true if the line also services a gas furnace. Upgrading a gas line could add several hundred dollars in extra costs or more. As a result of all the cost considerations above, DOE estimates that very few consumers would switch from GSWHs to GIWHs specifically as a result of the incremental costs of the amended energy conservation standard for GSWH, particularly in the case of an emergency replacement.

Ravnitzky expressed concern that the proposed standards favor heat pump water heaters over gas-fired or electric resistance water heaters. Ravnitzky claimed that the proposed standards would result in non-heat pump water heaters becoming more expensive and less competitive in the market and may force some consumers to switch to heat pump water heaters.[127] (Ravnitzky, No. 73 at p. 1)

In response, given the upfront cost differential for heat pump electric storage water heaters and gas-fired water storage heaters, DOE does not expect that the adopted standards would induce consumers to switch to heat pump water heaters. In addition, DOE notes that gas-fired storage water heaters are not being eliminated as a result of the standards being established in this final rule.

According to NPGA, APGA, AGA, and Rinnai, DOE made an assumption about product switching, then reinforced its assumption without analysis, ignoring the possibility that consumers may want to switch product classes based on the proposed rule, but product classes may not be available for such switching, and based on this assumption, DOE conveniently omitted any installation costs in its LCC and PBP analysis, showing its market analysis is inherently flawed and must be reevaluated. (NPGA, APGA, AGA, and Rinnai, No. 441 at p. 4–5) DOE notes that its assessment is based on the comparison of total installed costs needed to switch from product class to product class. In response, DOE determined that there would be minimal switching due to the additional installation cost for a variety of possible scenarios, as discussed above. Specifically in the case of switching from a GSWH to a GIWH, these costs include upgrading gas lines and replacing the venting. Like-for-like replacement for the water heater product classes considered in this rulemaking, as DOE determined and summarized in the installation cost analysis, is the most cost efficient. DOE does not reject the idea that consumers may choose a different product class in response to the no new standards case for reasons other than just total costs. Indeed, the shipments projection accounts for recent market trends that show growing consumer demand for GIWHs compared to GSWHs.

NMHC and NAA stated that DOE's assumption of minimal product switching as a result of the proposed standard fails to account for forced product switching driven by typical

[126] For example, see: *www.homeadvisor.com/cost/plumbing/install-or-repair-gas-pipes/* (last accessed March 8, 2024).

[127] Ravnitsky incorrectly asserted that the proposed standards would require a minimum UEF of 0.96 for gas-fired water heaters, 0.95 for electric resistance water heaters, and 0.85 for heat pump water heaters.

space limitations in existing multifamily dwellings where frequently the water heater shares a small closet with stacked laundry facilities and owners will be forced to switch to instantaneous water heaters with additional installation costs associated with venting, larger-sized gas supply piping, or electrical panel upsizing. (NMHC and NAA, No. 996 at p. 5) In response, DOE notes that existing market trends are incorporated into the shipments analysis and projection. To the extent that some product classes are becoming more prevalent in certain types of buildings, that is reflected in the no-new-standards case shipments projection. The most commonly used electric water heater for the scenario described by NMHC and NAA would be a low-boy electric storage water heater, likely to be in the small ESWH product class. This rule does not amend standards for small ESWHs and therefore the consumers of this product class will not be impacted. As DOE has discussed above, the costs to switch product classes in response to amended standards are larger than simply purchasing standards-compliant products within the same product classes. Therefore DOE estimates that no additional switching will occur beyond existing market trends.

NRECA stated that a large percentage of co-op consumers have no access to natural gas service and have no affordable alternative option for a product that performs equivalent to electric resistance water heating, and therefore eliminating electric resistance water heating as an option in the market would pose a serious problem for many of the consumer-members served by cooperatives. They commented that these consumers that could not afford heat pump water heaters or their housing stock does not allow for their installation may be forced to choose electric tankless (or instantaneous) water heaters, which units may provide good comfort to consumers but have negative impacts to utilities by potentially creating spikes in demand of 20 kW instantaneously. NRECA commented that adding to a cooperative's peak demand can significantly raise their costs and add to the electric rates of all their consumer-members who must bear the cost. NRECA stated that at least one cooperative told them that most new housing stock in their territory is being equipped with electric tankless units and that it is not clear that DOE's analysis accounts for switching from electric storage to instantaneous electric. (NRECA, No. 1127 at p. 9) In response, DOE reiterates that a significant cost adder has been applied to the fraction of electric storage consumers that have challenging installation cases. For these consumers, DOE considered several downsizing options with significantly lower installation costs, including switching to a small electric storage water heater, and took that impact into account in its shipment analysis (see section IV.G.1.a of this document). In regards to the grid impact, this is discussed more in section III.A.3 of this document. Finally, DOE notes that although it did not analyze electric instantaneous water heaters, they represent a very small market share at present. DOE did include, however, an option to pair a small electric storage water heater with a ''booster'' instantaneous water heater as one of the switching options for medium electric storage water heaters (see section IV.G.1.a of this document).

Atmos Energy argued that because the cost to fuel switch is high, DOE fails to ''acknowledge the equally prohibitive costs that will be associated with high efficiency gas appliances as a result of this proposal and the lack of gas-fired replacements in the market.'' (Atmos Energy, No. 1183 at p. 6). Rinnai argued that DOE has failed to take into account substitution effects in replacement markets. Rinnai stated that the following are lacking from the analysis: replacement of water heaters with same category of consumer water heaters that meet a particular standard level; replacement with water heaters using different fuel or different product category (*e.g.,* GSWH to GIWH; GSWH to ESWH; ESWH to GSWH, *etc.*); and repair of existing product; thereby delaying the replacement. (Rinnai, No. 1186 at pp. 30–31) The Gas Association Commenters commented that the proposals in the July 2023 NOPR would create an enhanced market for heat pumps, diminishing competition between gas and electric water heaters. (Gas Association Commenters, No. 1181 at pp. 32–39) A.O. Smith stated that storage and tankless water heaters use incompatible venting systems (GSWH use Cat I while non-condensing tankless water heaters use Cat III). (A.O. Smith, No. 1182 at p. 15) As discussed above, DOE estimates that switching between gas-fired and electric water heaters as a result of the rule is likely to be negligible, as is switching from gas-fired storage to instantaneous water heaters, due to the high installation costs of such switching, (costs that are acknowledged to be high by Atmos Energy in their comment). DOE finds no evidence that there would be a lack of gas-fired water heater models available in the standards case for replacements. Many such models are currently available by multiple manufacturers. DOE acknowledges that in the standards case, many electric water heaters would transition to heat pump water heaters. However, since DOE estimates negligible switching between electric and gas-fired water heaters, there is no reason to expect this would alter the competition between electric and gas-fired water heater markets. Furthermore, many manufacturers produce both electric and gas-fired water heaters. Lastly, DOE agrees that gas-fired storage and instantaneous water heaters use incompatible venting systems and therefore switching from storage to instantaneous would require significant extra installation costs. See chapter 8 and appendix 8D of the final rule TSD for detailed description of the installation costs.

Noritz commented that the ability to replace a water heater in an emergency is an important attribute of value to consumers, and changes in installation patterns raise costs and impose other time-related constraints such as changing venting patterns, carpentry to make changes to the house, and possible electrical work to complete installation. (Noritz, No. 1202 at pp. 1–2) PHCC commented that in the case of replacement due to a failed water heater, many consumers will prioritize a water heater that is readily available within their price range and will not consider energy efficiency in their decision. According to PHCC, energy efficiency increases costs and decreases demand which leads to a longer wait time for installation and makes a more energy efficient water heater an unattractive option in a time when households simply care about having hot water and a working water heater as soon as possible. (PHCC, No. 1151 at p. 6) DOE agrees that in emergency replacement, like-for-like equipment provides the most convenience to the consumer. However, DOE estimates that the installation of condensing equipment, including the flue venting, the condensate pump, and neutralizer can be accomplished as part of an emergency replacement, meaning that for emergency replacements, non-condensing equipment do not bring significant additional value.

11. Analytical Results

AHRI commented that DOE does not provide a measure of uncertainty in LCC results. AHRI commented that each independent variable in LCC analysis has uncertainty, and DOE does not document how confident DOE should be in its estimates. AHRI asked DOE the

following questions related to model uncertainty: What is the estimated standard deviation around the mean change in LCC at each EL and for each product class? (AHRI, No. 1167 at p. 23) AHRI commented that DOE does not take account of the fact that operating costs, including energy, are deductible as business expenses for Federal and some state income taxes for commercial customers in its LCC analysis and asks for DOE's justification for not taking it into account. AHRI recommended that DOE considers the effects of this tax deductibility in computing the change in life cycle cost. AHRI claimed that failing to account for this is inconsistent with other aspects of DOE's analyses. (AHRI, No. 1167 at p. 16)

In response, DOE clarifies that it uses probability distributions for a number of input variables that are reasonably expected to exhibit natural variation and diversity in practice (*e.g.,* lifetime, repair cost, installation costs). These probability distributions are modeling diversity. In contrast, DOE addresses input uncertainty primarily with the use of sensitivity scenarios. To determine whether the conclusions of the analysis are robust, DOE performed several sensitivity scenarios with more extreme versions of these input variables (*e.g.,* high/low economic growth and energy price scenarios, alternative price trend scenarios, alternative mean lifetime scenarios). The relative comparison of potential standard levels in the analysis remains the same throughout these sensitivity scenarios, confirming that the conclusion of economic justification is robust despite some input uncertainty. Furthermore, DOE provides a range of statistics in the LCC spreadsheet, including median values and values at various percentiles for many intermediate variables, as well as the full data output table for all 10,000 samples. For example, the 25th and 75th percentiles of average LCC savings for all ELs for all product classes are available in the LCC spreadsheet. DOE also provides a distribution of impacts, including consumers with a net benefit, net cost, and not impacted by the rule in the LCC spreadsheet and in chapter 8 of the final rule TSD.

DOE develops probabilities for as many inputs to the LCC analysis as possible, to reflect the distribution of impacts as comprehensively as possible. For example, DOE develops probabilities for building sampling, installation costs, lifetime, discount rate, and efficiency distribution, among other inputs. If there are insufficient data with respect to a specific input parameter to create a robust probability distribution, DOE will utilize a single input parameter. Such approach is neither arbitrary nor capricious; it is informed by the available data.

The installation cost estimates are the result of a significant research and cite multiple sources, as discussed at length in section IV.F.2 and appendix 8D of the final rule TSD. DOE has incorporated feedback from various stakeholders and revised those costs for this final rule.

Regarding deductible business expenses, DOE notes that equipment purchases would also be deductible, and that increased equipment expenses and lower operating expenses would have opposing effects on total deductions. Even if overall deductions were to decrease as a result of the rule, those savings could be easily invested in other parts of the business in order to have no net impact on a business' tax burden. Furthermore, DOE notes that the estimation of commercial discount rates accounts for the tax deductibility of the energy costs and capital investment depreciation and therefore the net present value of the future operating cost savings in the LCC analysis should already reflect that effect.

DOE provides stakeholders with the opportunity to provide accurate data to represent a breadth of operating conditions, prices, and use cases. In the absence of stakeholder provided information, DOE makes a good-faith effort to collect reliable data from various sources and summarize assumptions on the missing parameters. The Monte Carlo simulation and its large number of samples (10,000 for each product class) ensures that the results converge to a representative average. For some inputs whose uncertainty is not well characterized, such as future equipment prices or economic growth conditions, DOE performed a series of sensitivity analyses to ensure that the results of the analysis are not strongly dependent on those inputs and that the conclusions of the analysis remain the same. As a result, DOE's conclusion of economic justification is robust to a broad range of sensitivity scenarios which capture the uncertainty inherent in economic projections.

DOE acknowledges that in the LCC, there may be a handful of outcomes with large benefits or costs. Large outlier LCC savings, both positive and negative, may affect the average of LCC savings across the whole sample of impacted consumers. In particular, for medium ESWHs, there are some outcomes with LCC savings that are over 10 times the average across the whole sample. Therefore, for medium ESWHs, DOE considered an additional sensitivity analysis that eliminated these outcomes with large benefits. Specifically, DOE removed outcomes with positive LCC savings that exceed the absolute magnitude of the largest LCC costs, so that the final distribution of outcomes is bounded by similar extremes (positive and negative). This sensitivity removes 245 outcomes out of 8,801 impacted consumers. The resulting average LCC savings in the sensitivity analysis are reduced to $581, compared to $859 in the reference case. Although the average LCC savings are reduced in this sensitivity analysis, they remain positive and there continue to be significant energy and environmental savings. DOE continues to conclude that the adopted standard level for medium ESWHs is economically justified even in this sensitivity analysis that eliminates large positive results.

DOE further notes that such cases in the LCC, represented with outcomes resulting in large benefits or large costs, are likely to occur in the real-world as a reflection of the variability in the household characteristics across the United States. For example, a household with high usage (*e.g.,* 5 plus occupants with frequent showering) located in an area with higher than average electricity rates, with lower than average installation costs (*e.g.,* there is sufficient electrical, drainage, and space to accommodate the heat pump water heater) will result in that household seeing net benefits greater than the average population. Such a scenario is reflected in the model as a high-benefits case. While DOE conducted the sensitivity to test its conclusion that the standards adopted are economically justified even with conservative assumptions, DOE also believes that such high benefits or high costs cases reflect the realities of household characteristics across the United States.

G. Shipments Analysis

DOE uses projections of annual product shipments to calculate the national impacts of potential amended or new energy conservation standards on energy use, NPV, and future manufacturer cash flows.[128] The shipments model takes an accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. The age distribution of in-service product stocks

[128] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general, one would expect a close correspondence between shipments and sales.

is a key input to calculations of both the NES and NPV, because operating costs for any year depend on the age distribution of the stock.

DOE developed shipment projections based on historical data and an analysis of key market drivers for each product. DOE estimated consumer water heater shipments by projecting shipments in three market segments: (1) replacement of existing consumer water heaters; (2) new housing; and (3) new owners in buildings that did not previously have a consumer water heater or existing water heater owners that are adding an additional consumer water heater.[129]

To project water heater replacement shipments, DOE developed retirement functions from water heater lifetime estimates and applied them to the existing products in the housing stock, which are tracked by vintage. DOE calculated replacement shipments using historical shipments and lifetime estimates. Annual historical shipments sources are: (1) Appliance Magazine; [130] (2) the Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') website; [131] (3) multiple AHRI data submittals; [132] (4) the BRG Building Solutions 2022 report; (5) ENERGY STAR unit shipments data; [133] (6) Oil Heating Magazine; [134] and the 2010 Heating Products Final Rule. In addition, DOE adjusted replacement shipments by taking into account demolitions, using the estimated changes to the housing stock from *AEO2023.*

To project shipments to the new housing market, DOE used the *AEO2023* housing starts and commercial building floor space projections to estimate future numbers of new homes and commercial building floor space. DOE then used data from U.S. Census Characteristics of New Housing,[135] [136] Home Innovation Research Labs Annual Builder Practices Survey,[137] RECS 2020, AHS 2021, and CBECS 2018 to estimate new construction water heater saturations by consumer water heater product class.[138]

DOE estimated shipments to the new owners' market based on residual shipments from the calculated replacement and new construction shipments compared to historical shipments in the last 5 years (2018–2023 for this NOPR). DOE compared this with data from the Decision Analysts' 2002 to 2022 American Home Comfort Study [139] and 2022 BRG data, which showed similar historical fractions of new owners. DOE assumed that the new owner fraction in 2030 would be equal to the 10-year average of the historical data (2013–2022) and then decrease to zero by the end of the analysis period (2059). If the resulting fraction of new owners is negative, DOE assumed that it was primarily due to equipment switching or non-replacement and added this number to replacements (thus reducing the replacements value).

For the preliminary analysis and NOPR, assumptions regarding future policies encouraging electrification of households and electric water heating were speculative at that time, so such policies were not incorporated into the shipments projection.

DOE acknowledges, however, that ongoing electrification policies at the Federal, State, and local levels are likely to encourage installation of electric water heaters in new homes and adoption of electric water heaters in homes that currently use gas-fired water heaters. For example, the Inflation Reduction Act includes incentives for heat pump water heaters and electrical panel upgrades. However, there are many uncertainties about the timing and impact of these policies that make it difficult to fully account for their likely impact on gas and electric water heater market shares in the time frame for this analysis (*i.e.,* 2030 through 2059). Nonetheless, DOE's shipments projections account for impacts that are most likely in the relevant time frame. The assumptions are described in chapter 9 and appendix 9A of the final rule TSD. The changes result in a decrease in gas-fired storage water heater shipments in the no-new-standards case in 2030 compared to the preliminary analysis. DOE acknowledges that electrification policies may result in a larger decrease in shipments of gas-fired water heaters than projected in this final rule, especially if stronger policies are adopted in coming years. However, this would occur in the no-new amended standards case and thus would only reduce the energy savings estimated in this adopted rule. For example, if incentives and rebates shifted 5 percent of shipments in the no-new amended standards case from gas-fired storage water heaters to heat pump electric storage water heaters, then the energy savings estimated for gas-fired storage water heaters in this adopted rule would decline by approximately 5 percent. The estimated consumer impacts are likely to be similar, however, except that the percentage of consumers with no impact at a given efficiency level would increase. DOE notes that the economic justification for the adopted rule would not change if DOE included the impact of incentives and rebates in the no-new-standards case, even if the absolute magnitude of the savings were to decline.

Gas Association Commenters advised that DOE should use State-level data rather than national data with differentiation between new and replacement market shares for each efficiency level in its analysis. Gas Association Commenters included specifics that they believe support this approach. (Gas Association Commenters, No. 1181 at pp. 35–37)

[129] The new owners primarily consist of households that add or switch to a different water heater option during a major remodel. Because DOE calculates new owners as the residual between its shipments model compared to historical shipments, new owners also include shipments that switch away from water heater product class to another.

[130] Appliance Magazine. *Appliance Historical Statistical Review: 1954–2012.* 2014. UBM Canon.

[131] Air-Conditioning, Heating, and Refrigeration Institute. Water Heaters Historical Data. Available at: *www.ahrinet.org/resources/statistics/historical-data/residential-storage-water-heaters-historical-data* (last accessed Dec. 1, 2023).

[132] AHRI. Confidential Instantaneous Gas-fired Water Heater Shipments Data from 2004–2007 to LBNL. March 3, 2008; AHRI. Oil-fired Storage Water Heater (30/32 gallons) Shipments Data provided to DOE. 2008.

[133] ENERGY STAR. Unit Shipments data 2010–2021. multiple reports. Available at *www.energystar.gov/partner_resources/products_partner_resources/brand_owner_resources/unit_shipment_data* (last accessed Dec. 1, 2023).

[134] Oil Heating Magazine. Merchandising News: Monthly Data on Water Heaters Installed by Dealers 1997–2007. 2007.

[135] U.S. Census. Characteristics of New Housing from 1999–2022. Available at *www.census.gov/construction/chars/* (last accessed Dec. 1, 2023).

[136] U.S. Census. Characteristics of New Housing (Multi-Family Units) from 1973–2022. Available at *www.census.gov/construction/chars/mfu.html* (last accessed Dec. 1, 2023).

[137] Home Innovation Research Labs (independent subsidiary of the National Association of Home Builders (''NAHB''). Annual Builder Practices Survey (2015–2019). Available at *www.homeinnovation.com/trends_and_reports/data/new_construction* (last accessed Dec. 1, 2023).

[138] Note that DOE does not project housing regionally. New housing is therefore assumed to grow in the same regional distribution as the current data would suggest.

[139] Decision Analysts, 2002, 2004, 2006, 2008, 2010, 2013, 2016, 2019, and 2022 American Home Comfort Study. Available at *www.decisionanalyst.com/Syndicated/HomeComfort/* (last accessed Dec. 1, 2023).

DOE has taken into account differences between new and replacement market throughout its shipments analysis. DOE does not have detailed State-level data and so did not consider it in its analysis.

GAAS commented that the shipment analysis should include historical and projections of shipments for water heaters broken down by end use applications and replacement versus new construction values. GAAS stated this would show that high efficiency options are gaining in market share without the need for more stringent energy efficiency standards. GAAS also commented that the Inflation Reduction Act (''IRA'') projections should be included in electric water heater sale projections. (GAAS, No. 1139 at p. 7)

DOE's shipments analysis has considered historical and projected shipments disaggregated by applications and by replacement vs. new constructions markets using available data. Further details are available in chapter 9 and appendix 9A of the final rule TSD. DOE has accounted for recent trends in the adoption of high efficiency products in its analysis, including the impacts of recent policies incentivizing higher efficiency products in some jurisdictions.

BWC asked for further clarification on what measures were taken by DOE to ensure that product shipments that may have been recorded in several of the referenced sources in section IV.G of this document were not accounted for multiple times, thus skewing the results of the data. (BWC, No. 1164 at p. 22)

DOE carefully evaluated each data source and then cross-checked against multiple available data sources. DOE validated its estimates to avoid double-counting. Chapter 9 and appendix 9A provide a description of how data sources were utilized in the shipments analysis. In summary, some data sources provided an overview of the overall market (*e.g.,* BRG data) whereas other data sources focused on a narrower subset (*e.g.,* ENERGY STAR shipments) by efficiency level, capacity, or other characteristic. All of these data sources complement each other.

BWC disagreed with DOE's estimate that heat pump water heaters currently account for approximately 8 percent of current sales in the United States. (BWC No. 1164 at p. 14) BWC disagreed with DOE's assumption that small electric storage water heaters make up 11 percent of the total market for electric storage water heaters with capacities ranging from 20 to 55 gallons and expressed that the actual figure is much higher. BWC commented that it is prepared to discuss the basis for this belief in a confidential conversation with DOE. (BWC, No. 1164 at p. 15)

DOE derived its estimates based on available data sources of historical shipments and markets shares as discussed in further detail in chapter 9 and appendix 9A. DOE clarifies that its estimate of small electric storage water heaters are specifically for those that meet the definition of the small electric storage water heater product class, based on the distribution of capacities and first-hour ratings available in the data sources and model databases. Some smaller capacity storage water heaters may not meet the definition of small electric storage water heaters. DOE also clarifies that its estimate of market shares at various efficiency levels (including heat pump water heaters), based on the data sources discussed in chapter 8 and appendix 8I, are presented for the first year of compliance (2030) and account for any recent historical trends. By 2030, DOE estimates that the heat pump water heater market share of the electric storage water heater market will exceed 10 percent.

EEI commented that DOE projects electric storage water heater (20–55 gallons except small electric storage water heaters) shipments dropping by well over 30 percent in the first year and never recovering compared to the ''no new standards'' case under the proposed rule, and this type of demand destruction could lead manufacturers to invest in and increase production of other less-efficient products. (EEI, No. 1198 at p. 4)

DOE acknowledges that some consumers may opt to change products, from electric storage water heaters to small electric storage water heaters, in response to the standard. This market dynamic is discussed in more detail in section IV.G.1.a of this document. Although DOE estimates that approximately 30 percent of electric storage water heater shipments will shift to small electric storage water heaters in the amended-standards case, this is not demand destruction as the commenter as characterized. This is a shift in consumer demand to an alternate product that is currently available. DOE acknowledges that that this shift will result in lower energy savings than if no consumers switched products, and this is accounted for in the analyses. DOE further notes that at the adopted standard level, the minimum efficiency requirement for small electric storage water heaters is still achievable with electric resistance heating technology; therefore, for this product class, manufacturers will continue to produce similar water heaters to those that are produced today. While there will be an increase in production for small electric water heaters to meet this increased demand, there will also be an increase in the production of efficient water heaters to meet the demand of the rest of the electric storage water heater market.

1. Impact of Potential Standards on Shipments

a. Impact of Consumer Choice for Electric Storage Water Heaters

DOE applied a consumer choice model to estimate the impact on electric storage water heaters shipments in the case of a heat pump water heater standard. As noted previously (*see* section IV.F.10 of this document), DOE did not include other product switching (*e.g.,* using different fuels) in its analysis as this is likely to be a minimal effect. This is especially true in the case of an emergency replacement.

DOE accounted for the potential of consumers selecting one or more smaller electric storage water heaters with or without a ''booster'' instantaneous water heater instead of replacing a larger electric storage water heater with a heat pump water heater.[140] DOE analyzed two main scenarios for a heat pump standard: (1) When electric storage water heaters ≥20 gal and ≤55 gal, excluding small ESWHs, could potentially downsize to the small electric storage water heater product class, due to a heat pump standard to electric storage water heaters ≥20 gal and ≤55 gal, excluding small ESWHs only; and (2) A heat pump water heater standard for all ESWH product classes, where ESWHs could potentially downsize to very small water heaters. DOE identified households from the electric consumer water heater sample that might downsize at each of the considered standard levels based on water heater sizing criteria and matching to the different consumer choice options that would result in no loss of utility. DOE assigned an effective storage volume and draw pattern to sampled consumer water heaters based on data from RECS 2020 and CBECS 2018. DOE selected the households or buildings that would downsize based on the fact that the consumer would have a financial incentive to downsize in the short term (*e.g.,* lower first cost), even though in some cases downsizing might not be advantageous in the long run compared

[140] *See* Rheem's booster instantaneous water heater, which can increase the availability of hot water for storage tank water heaters at *www.rheem.com/innovations/innovation_residential/water-heater-booster/.*

to installing a heat pump water heater. Table IV.27 and Table IV.28 show the resulting estimated shipment market share impacted for each scenario. Additional details of this analysis can be found in chapter 9 and appendix 8D of the TSD.

Table IV.27 Consumer Choice Results for Electric Storage Water Heaters (Assuming Heat Pump Standard for Electric Storage Water Heaters, ≥ 20 gal and ≤ 55 gal, excluding Small ESWHs Only)

Consumer Choice Options	Efficiency Level, Market Share Impacted (%)			
	0	1	2	3
Not Switching	100%	70%	70%	70%
Small ESWH	0%	15%	15%	15%
Small ESWH + Booster	0%	9%	9%	9%
Two Small ESWH	0%	5%	5%	5%

Table IV.28 Consumer Choice Results for Electric Storage Water Heaters (Assuming Heat Pump Standard for all Electric Storage Water Heater Product Classes)

Consumer Choice Options	Efficiency Level, Market Share Impacted (%)			
	0	1	2	3
Small Electric Storage Water Heaters, ≥ 20 gal and ≤ 35 gal and FHR < 51 gal				
Not Switching	100%	6%		
Very Small ESWH + One Booster	0%	90%		
Two Very Small ESWH	0%	3%		
Two Very Small ESWH + One Booster	0%	0%		
Electric Storage Water Heaters, ≥ 20 gal and ≤ 55 gal, excluding Small ESWHs				
Not Switching	100%	82%	83%	81%
Very Small ESWH + One Booster	0%	9%	9%	9%
Two Very Small ESWH	0%	6%	6%	6%
Two Very Small ESWH + One Booster	0%	3%	3%	4%

The shipments model considers the switching that might occur in each year of the analysis period (2030–2059). To do so, DOE estimated the switching in the first year of the analysis period (2030), using data on willingness to pay, in the LCC analysis and derived trends from 2030 to 2059. The shipments model also tracks the number of additional consumer water heaters shipped in each year. *See* appendix 9A of this final rule TSD for further details regarding how DOE estimated switching between various electric water heater options.

BWC commented that the findings presented in appendix 9A of the July 2023 NOPR TSD do not align with its understanding of what has occurred in the residential water heater market since the most recent rulemaking on these products took effect in 2015. BWC also questioned how DOE could have accounted for grid-enabled water heater shipments in this appendix when the BRG report, referenced as the source for this appendix's findings, does not account for shipments of these types of products. For these reasons, BWC would welcome an opportunity to discuss this matter further confidentially with DOE. (BWC, No. 1164 at p. 22)

DOE derived its estimates based on multiple available data sources and shipments model. The BRG report is only one data source. Other sources include AHRI shipments data available online, shipments data submitted confidentially to DOE, shipment estimates from ENERGY STAR, EIA's Annual Electric Power Industry Report, and estimates from trade magazines, as discussed in chapter 9. DOE used the combination of all these data to estimate shipments of the smaller product classes, such as electric storage water heaters greater than 55 gallons. DOE also clarifies that it did not propose or adopt standards for grid-enabled water heaters and therefore they were not specifically considered in the analysis.

BWC recommended that DOE utilize information that is specific to the residential water heater market in supporting its claims relative to consumer preferences. In the absence of such information, BWC asked that DOE take a proactive approach by working directly with manufacturers, trade associations, consumer advocates, and other knowledgeable stakeholders to collect information that is timely and relevant to the products that are subject to this rulemaking through confidential interviews and disaggregated surveys. (BWC, No. 1164 at p. 24)

DOE has considered available information and data sources, including interviews with manufacturers, industry market research reports, confidentially submitted data, and feedback from an industry consultant. There are, however, no specific data or studies on consumer decision-making preferences that DOE is aware of, specifically with respect to the water heater market, other than what is revealed by shipments data and the market share of various products currently available. DOE derived its estimates of efficiency distributions based on these market data. Regarding DOE's estimates of consumer preferences and market failures, these are based on a wide body of economics literature as discussed in more detail in section IV.F.8 of this document.

b. Impact of Repair vs. Replace

DOE estimated a fraction of consumer water heater replacement installations

that choose to repair their equipment, rather than replace their equipment in the new standards case. The approach captures not only a decrease in consumer water heater replacement shipments, but also the energy use from continuing to use the existing consumer water heater and the cost of the repair. DOE assumes that the demand for water heating is inelastic and, therefore, that no household or commercial building will forgo either repairing or replacing their equipment (either with a new consumer water heater or a suitable water heating alternative).

For details on DOE's shipments analysis, consumer choice, and the repair option, *see* chapter 9 of the final rule TSD.

H. National Impact Analysis

The NIA assesses the national energy savings (''NES'') and the NPV from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific efficiency levels.[141] (''Consumer'' in this context refers to consumers of the product being regulated.) DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of consumer water heaters sold from 2030 through 2059.

DOE evaluates the impacts of new or amended standards by comparing a case without such standards with standards-case projections. The no-new-standards case characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels (*i.e.,* the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.29 summarizes the inputs and methods DOE used for the NIA analysis for the final rule. Discussion of these inputs and methods follows the table. *See* chapter 10 of the final rule TSD for further details.

Table IV.29 Summary of Inputs and Methods for the National Impact Analysis

Inputs	Method
Shipments	Annual shipments from shipments model.
Compliance Date of Standard	2030
Efficiency Trends	No-new-standards case: Based on historical data. Standard cases: Roll-up in the compliance year and then DOE estimated growth in shipment-weighted efficiency in all the standards cases.
Annual Energy Consumption per Unit	Annual weighted-average values are a function of energy use at each TSL.
Total Installed Cost per Unit	Annual weighted-average values are a function of cost at each TSL. Incorporates projection of future product prices based on historical data.
Annual Energy Cost per Unit	Annual weighted-average values as a function of the annual energy consumption per unit and energy prices.
Repair and Maintenance Cost per Unit	Annual values do not change with efficiency level.
Energy Price Trends	*AEO2023* projections (to 2050) and extrapolation thereafter.
Energy Site-to-Primary and FFC Conversion	A time-series conversion factor based on *AEO2023*.
Discount Rate	Three and seven percent.
Present Year	2023

1. Product Efficiency Trends

A key component of the NIA is the trend in energy efficiency projected for the no-new-standards case and each of the standards cases. Section IV.F.8 of this document describes how DOE developed an energy efficiency distribution for the no-new-standards case (which yields a shipment-weighted average efficiency) for each of the considered product classes for the year of anticipated compliance with an amended or new standard. To project the trend in efficiency absent amended standards for consumer water heaters over the entire shipments projection period, DOE used available historical shipments data and manufacturer input. The approach is further described in chapter 10 of the final rule TSD.

For the standards cases, DOE used a ''roll-up'' scenario to establish the shipment-weighted efficiency for the year that standards are assumed to become effective (2030). In this scenario, the market shares of products in the no-new-standards case that do not meet the standard under consideration

[141] The NIA accounts for impacts in the United States and U.S. territories.

would ''roll up'' to meet the new standard level, and the market share of products above the standard would remain unchanged.

To develop standards-case efficiency trends after 2030, DOE used historical shipment data and current consumer water heater model availability by efficiency level (*see* chapter 8). DOE estimated growth in shipment-weighted efficiency by assuming that the implementation of ENERGY STAR's performance criteria and other incentives would gradually increase the market shares of higher efficiency water heaters meeting ENERGY STAR requirements such as EL 3 and above for gas-fired storage water heaters and EL 2 and above for electric storage water heaters (≥20 gal V_{eff} >55 gal).DOE also took into account increased incentives for higher efficiency equipment and electrification efforts. For oil-fired storage water heaters and electric storage water heaters (>55 gal V_{eff} ≤120 gal), DOE assumed a constant market share throughout the analysis period (2030–2059).

BWC cautioned DOE against using ENERGY STAR performance criteria data to assume growth in market shares for higher efficiency water heaters after 2030 in the no-new-standards case. BWC noted that ENERGY STAR's Residential Water Heater Specification 4.0 (effective March 29, 2022, to April 18, 2023) incentivized the purchase of high efficiency water heater products, such as heat pump water heaters, but the penetration rate for these products in the market remains low, as ENERGY STAR's 2022 Unit Shipment and Market Penetration Report Summary reports only a 3-percent market penetration for these products. In contrast, Figure 10.2.2 of the NOPR TSD assumes heat pump water heaters making up 11 percent of the market by 2030 in the no-new-standards case, which appears unlikely when considering the information released by ENERGY STAR cited above. (BWC, No. 1164 at p. 3)

DOE derived its estimates based on multiple available data sources and shipments model, not just ENERGY STAR shipment data. DOE's estimated market share of higher efficiency equipment is based on these data as well as on existing policies and incentives that drive a higher adoption of higher efficiency equipment in the no-new-standards case, as discussed in more detail in appendix 8I and 9A. DOE notes that if the analysis assumed a lower market share projection of heat pump water heaters in the no-new-standards case, this would result in a higher estimate of energy savings from the adopted standards, which would only further support DOE's conclusion of economic justification.

2. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each potential standards case (''TSL'') and the case with no new or amended energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-new-standards case and for each higher efficiency standard case. DOE estimated energy consumption and savings based on site energy and converted the electricity consumption and savings to primary energy (*i.e.,* the energy consumed by power plants to generate site electricity) using annual conversion factors derived from *AEO2023.* Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

Use of higher-efficiency products is sometimes associated with a direct rebound effect, which refers to an increase in utilization of the product due to the increase in efficiency. DOE examined a 2009 review of empirical estimates of the rebound effect for various energy-using products.[142] This review concluded that the econometric and quasi-experimental studies suggest a mean value for the direct rebound effect for household water heating of around 10 percent. DOE also examined a 2012 ACEEE paper[143] and a 2013 paper by Thomas and Azevedo.[144] Both of these publications examined the same studies that were reviewed by Sorrell, as well as Greening *et al.*,[145] and identified methodological problems with some of the studies. The studies believed to be most reliable by Thomas and Azevedo show a direct rebound effect for water heating products in the 1-percent to 15-percent range, while Nadel concludes that a more likely range is 1 to 12 percent, with rebound effects sometimes higher for low-income households that could not afford to adequately heat their homes prior to weatherization. DOE applied a rebound effect of 10 percent for consumer water heaters used in residential applications based on studies of other residential products and the value used for consumer water heaters in the 2010 Final Rule for Heating Products, and 0 percent for consumer water heaters in commercial applications, which also matches EIA's National Energy Modeling System (''NEMS'') for residential and commercial water heating and is consistent with other recent energy conservation standards rulemakings.[146] [147] [148] [149] The calculated NES at each efficiency level is therefore reduced by 10 percent in residential applications. DOE also included the rebound effect in the NPV analysis by accounting for the additional net benefit from increased consumer water heaters usage, as described in section IV.H.3 of this document.

In 2011, in response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's

[142] Steven Sorrell, *et al.,* Empirical Estimates of the Direct Rebound Effect: A Review, 37 *Energy Policy* 1356–71 (2009). Available at *www.sciencedirect.com/science/article/pii/S0301421508007131* (last accessed Dec. 1, 2023).

[143] Steven Nadel, ''The Rebound Effect: Large or Small?'' ACEEE White Paper (August 2012). Available at *www.aceee.org/files/pdf/white-paper/rebound-large-and-small.pdf* (last accessed Dec. 1, 2023).

[144] Brinda Thomas and Ines Azevedo, Estimating Direct and Indirect Rebound Effects for U.S. Households with Input-Output Analysis, Part 1: Theoretical Framework, 86 *Ecological Econ.* 199–201 (2013). Available at *www.sciencedirect.com/science/article/pii/S0921800912004764*) (last accessed Dec. 1, 2023).

[145] Lorna A. Greening, *et al.,* Energy Efficiency and Consumption—The Rebound Effect—A Survey, 28 *Energy Policy* 389–401 (2002). Available at *www.sciencedirect.com/science/article/pii/S0301421500000215* (last accessed Dec. 1, 2023).

[146] *See www.eia.gov/outlooks/aeo/nems/documentation/residential/pdf/m067(2020).pdf* (last accessed Dec. 1, 2023.

[147] DOE. Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards for Small, Large, and Very Large Air-Cooled Commercial Package Air Conditioning and Heating Equipment and Commercial Warm Air Furnaces; Direct final rule. 81 FR 2419 (Jan. 15, 2016). Available at *www.regulations.gov/document/EERE-2013-BT-STD-0021-0055* (last accessed Dec. 1, 2023).

[148] DOE. Energy Conservation Program: Energy Conservation Standards for Residential Boilers; Final rule. 81 FR 2319 (Jan. 15, 2016). Available at *www.regulations.gov/document/EERE-2012-BT-STD-0047-0078* (last accessed Dec. 1, 2023).

[149] DOE. Energy Conservation Program: Energy Conservation Standards for Commercial Packaged Boilers; Final Rule. 85 FR 1592 (Jan. 10, 2020). Available at *www.regulations.gov/document/EERE-2013-BT-STD-0030-0099* (last accessed Dec. 1, 2023).

National Energy Modeling System (''NEMS'') is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector [150] that EIA uses to prepare its *Annual Energy Outlook.* The FFC factors in corporate losses in production and delivery in the case of natural gas (including fugitive emissions) and additional energy used to produce and deliver the various fuels used by power plants. The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the final rule TSD.

EEI commented that the fossil fuel equivalency methodology, employed in DOE's impact assessment of proposed changes to efficiency standards, was developed in an earlier era when the penetration of renewable energy generation was low. EEI commented that continuing to apply fossil fuel equivalency factors leads to the false conclusion that renewable energy generation has the same primary energy losses as fossil generation and that these energy losses represent similar economic loss. EEI stated that EIA is moving to the captured energy approach in all of its analyses as of June 2023, and DOE should follow EIA's lead and update its methodology as soon as possible to create more realistic estimates of primary energy savings and electricity sector emissions reductions. (EEI, No. 1198 at pp. 6–8)

As previously mentioned, DOE converts electricity consumption and savings to primary energy using annual conversion factors derived from the EIA's *AEO2023.* Traditionally, EIA has used the fossil fuel equivalency approach to report noncombustible renewables' contribution to total primary energy. The fossil fuel equivalency approach applies an annualized weighted-average heat rate for fossil fuel power plants to the electricity generated (in kWh) from noncombustible renewables. EIA recognizes that using captured energy (the net energy available for direct consumption after transformation of a noncombustible renewable energy into electricity) or incident energy (the mechanical, radiation, or thermal energy that is measurable as the ''input'' to the device) are possible approaches for converting renewable electricity to a common measure of primary energy, but used the fossil fuel equivalency approach in *AEO2023* and other reporting of energy statistics used in this final rule. DOE contends that it is important for it to maintain consistency with *AEO2023* in DOE's accounting of primary energy savings from energy efficiency standards.

3. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual operating costs (energy costs and repair and maintenance costs), and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the projection period.

As discussed in section IV.F.1 of this document, DOE used constant prices as the default price assumption to project future consumer water heater prices. However, DOE also developed consumer water heater price trends based on historical PPI data. DOE applied the same trends to project prices for each product class at each considered efficiency level as a sensitivity analysis. DOE's projection of product prices is described in appendix 10C of the final rule TSD.

To evaluate the effect of uncertainty regarding the price trend estimates, DOE investigated the impact of different product price projections on the consumer NPV for the considered TSLs for consumer water heaters. In addition to the default price trend, DOE considered two product price sensitivity cases: (1) a price decline case and (2) price increase case based on PPI data. The derivation of these price trends and the results of these sensitivity cases are described in appendix 10C of the final rule TSD.

The energy cost savings are calculated using the estimated energy savings in each year and the projected price of the appropriate form of energy. To estimate energy prices in future years, DOE multiplied the average regional energy prices by the projection of annual national-average residential energy price changes in the Reference case from *AEO2023,* which has an end year of 2050. To estimate price trends after 2050, the 2046–2050 average was used for all years. As part of the NIA, DOE also analyzed scenarios that used inputs from variants of the *AEO2023* Reference case that have lower and higher economic growth. Those cases have lower and higher energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10C of the final rule TSD.

In considering the consumer welfare gained due to the direct rebound effect, DOE accounted for change in consumer surplus attributed to additional water heating from the purchase of a more efficient unit. Overall consumer welfare is generally understood to be enhanced from rebound. The net consumer impact of the rebound effect is included in the calculation of operating cost savings in the consumer NPV results. *See* appendix 10E of the final rule TSD for details on DOE's treatment of the monetary valuation of the rebound effect.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this final rule, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (''OMB'') to Federal agencies on the development of regulatory analysis.[151] The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

Atmos Energy argued that increased efficiency in water heaters could lead to an increase in water usage which could further drought in southern and western states. Atmos Energy argued that a full evaluation of rebound effects of the proposal should be conducted and that increased water usage should be calculated and evaluated as an environmental cost of the proposal. (Atmos Energy, No. 1183 at p. 5)

DOE has considered rebound effects in its analysis. DOE notes that the impacts of changes in water usage on regional water supply are not captured

[150] For more information on NEMS, refer to *The National Energy Modeling System: An Overview 2009,* DOE/EIA–0581(2009), October 2009. Available at *www.eia.gov/forecasts/aeo/index.cfm* (last accessed Dec. 1, 2023).

[151] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* Available at *www.whitehouse.gov/omb/information-for-agencies/circulars* (last accessed Mar. 5, 2024). DOE used the prior version of Circular A–4 (September 17, 2003) in accordance with the effective date of the November 9, 2023 version. Available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf* (last accessed Dec. 1, 2023).

within the scope of DOE's standards analysis.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this final rule, DOE analyzed the impacts of the considered standard levels on three subgroups: (1) low-income households, (2) senior-only households, and (3) small businesses. The analysis used subsets of the RECS 2020 sample composed of households and CBECS 2018 sample composed of commercial buildings that meet the criteria for the three subgroups. DOE used the LCC and PBP spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups. Chapter 11 in the FR TSD describes the consumer subgroup analysis.

1. Low-Income Households

Low-income households are significantly more likely to be renters or live in subsidized housing units and less likely to be homeowners. DOE notes that in these cases, the landlord purchases the equipment and may pay the gas bill as well. RECS 2020 includes data on whether a household pays for the gas bill, allowing DOE to categorize households appropriately in the analysis.[152] For this consumer subgroup analysis, DOE considers the impact on the low-income household narrowly, excluding any costs or benefits that are accrued by either a landlord or subsidized housing agency. This allows DOE to determine whether low-income households are disproportionately affected by an amended energy conservation standard in a more representative manner. DOE takes into account a fraction of renters that face product switching (when landlords switch to products that have lower upfront costs but higher operating costs, which will be incurred by tenants).

The majority of low-income households that experience a net cost at higher efficiency levels are homeowner households, as opposed to renters. These households either have a smaller capacity water heater or lower hot water use. Unlike renters, homeowners would bear the full cost of installing a new water heater. For these households, a potential rebate program to reduce the total installed costs would be effective in lowering the percentage of low-income consumers with a net cost. DOE understands that the landscape of low-income consumers with a water heater may change before the compliance date of amended energy conservation standards, if finalized. For example, point-of-sale rebate programs are being considered that may moderate the impact on low-income consumers to help offset the total installed cost of a higher efficiency water heater, particularly given the lower total installed cost of smaller capacity water heater. Currently, DOE is aware that the Inflation Reduction Act will likely include incentives for certain water heaters, although the specific implementation details have yet to be finalized. DOE is also aware of State or utility program rebates in the Northeast or California, for example, that support additional heat pump deployment as a result of decarbonization policy goals. Point-of-sale rebates or weatherization programs could also reduce the total number of low-income consumers that would be impacted because the household no longer has a water heater to upgrade.

BWC cautioned DOE against relying as heavily as it does in this proposal on state, local, and/or utility rebate programs to decrease the upfront installation costs for condensing gas-fired water heaters, as well as heat pump water heaters. While recognizing the existence of many rebate programs today, BWC questions how many of these rebates will continue in place if the Department finalizes this proposal. This is therefore a scenario BWC urged DOE to account for in its subgroup analysis as BWC believes it will reveal cost burdens that are much higher on the low-income households than what is presently assumed in this NOPR. (BWC, No. 1164 at p. 19). For consumers in subsidized housing, BWC urged the Department to consider two realistic outcomes regarding product rebates that are designed to cover upfront installation costs. The first is that many or all third parties will stop offering these rebates once federal, state, and/or local regulatory bodies require the use of high-efficiency appliances. (BWC No. 1164 at p. 26) The second is the cost that these consumers will experience when their highly efficient product reaches the end of its useful life. Many rebate programs are designed to assist consumers with project costs associated with fuel-switching or upgrading a lower efficiency product with a more expensive, higher efficiency counterpart. However, many if not most of these rebate programs do not apply to installations where a highly efficient product is undergoing a like-for-like replacement. (BWC No. 1164 at p. 27)

Rheem argued that IRA will not impact water heaters sold at the efficiency levels proposed by DOE; therefore, low-income households will not benefit from 25C tax credits. Rheem pointed out that Energy Star specification has recently been updated and recommended that DOE address the new levels. This includes that Energy Star has indicated that they will sunset gas-fired water heater specification and therefore should not be used to determine uptake of higher efficiency gas-fired WH. (Rheem, No. 1177 at pp. 16–17).

In response to the above comments regarding rebates, DOE clarifies that it does not rely on the existence of rebate programs to justify the energy conservation standards. DOE's installation costs are estimated based on labor and material costs, as described in chapter 8 and appendix 8D, without any rebates. DOE merely notes that the potential existence of such programs in the future would only improve the economic justification of this rule.

Health Advocates and Joint Advocates of Energy Efficiency argued that 67 percent of low-income households face a high-energy burden where they must spend 3 times more of their income on energy costs compared to median spending (8.1 percent vs 2.3 percent). Health Advocates argued that renters (disproportionately low-income households) would benefit from this rule because landlords have no incentive to install efficient water heaters as tenants usually pay the energy bills. (Health Advocates, No. 1179 at p. 2; Joint Advocates of Energy Efficiency, No. 1165 at p. 2) In response, DOE notes that it has considered the impacts on low-income households. Low-income homeowners (including owners of manufactured homes) are more likely to have smaller water heaters that either are not subject to amended standards (in the case of small ESWHs) or have modest incremental costs. Low-income renters are unlikely to bear the equipment and installation costs of replacing their water heater but

[152] RECS 2020 includes a category for households that pay only some of the gas bill. For the low-income consumer subgroup analysis, DOE assumes that these households pay 50 percent of the gas bill, and, therefore, would receive 50 percent of operating cost benefits of an amended energy conservation standard.

are more likely to pay energy costs and therefore see operating benefits from the rule. DOE has evaluated the full distribution of impacts in the LCC analysis, including consumers that experience a net cost and consumers that experience a net benefit, and concludes that on the whole, the rule is economically justified.

Gas Association Commenters argued that if better regional market share data were used, regions with low or negative LCC savings would impact the overall outcome differently. Gas Association Commenters included tables in their submitted comment summarizing these argued regional impacts. Gas Association Commenters also argued that DOE is missing subsets of low-income households by only using those who are most likely to directly pay utility bills. They stated that utilities can also be a function of rent where higher utility costs can still be passed on to the end user. (Gas Association Commenters, No. 1181 at p. 6 and pp. 23–25) DOE acknowledges that there may be some regional variation in LCC impacts and these results are available in the LCC spreadsheet. DOE further acknowledges that some fraction of consumers will experience a net cost, as presented in the LCC. However, DOE concludes that on the whole, the rule continues to be economically justified, with the incorporation of a much larger RECS 2020 sample. The average LCC savings remain positive. With respect to low-income households, DOE took into account both scenarios where the households do or do not directly pay their utility bills, and these are included in the low-income subgroup analysis as discussed in chapter 11.

NRECA commented that the subgroup is too narrowly defined to include low-income homeowners and urged DOE to account for consumers near but above the poverty level who can also experience a high burden when the installation cost for a heat pump water heater easily takes up 10 percent of their annual income. NRECA also noted that manufactured housing comprises 25 percent or more of the co-op's residential housing stock and that these same homes present challenges for heat pump water heater adoption due to space constraints. NRECA suggested that DOE should improve its analysis by using low-and-moderate income instead of poverty-level in the subgroup and assigning proportionally higher occurrences of expensive installations to this subgroup. (NRECA, No. 1127 at pp. 5–6) In contrast, NYSERDA commented that the proposed standard will bring significant benefits to low-and-moderate income households and to disadvantaged communities. (NYSERDA, No. 1192 at p. 3) DOE notes that the low-income subgroup is specifically defined for households meeting poverty thresholds, as defined in chapter 11. While households slightly above these thresholds are not included in the low-income subgroup analysis, they are part of the overall LCC analysis. On the whole, DOE concludes that the rule is economically justified for both the overall LCC consumer sample as well as the low-income subgroup. Households that do not meet the low-income threshold but are nonetheless energy insecure are likely to experience impacts that fall in between the overall LCC results and the low-income subgroup results, which would still be economically justified. As noted above, energy insecure homeowners with smaller water heaters will either experience smaller incremental equipment costs on average or have water heaters not subject to amended standards, and energy insecure renters would benefit similarly to low-income renters.

ECSC argued that heat pump water heater installations will be hindered by lack of contractor availability in rural areas. (ECSC, No. 1185 at pp. 1–2) Regarding contractor availability, DOE notes that while heat pump water heaters are not as common today, they will become very common by the compliance date of the rule. Many contractors at present are able to install different types of water heaters, including heat pump water heaters. At the adopted standard level, the existing market for small electric storage water heaters is preserved, which reduces the level of contractor training and investment needed than if higher standards were adopted for all electric storage water heaters. While DOE acknowledges there is a ramp up in contractor training required by 2030, the adopted standard level allows for a more incremental transition to heat pump technology. Furthermore, DOE notes that the emergence of workforce programs supported by the Inflation Reduction Act and the Bipartisan Infrastructure Law will begin to support the training and education of the workforce needed to support the clean energy transition.

BWC disagreed with the Department excluding any costs or benefits that are accrued by a landlord when analyzing impacts to the low-income household subgroup. While BWC understood that these costs and benefits are not imposed directly on renters, they will indirectly lead to impacts on renters that DOE should account for, such as increased rent rates resulting from landlords attempting to recoup the initial project installation costs, as well as increased maintenance costs likely to result for the installation of a higher efficiency product. (BWC No. 1164 at p. 26) Armada argued that DOE failed to acknowledge that landlords will be forced to increase rent or other costs to cover the purchase and installation of more efficient options, and a landlord will have to dedicate a bedroom to a water heater or reconfigure the duct-work of the property to accommodate the water heater. Armada argued that these are major changes that will harm residents the most, and these proposed efficiency standards which will effectively mandate heat pump technology will only compound the existing affordable housing issue. (Armada, No. 1193 at pp. 6–7) DOE finds no evidence that significant rental cost increases would occur. Rental prices are largely dictated by supply and demand of housing in individual locations, not the sum of equipment costs in those rentals, such that two similar rentals could have widely differing prices in different cities. Furthermore, a landlord would be responsible for replacing an end-of-life water heater in the no-new-standards case as well yet the rent is unlikely to increase simply because of this regular maintenance. The installation costs estimated in the LCC already include any potential replacement of venting for gas-fired water heaters and other installation costs for ESWHs, however there is never a need to ''dedicate a bedroom'' to a new water heater. Additionally, even if there are significant extra costs for the installation of a heat pump water heater (see section IV.F.2.d of this document), the analysis includes the potential to switch to a small ESWH for consumers with lower hot water demand as an alternative to minimize installation costs (see section IV.G.1 of this document). Finally, even if a landlord were to fully pass on the incremental costs due to amended standards, those costs would presumably be spread out over a monthly rent spanning many years, possibly the lifetime of the water heater, resulting in relatively small monthly rent increases. It is for these reasons that the low-income subgroup analyzes impacts assuming renters do not bear installation costs. However, as described in section IV.F of this document, for the overall LCC analysis, DOE makes the simplifying assumption that all installation and equipment costs are paid for by the consumer of the equipment, including renters. Therefore, the main LCC results do assume that

landlords pass on all costs and yet the analysis still finds that the rule is economically justified.

For consumers in subsidized housing, BWC urged the Department to consider two realistic outcomes regarding product rebates that are designed to cover upfront installation costs. The first is that many or all third parties will stop offering these rebates once federal, state, and/or local regulatory bodies require the use of high-efficiency appliances. (BWC No. 1164 at p. 26) The second is the cost that these consumers will experience when their highly efficient product reaches the end of its useful life. Many rebate programs are designed to assist consumers with project costs associated with fuel-switching or upgrading a lower efficiency product with a more expensive, higher efficiency counterpart. However, many if not most of these rebate programs do not apply to installations where a highly efficient product is undergoing a like-for-like replacement. (BWC No. 1164 at p. 27)

DOE clarifies that the analysis does not assume that installation costs are reduced by rebates or incentives. Rather, the analysis uses these existing programs as part of the shipments projection and the projection of market shares at different efficiency levels in the no-new-standards case. This merely characterizes the market up to the compliance date of the adopted standards.

2. Senior-Only Households

Senior-only households are households with occupants who are all at least 65 years of age. RECS 2020 includes information on the age of household occupants, allowing for the identification of senior-only households from the sample. Senior-only households comprised 23.5 percent of the country's households. In estimating the LCC impacts to senior-only households, it is assumed that any residual value of a long-lived product is capitalized in the value of the home.

3. Small Business Subgroup

DOE identified small businesses in CBECS 2018 using threshold levels for maximum number of employees within each building principal building activity. DOE received no comments regarding small businesses impacts relevant to products within the scope of this final rule.

J. Manufacturer Impact Analysis

1. Overview

DOE performed an MIA to estimate the financial impacts of amended energy conservation standards on manufacturers of consumer water heaters and to estimate the potential impacts of such standards on direct employment and manufacturing capacity. The MIA has both quantitative and qualitative aspects and includes analyses of projected industry cash flows, the INPV, investments in research and development (''R&D'') and manufacturing capital, and domestic manufacturing employment. Additionally, the MIA seeks to determine how amended energy conservation standards might affect manufacturing employment, capacity, and competition, as well as how standards contribute to overall regulatory burden. Finally, the MIA serves to identify any disproportionate impacts on manufacturer subgroups, including small business manufacturers.

The quantitative part of the MIA primarily relies on the GRIM, an industry cash flow model with inputs specific to this rulemaking. The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in R&D and manufacturing capital required to produce compliant products. The key GRIM outputs are the INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact to domestic manufacturing employment. The model uses standard accounting principles to estimate the impacts of more stringent energy conservation standards on a given industry by comparing changes in INPV and domestic manufacturing employment between a no-new-standards case and the various standards cases. To capture the uncertainty relating to manufacturer pricing strategies following amended standards, the GRIM estimates a range of possible impacts under different manufacturer markup scenarios.

The qualitative part of the MIA addresses manufacturer characteristics and market trends. Specifically, the MIA considers such factors as a potential standard's impact on manufacturing capacity, competition within the industry, the cumulative impact of other DOE and non-DOE regulations, and impacts on manufacturer subgroups. The complete MIA is outlined in chapter 12 of the final rule TSD.

DOE conducted the MIA for this rulemaking in three phases. In Phase 1 of the MIA, DOE prepared a profile of the consumer water heater manufacturing industry based on the market and technology assessment, preliminary manufacturer interviews, and publicly available information. This included a top-down analysis of consumer water heater manufacturers that DOE used to derive preliminary financial inputs for the GRIM (*e.g.,* revenues; materials, labor, overhead, and depreciation expenses; selling, general, and administrative expenses (''SG&A''); and R&D expenses). DOE also used public sources of information to further calibrate its initial characterization of the consumer water heater manufacturing industry, including company filings of form 10–K from the SEC,[153] corporate annual reports, the U.S. Census Bureau's *Quarterly Survey of Plant Capacity Utilization*,[154] U.S. Census Bureau's *Annual Survey of Manufactures* (''*ASM*''),[155] and reports from D&B Hoovers.[156]

In Phase 2 of the MIA, DOE prepared a framework industry cash-flow analysis to quantify the potential impacts of amended energy conservation standards. The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of the standard and extending over a 30-year period following the compliance date of the standard. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) creating a need for increased investment, (2) raising production costs per unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

In addition, during Phase 2, DOE developed interview guides to distribute to manufacturers of consumer water heaters in order to develop other key GRIM inputs, including product and capital conversion costs, and to gather additional information on the anticipated effects of energy conservation standards on revenues, direct employment, capital assets, industry competitiveness, and subgroup impacts.

In Phase 3 of the MIA, DOE conducted structured, detailed

[153] U.S. Securities and Exchange Commission. Company Filings. Available at*www.sec.gov/edgar/searchedgar/companysearch.html* (last accessed Aug. 2, 2022).

[154] The U.S. Census Bureau. Quarterly Survey of Plant Capacity Utilization. Available at *www.census.gov/programs-surveys/qpc/data/tables.html* (last accessed Aug. 2, 2022).

[155] U.S. Census Bureau's Annual Survey of Manufactures: 2018–2021 (Available at: *www.census.gov/programs-surveys/asm/data/tables.html*) (last accessed January 18, 2024).

[156] The D&B Hoovers login is available at *app.dnbhoovers.com* (last accessed Dec. 1, 2023).

interviews with representative manufacturers. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics to validate assumptions used in the GRIM and to identify key issues or concerns. As part of Phase 3, DOE also evaluated subgroups of manufacturers that may be disproportionately impacted by amended standards or that may not be accurately represented by the average cost assumptions used to develop the industry cash flow analysis. Such manufacturer subgroups may include small business manufacturers, low-volume manufacturers, niche players, and/or manufacturers exhibiting a cost structure that largely differs from the industry average. DOE identified one subgroup for a separate impact analysis: small business manufacturers. The small business subgroup is discussed in section VI.B of this document, ''Review under the Regulatory Flexibility Act'' and in chapter 12 of the final rule TSD.

2. Government Regulatory Impact Model and Key Inputs

DOE uses the GRIM to quantify the changes in cash flow due to new or amended standards that result in a higher or lower industry value. The GRIM uses a standard, annual, discounted cash-flow analysis that incorporates manufacturer costs, manufacturer markups, shipments, and industry financial information as inputs. The GRIM models changes in costs, distribution of shipments, investments, and manufacturer margins that could result from an amended energy conservation standard. The GRIM spreadsheet uses the inputs to arrive at a series of annual cash flows, beginning in 2023 (the base year of the analysis) and continuing to 2059. DOE calculated INPVs by summing the stream of annual discounted cash flows during this period. For manufacturers of consumer water heaters, DOE used a real discount rate of 9.3 percent, which was derived from industry financials and then modified according to feedback received during manufacturer interviews.

The GRIM calculates cash flows using standard accounting principles and compares changes in INPV between the no-new-standards case and each standards case. The difference in INPV between the no-new-standards case and a standards case represents the financial impact of the new or amended energy conservation standard on manufacturers. As discussed previously, DOE developed critical GRIM inputs using a number of sources, including publicly available data, results of the engineering analysis, and information gathered from industry stakeholders during the course of manufacturer interviews. The GRIM results are presented in section V.B.2 of this document. Additional details about the GRIM, the discount rate, and other financial parameters can be found in chapter 12 of the final rule TSD.

a. Manufacturer Production Costs

Manufacturing more efficient products is typically more expensive than manufacturing baseline products due to the use of more complex components, which are typically more costly than baseline components. The changes in the MPCs of covered products can affect the revenues, gross margins, and cash flow of the industry.

As discussed in section IV.C.1 of this document, DOE conducted a market analysis of currently available models listed in DOE's CCD to determine which efficiency levels were most representative of the current distribution of consumer water heaters available on the market. DOE also completed physical teardowns of commercially available units to determine which design options manufacturers may use to achieve certain efficiency levels for each water heater category analyzed. DOE requested comments from stakeholders and conducted interviews with manufacturers concerning these initial efficiency levels, which have been updated based on the feedback DOE received. For a complete description of the MPCs, *see* section IV.C of this document and chapter 5 of the final rule TSD.

b. Shipments Projections

The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of those shipments by efficiency level. Changes in sales volumes and efficiency mix over time can significantly affect manufacturer finances. For this analysis, the GRIM uses the NIA's annual shipment projections derived from the shipments analysis from 2023 (the base year) to 2059 (the end year of the analysis period). *See* section IV.G of this document and chapter 9 of the final rule TSD for additional details.

c. Product and Capital Conversion Costs

Amended energy conservation standards could cause manufacturers to incur conversion costs to bring their production facilities and equipment designs into compliance. DOE evaluated the level of conversion-related expenditures that would be needed to comply with each considered efficiency level in each product class. For the MIA, DOE classified these conversion costs into two major groups: (1) product conversion costs; and (2) capital conversion costs. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new compliant product designs can be fabricated and assembled.

To evaluate the level of product conversion costs manufacturers would likely incur to comply with amended energy conservation standards, DOE relied on feedback from manufacturer interviews. DOE contractors conducted interviews with manufacturers of gas-fired storage, gas-fired instantaneous, oil-fired storage, electric storage, electric instantaneous, tabletop, and grid-enabled water heaters. The interviewed manufacturers account for approximately 84 percent of sales of consumer water heaters covered by this rulemaking. DOE used market share weighted feedback from interviews to extrapolate industry-level product conversion costs from the manufacturer feedback.

To evaluate the level of capital conversion costs manufacturers would likely incur to comply with amended energy conservation standards, DOE relied on estimates of equipment and tooling from its engineering analysis and on feedback from manufacturer interviews. DOE modeled the green field investments required for a major manufacturer to set up a production facility. The investment figures included capital required for manufacturing equipment, tooling, conveyors, and facility. DOE then modeled the incremental investment required by more stringent standards. DOE multiplied the incremental investment by the number of ''major'' (*i.e.,* high-volume) manufacturers. These investment levels aligned with feedback from interviews. Additionally, DOE determined that smaller manufacturers would have lower investment levels given their lower production volumes, relative to ''major'' manufacturers, and accounted for those lower investments for manufacturers with lower market share. DOE updated its conversion cost estimates for the product classes analyzed in this final rule by incorporating refined equipment, tooling, conveyor, and space estimates generated from the product teardown analysis, but otherwise maintained its

conversion cost methodology from the July 2023 NOPR.

In general, DOE assumes all conversion-related investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard. The conversion cost figures used in the GRIM can be found in section V.B.2 of this document. For additional information on the estimated product and capital conversion costs, *see* chapter 12 of the final rule TSD.

d. Manufacturer Markup Scenarios

MSPs include direct manufacturing production costs (*i.e.,* labor, materials, and overhead estimated in DOE's MPCs) and all non-production costs (*i.e.,* SG&A, R&D, and interest), along with profit. To calculate the MSPs in the GRIM, DOE applied manufacturer markups to the MPCs estimated in the engineering analysis for each analyzed product class and efficiency level. Modifying these manufacturer markups in the standards case yields different sets of impacts on manufacturers. For the MIA, DOE modeled two standards-case manufacturer markup scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of amended energy conservation standards: (1) a preservation of gross margin percentage scenario; and (2) a preservation of operating profit scenario. These scenarios lead to different manufacturer markup values that, when applied to the MPCs, result in varying revenue and cash flow impacts.

Under the preservation of gross margin percentage scenario, DOE applied a single uniform ''gross margin percentage'' across all efficiency levels, which assumes that manufacturers would be able to maintain the same amount of profit as a percentage of revenues at all efficiency levels within a product class. As MPCs increase with efficiency, this scenario implies that the per-unit dollar profit will increase. DOE estimated gross margin percentages of 24 percent for the gas-fired storage water heaters, 22 percent for electric storage water heaters, and 23 percent for oil-fired storage water heaters.[157] Manufacturers tend to believe it is optimistic to assume that they would be able to maintain the same gross margin percentage as their production costs increase, particularly for minimally efficient products. Therefore, this scenario represents a high bound to industry profitability under an amended energy conservation standard.

Under the preservation of operating profit scenario, DOE modeled a situation in which manufacturers are not able to increase per-unit operating profit in proportion to increases in MPCs. In the preservation of operating profit scenario, as the cost of production goes up under a standards case, manufacturers are generally required to reduce their manufacturer markups to a level that maintains base-case operating profit. DOE implemented this scenario in the GRIM by lowering the manufacturer markups at each TSL to yield approximately the same earnings before interest and taxes in the standards case as in the no-new-standards case in the year after the compliance date of the amended standards. The implicit assumption behind this scenario is that the industry can only maintain its operating profit in absolute dollars after the standard.

A comparison of industry financial impacts under the two scenarios is presented in section V.B.2.a of this document.

3. Discussion of MIA Comments

a. Conversion Costs

In response to the July 2023 NOPR, BWC submitted written comments about the accuracy of DOE's conversion cost estimates. BWC stated that it continues to appreciate DOE considering conversion costs as part of its analysis. However, BWC asserted that the industry conversion costs DOE estimated in the July 2023 NOPR are understated and far lower than the cost that manufacturers will realistically incur. BWC offered to discuss these findings during confidential conversation with the consultants that DOE engaged for this rulemaking. (BWC, 1164 at pp. 4–5)

AHRI asserted that under the standards proposed in the July 2023 NOPR, manufacturers would need to produce exponentially more heat pump water heaters, requiring many manufacturers to build new plants, retrofit existing lines, or both. Additionally, AHRI expressed concern that supply chains and labor shortages could compound these difficulties. (AHRI, No. 1167 at p. 12)

To evaluate the level of conversion costs industry would likely incur to comply with potential amended energy conservation standards, DOE relied on feedback from confidential manufacturer interviews and estimates of equipment, tooling, conveyor, and space from the engineering and product teardown analyses. DOE interviewed a range of manufacturers in advance of the July 2023 NOPR, which together account for approximately 84 percent of U.S. sales of consumer water heaters covered by this final rule. For this final rule, DOE reexamined its conversion cost estimates from the July 2023 NOPR. For all product classes analyzed in this final rule, DOE updated its conversion cost estimates by incorporating refined equipment, tooling, conveyor, and space estimates generated from the product teardown analysis, but otherwise maintained its conversion cost methodology from the July 2023 NOPR. *See* section IV.J.2.c of this document and chapter 12 of the final rule TSD for additional details on DOE's conversion cost methodology and investment estimates.

In response to the July 2023 NOPR, AHRI stated that it supported the inclusion of amortization of product conversion costs under standards into the projected MSP in a recent rulemaking for microwave ovens, and urges DOE to use this methodology in all rulemakings.[158] AHRI further asked DOE to explain the justification for amortizing conversion costs in one instance but not in all. (AHRI, No. 1167 at pp. 20–21)

DOE models different standards-case manufacturer markup scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of amended energy conservation standards. The analyzed manufacturer markup scenarios vary by rulemaking as they are meant to reflect the potential range of financial impacts for manufacturers of the specific covered product or equipment. For the July 2023 NOPR, DOE applied a preservation of gross margin percentage scenario to reflect an upper bound to industry profitability under amended standards and a preservation of operating profit scenario to reflect a lower bound of industry profitability under amended standards. 88 FR 49058, 49128. For consumer water heaters, manufacturing more efficient products is generally more expensive than manufacturing baseline or minimally efficient products, as reflected by the MPCs estimated in the engineering analysis (*see* section IV.C.1.e of this document). Under the preservation of gross margin scenario for consumer

[157] The gross margin percentage of 24 percent for gas-fired storage is based on a manufacturer markup of 1.31. The gross margin percentage of 22 percent for electric storage is based on a manufacturer markup of 1.28. The gross margin percentage of 23 percent for oil-fired storage is based on a manufacturer markup of 1.30.

[158] Technical Support Document: Energy Efficiency Program For Commercial And Industrial Equipment: Microwave Ovens. Available at *www.regulations.gov/document/EERE-2017-BT-STD-0023-0022*.

water heaters, incremental increases in MPCs at higher efficiency levels result in an increase in per-unit dollar profit per unit sold. As shown in Table V.18, under the preservation of gross margin scenario, the standards case INPV increases relative to the no-new-standards case INPV for the adopted TSL (*i.e.,* TSL 2). This implies that the increase in cashflow from the higher MSP is outweighed by the estimated conversion costs at the adopted level. In other words, under the preservation of gross margin scenario, the consumer water heater industry *recovers* conversion costs incurred as a result of amended standards. The approach used in the microwave ovens rulemaking (*i.e.,* a conversion cost recovery scenario) modeled a scenario in which manufacturers recover investments through an increase in their manufacturer markup. 88 FR 39912, 39935. DOE implemented this scenario in the microwave ovens GRIM by calibrating the standards case manufacturer markups for each product class at each efficiency level to cause manufacturer INPV in the standards cases to be equal to the INPV in the no-new-standards case. Thus, if DOE applied a conversion cost recovery scenario in this rulemaking, the potential change in INPV at the adopted TSL would be within the range of estimated impacts resulting from the preservation of gross margin scenario and preservation of operating profit scenario. As such, DOE maintained the two standards-case manufacturer markup scenarios used in the July 2023 NOPR for this final rule as they most appropriately reflect the upper (least severe) and lower (more severe) impacts to manufacturer profitability under amended standards.

b. Cumulative Regulatory Burden

In response to the July 2023 NOPR, AHRI submitted written comments regarding cumulative regulatory burden. AHRI urged DOE to consider the high volume of regulatory activity that directly affects manufacturers of consumer water heaters and expressed concern that DOE was rushing to publish recent rulemakings, risking significant revision that will prolong uncertainty, confuse consumers, and potentially undermine broader policy goals. AHRI cited standards and test procedure rulemakings in regards not only to consumer water heaters, but also to consumer boilers, consumer pool heaters, a final rule pertaining to standards for commercial water heaters, small electric motors, commercial and industrial pumps, commercial and multifamily high-rise and low-rise residential, as well as low and zero NOx actions by California Air Resources Board (''CARB'') and individual air quality management districts, State building code changes, ENERGY STAR potentially setting a max-tech requirement for gas storage water heaters, and Federal and State refrigerant regulations as regulatory actions that impact consumer water heater manufacturers. (AHRI, No. 1167 at pp. 7–9)

In response to the July 2023 NOPR, BWC commented that the impact of cumulative regulatory burden experienced by manufacturers is not limited to conversion costs, but also to the preparations manufacturers must undergo in order to respond to proposed rules. BWC further stated that DOE has promulgated several major rulemakings that will directly impact the products that BWC manufactures, in addition to actions undertaken by other governments and programs, and that the ability of manufacturers to draw on outside resources for assistance will be severely limited by the concurrent needs of many manufacturers across rulemakings, particularly in the case of third-party laboratories. BWC stated that due to the burden this rulemaking will place on third-party labs, as well as the general burden of multiple concurrent ongoing regulatory actions, BWC strongly disagreed with DOE's decision not to consider test rulemakings as part of its analysis. (BWC, No. 1164 at pp. 24–26) BWC also stated that, due to concurrent regulatory actions regarding energy efficiency at both the State and Federal levels, it disagreed with DOE's conclusion in section VI.B.5 of the July 2023 NOPR that there are no rules or regulations that duplicate, overlap, or conflict with this proposed rule and encouraged DOE to account for all of these issues, ideally allowing manufacturers more time to review and respond to DOE rulemakings when requested. (BWC, No. 1164 at p. 24)

DOE analyzes cumulative regulatory burden pursuant to section 13(g) of Appendix A. 10 CFR part 430, subpart C, appendix A, section 13(g); 10 CFR 431.4. DOE notes some of the rules (*e.g.,* consumer boilers) detailed by AHRI are not finalized. Regulations that are not yet finalized are not considered as cumulative regulatory burden, as the timing, cost, and impacts of unfinalized rules are speculative. However, to aid stakeholders in identifying potential cumulative regulatory burden, DOE does list rulemakings that have proposed rules, which have tentative compliance dates, compliance levels, and compliance cost estimates. The results of this analysis can be found in section V.B.2.e of this document. As shown in Table V.21, DOE analyzed the consumer boilers, consumer pool heaters, and commercial water heaters rulemakings as part of its cumulative regulatory burden analysis. Regarding small electric motors, DOE published a notice of proposed determination (''NOPD'') on February 6, 2023. As such, DOE would not consider the small electric motors rulemaking as contributing to cumulative regulatory burden since DOE did not propose to amend its energy conservation standards. 88 FR 7629. Regarding commercial and industrial pumps, DOE similarly would not consider the commercial and industrial pumps rulemaking as contributing to cumulative regulatory burden since DOE did not propose to amend its energy conservations standards.

Regarding AHRI's comment about ultra-low NO_X and zero NO_X regulations, DOE notes that in its analysis of cumulative regulatory burden, DOE considers Federal, product specific regulations that have compliance dates within 3 years of one another. DOE is not aware of any Federal or State ultra-low NO_X or zero NO_X regulations specific to consumer water heaters with compliance dates within the 7-year cumulative regulatory burden timeframe (2027–2033).[159] DOE notes that certain localities (*i.e.,* California Air Districts) have adopted regulations requiring ultra-low NO_X consumer water heaters. DOE accounts for the portion of ultra-low NO_X shipments in its analysis. DOE notes that a California Air District—the Bay Area Air Quality Management District Board of Directors—has adopted amendments to eliminate NO_X emissions from certain gas-fired consumer water heaters beginning in 2027.[160] There are currently no natural gas-fired water heaters on the market that would meet the zero NO_X standards, though manufacturers may choose to develop them. Regarding building code changes in states

[159] California Air Resources Board (''CARB'') has stated that it is committed to explore developing and proposing zero-emission GHG standards for new space and water heaters sold in California as part of the 2022 State Strategy for the State Implementation Plan adopted in September 2022. However, at the time of issuance, CARB has not proposed or adopted such standards for consumer water heaters. Additional information is available at: *ww2.arb.ca.gov/our-work/programs/zero-emission-appliance-standards/about.* (Last accessed Nov. 29, 2023).

[160] Available at: *www.baaqmd.gov/~/media/dotgov/files/rules/reg-9-rule-4-nitrogen-oxides-from-fan-type-residential-central-furnaces/2021-amendments/documents/20230315_rg0906-pdf.pdf?rev=436fcdb037324b0b8f0c981d869e684d&sc_lang=en.*

requiring heat pump water heating, DOE's accounts for increased incentives for higher efficiency equipment and electrification efforts in its shipments analysis. *See* section IV.H.1 of this document for additional information on product efficiency trends.

Regarding Federal and State refrigerant regulations, EPA published a final rule pertaining to the phaseout of HFC refrigerants with high global warming potential (''GWP'') in specific sectors or subsectors on October 24, 2023. 88 FR 73098. However, EPA does not adopt provisions to limit the manufacture of heat pump water heaters with HFC refrigerants in that final rule. EPA restricts the use of HFCs and blends containing HFCs with a GWP of 150 or greater beginning January 1, 2025 for all foam subsectors, including rigid polyurethane for use in water heaters. As discussed in chapter 3 of the final rule TSD, DOE found that water heater manufacturers have already begun transitioning to alternative blowing agents for insulation foam. Additionally, DOE notes that the January 1, 2025 compliance date falls outside the cumulative regulatory burden timeframe. Regarding the comments about EPA's new ENERGY STAR levels, DOE notes that participating in ENERGY STAR is voluntary and not considered in DOE's analysis of cumulative regulatory burden.

Regarding BWC's request that DOE not discount the costs for stakeholders to review rulemakings, although appreciative that monitoring and responding to rulemakings does impose costs for stakeholders, DOE believes that this is outside the scope of analysis for individual product rulemakings. Because EPCA requires DOE to establish and maintain the energy conservation program for consumer products and to periodically propose new and amended standards (or propose that standards for products do not need to be amended) and test procedures, DOE considers this rulemaking activity to be part of the analytical baseline (*i.e.,* in the no-new-standards case and the standards case). That is, these activities (*e.g.,* reviewing proposed rules or proposed determinations) would exist regardless of the regulatory option that DOE adopts through a rulemaking and would be independent from the conversion costs required to adapt product designs and manufacturing facilitates to meet an amended standard.

c. Manufacturing Capacity

A.O. Smith noted that while it supports the intent of DOE's proposal to move the minimum energy conservation standards for a subset of consumer water heaters, A.O. Smith remains concerned with the feasibility of implementing these dramatic shifts in the time frame proposed. A.O. Smith commented that the July 2023 NOPR would drive an unprecedented transformation for the water heater industry, impacting manufacturers, its supply chain, distributors, plumbers, and installers. A.O. Smith noted that it invested significant capital in its heat pump manufacturing facility following the April 2010 Final Rule in anticipation of a ramp up in demand, which did not materialize. A.O. Smith noted it plans to make the necessary investments to transition to heat pump water heaters, but expressed concern that uncertainty in the market may place these investments at risk. A.O. Smith further expressed concern about the availability of the necessary components at the scale the July 2023 NOPR would require, as well as the current shortage of workers with the necessary skills and experience to manufacture heat pump water heaters. (A.O. Smith, No. 1182 at pp. 17–19) Gas Association Commenters questioned the realism of ramping up heat pump water heater capacity, stating that DOE did not provide sufficient analysis showing how manufacturers could produce an additional 3 to 4 million electric heat pump water heaters per year. (Gas Association Commenters, No. 1181 at p. 33)

Rheem commented it is committed to transitioning the majority of its electric storage water heaters to heat pump water heaters within the 5-year compliance period, which Rheem views as sufficiently long to complete the conversion. Rheem recommended that DOE and other Federal agencies promote awareness of this rulemaking and the future of water heating in the United States, particularly among plumbers, contractors, and consumers. (Rheem, No. 1177 at p. 10)

DOE recognizes that the standards proposed in the July 2023 NOPR and adopted in this final rule would require investments to update production facilities and redesign products. DOE accounts for product and capital conversion costs in the MIA. *See* section IV.J.2.c of this document. Regarding industry's ability to ramp up production within the 5-year compliance period, DOE believes that having a major manufacturer sign on to the Joint Stakeholder Recommendation is a testament to industry's ability to ramp up capacity to produce the volumes necessary to support the heat pump water heater market that will be required by TSL 2 by the compliance date of the amended standards. Regarding the uncertainty in the market related to heat pump water heaters, DOE recognizes that amended standards could lead to shifts in the market towards smaller electric storage water heater sizes which can meet the adopted standard levels without the use of heat pump technology. DOE accounts for the potential market shift in its shipments analysis, a key input to the GRIM. For this final rule, DOE assumes a portion of consumers would select one or more smaller electric storage water heaters with or without a ''booster'' instantaneous water heater instead of replacing a larger electric storage water heater with a heat pump water heater under amended standards, *see* IV.G.1 of this document for additional details. DOE notes that measures such as requiring high-temperature testing will be required for certain electric storage water heaters. As discussed in section V.D.1 of this document, the use of high-temperature testing will be required for small electric resistance water heaters that are able to continuously store water at a higher temperature than the delivered water temperature setpoint since DOE expects that consumers will use the high-temperature mode as part of the regular operation of their water heater. By implementing the high-temperature test method for certain smaller electric storage water heaters designed to compete with larger electric storage water heaters by operating at a higher temperature, DOE will ensure that representations for such products are accurate and provide consumers with the means to directly compare these products to the larger water heaters they will likely compete with. In other words, the high-temperature test method would create an equivalent basis of comparison for products which can offer the same effective storage capacity. *See* section V.D.1 of this document for information on high-temperature testing.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the impacts of potential standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the reductions in emissions of other gases due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion.

The analysis of electric power sector emissions of CO_2, NO_X, SO_2, and Hg

uses emissions intended to represent the marginal impacts of the change in electricity consumption associated with amended or new standards. The methodology is based on results published for the *AEO,* including a set of side cases that implement a variety of efficiency-related policies. The methodology is described in appendix 13A in the final rule TSD. The analysis presented in this notice uses projections from *AEO2023.* Power sector emissions of CH_4 and N_2O from fuel combustion are estimated using Emission Factors for Greenhouse Gas Inventories published by the EPA.[161]

The on-site operation of consumer water heaters involves combustion of fossil fuels and results in emissions of CO_2, NO_X, SO_2, CH_4, and N_2O where these products are used. Site emissions of these gases were estimated using Emission Factors for Greenhouse Gas Inventories and, for NO_X and SO_2, emissions intensity factors from an EPA publication.[162]

FFC upstream emissions, which include emissions from fuel combustion during extraction, processing, and transportation of fuels, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2, are estimated based on the methodology described in chapter 15 of the final rule TSD.

The emissions intensity factors are expressed in terms of physical units per MWh or MMBtu of site energy savings. For power sector emissions, specific emissions intensity factors are calculated by sector and end use. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

BWC recommended including emissions as a result of increased manufacturing of parts at a higher standard level, such as compressors, evaporators, and other parts for heat pump water heaters. Additionally, BWC mentioned that the leaking of refrigerant in heat pump water heaters may result in additional unaccounted-for emissions and BWC is discouraged that DOE has already declined to take the emission from refrigerant leakages into account in the Energy Conservation Standards for Consumer Pool Heater Final Rule. BWC commented that ASHRAE standards are in development to measure refrigerant leakage expectations for heat pump products that could be leveraged in future DOE analysis. (BWC No. 1164 at p. 5)

DOE's emissions analysis is guided by section 16.h of Appendix A,[163] which states that DOE calculates emissions reductions of carbon dioxide, sulfur dioxide, nitrogen oxides, methane, nitrous oxides, and mercury likely to be avoided based on an analysis that includes specific components. These components only include direct emissions from use of covered products and emissions in the full-fuel-cycle. DOE has never considered air pollutant emissions associated with manufacturing or transport of products or emissions of refrigerants. Even if DOE considered the emissions from refrigerants, DOE estimates that refrigerant leakages in heat pump water heaters will be rare and can be prevented with regular inspection and repair, which DOE accounts for as repair and maintenance costs in its LCC analysis. If refrigerant leaks do occur, the associated emissions increase would still be negligible compared to the emissions savings of this rule. Accounting for refrigerant leakage would not change the economic justification of the rule.

1. Air Quality Regulations Incorporated in DOE's Analysis

DOE's no-new-standards case for the electric power sector reflects the *AEO,* which incorporates the projected impacts of existing air quality regulations on emissions. *AEO2023* reflects, to the extent possible, laws and regulations adopted through mid-November 2022, including the emissions control programs discussed in the following paragraphs the emissions control programs discussed in the following paragraphs, and the Inflation Reduction Act.[164]

SO_2 emissions from affected electric generating units (''EGUs'') are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (''DC''). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from numerous States in the eastern half of the United States are also limited under the Cross-State Air Pollution Rule (''CSAPR''). 76 FR 48208 (Aug. 8, 2011). CSAPR requires these States to reduce certain emissions, including annual SO_2 emissions, and went into effect as of January 1, 2015.[165] The *AEO* incorporates implementation of CSAPR, including the update to the CSAPR ozone season program emission budgets and target dates issued in 2016. 81 FR 74504 (Oct. 26, 2016). Compliance with CSAPR is flexible among EGUs and is enforced through the use of tradable emissions allowances. Under existing EPA regulations, for states subject to SO_2 emissions limits under CSAPR, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by another regulated EGU.

However, beginning in 2016, SO_2 emissions began to fall as a result of the Mercury and Air Toxics Standards (''MATS'') for power plants.[166] 77 FR 9304 (Feb. 16, 2012). The final rule establishes power plant emission standards for mercury, acid gases, and non-mercury metallic toxic pollutants. Because of the emissions reductions under the MATS, it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by another regulated EGU. Therefore, energy conservation standards that decrease electricity generation will generally reduce SO_2 emissions. DOE estimated SO_2 emissions reduction using emissions factors based on *AEO2023.*

[161] Available at *www.epa.gov/sites/production/files/2021–04/documents/emission-factors_apr2021.pdf* (last accessed Dec. 1, 2023).

[162] U.S. Environmental Protection Agency. External Combustion Sources. In *Compilation of Air Pollutant Emission Factors.* AP–42. Fifth Edition. Volume I: Stationary Point and Area Sources. Chapter 1. Available at *www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors#Proposed/* (last accessed July 12, 2021).

[163] Appendix A to Subpart C of Part 430—Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment. *https://www.ecfr.gov/current/title-10/chapter-II/subchapter-D/part-430/subpart-C/appendix-Appendix%20A%20to%20Subpart%20C%20of%20Part%20430.*

[164] For further information, see the Assumptions to *AEO2023* report that sets forth the major assumptions used to generate the projections in the Annual Energy Outlook. Available at *www.eia.gov/outlooks/aeo/assumptions/* (last accessed Dec. 1, 2023).

[165] CSAPR requires States to address annual emissions of SO_2 and NO_X, precursors to the formation of fine particulate matter (''$PM_{2.5}$'') pollution, in order to address the interstate transport of pollution with respect to the 1997 and 2006 $PM_{2.5}$ National Ambient Air Quality Standards (''NAAQS''). CSAPR also requires certain States to address the ozone season (May–Sept.) emissions of NO_X, a precursor to the formation of ozone pollution, in order to address the interstate transport of ozone pollution with respect to the 1997 ozone NAAQS. 76 FR 48208 (Aug. 8, 2011). EPA subsequently issued a supplemental rule that included an additional five States in the CSAPR ozone season program; 76 FR 80760 (Dec. 27, 2011) (Supplemental Rule), and EPA issued the CSAPR Update for the 2008 ozone NAAQS. 81 FR 74504 (Oct. 26, 2016).

[166] In order to continue operating, coal power plants must have either flue gas desulfurization or dry sorbent injection systems installed. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions.

CSAPR also established limits on NO_X emissions for numerous States in the eastern half of the United States. Energy conservation standards would have little effect on NO_X emissions in those States covered by CSAPR emissions limits if excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other EGUs. In such case, NOx emissions would remain near the limit even if electricity generation goes down. Depending on the configuration of the power sector in the different regions and the need for allowances, however, NO_X emissions might not remain at the limit in the case of lower electricity demand. That would mean that standards might reduce NOx emissions in covered States. Despite this possibility, DOE has chosen to be conservative in its analysis and has maintained the assumption that standards will not reduce NO_X emissions in States covered by CSAPR. Standards would be expected to reduce NO_X emissions in the States not covered by CSAPR. DOE used *AEO2023* data to derive NO_X emissions factors for the group of States not covered by CSAPR.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would be expected to slightly reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO2023*, which incorporates the MATS.

L. Monetizing Emissions Impacts

As part of the development of this final rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from each of the TSLs considered. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the projection period for each TSL. This section summarizes the basis for the values used for monetizing the emissions benefits and presents the values considered in this final rule.

To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

1. Monetization of Greenhouse Gas Emissions

DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the SC (''SC'') of each pollutant (*e.g.,* SC–CO_2). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services.

DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive orders, and DOE would reach the same conclusion presented in this rulemaking in the absence of the social cost of greenhouse gases. That is, the social costs of greenhouse gases, whether measured using the February 2021 interim estimates presented by the IWG on the Social Cost of Greenhouse Gases or by another means, did not affect the rule ultimately adopted by DOE.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions using SC–GHG values that were based on the interim values presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990,* published in February 2021 by the IWG (''February 2021 SC–GHG TSD''). The SC–GHG is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, the SC–GHG includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHG therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHG is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH4 emissions.

As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agreed that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates are developed reflecting the latest, peer-reviewed science. *See* 87 FR 78382, 78406–78408 for discussion of the development and details of the IWG SC–GHG estimates.

There are a number of limitations and uncertainties associated with the SC–GHG estimates. First, the current scientific and economic understanding of discounting approaches suggests discount rates appropriate for intergenerational analysis in the context of climate change are likely to be less than 3 percent, near 2 percent or lower.[167] Second, the IAMs used to produce these interim estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature and the science underlying their ''damage functions''—*i.e.,* the core parts of the IAMs that map global mean temperature changes and other physical impacts of climate change into economic (both market and nonmarket) damages—lags behind the most recent research. For example, limitations include the incomplete treatment of catastrophic and non-catastrophic impacts in the integrated assessment models, their incomplete treatment of adaptation and technological change, the incomplete way in which inter-regional and intersectoral linkages are modeled, uncertainty in the extrapolation of damages to high temperatures, and inadequate representation of the relationship between the discount rate and uncertainty in economic growth over long time horizons. Likewise, the socioeconomic and emissions scenarios used as inputs to the models do not reflect new information from the last decade of scenario generation or the full range of projections. The modeling limitations do not all work in the same direction in terms of their influence on the SC–CO_2 estimates. However, as discussed in the February 2021 SC–GHG TSD, the IWG has recommended that, taken together, the limitations suggest that the interim SC–GHG estimates used in this final rule likely underestimate the damages from GHG emissions. DOE concurs with this assessment.

DOE's derivations of the SC–CO_2, SC–N_2O, and SC–CH_4 values used for this

[167] Interagency Working Group on Social Cost of Greenhouse Gases. 2021. Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990. February. United States Government. Available at *www.whitehouse.gov/briefing-room/blog/2021/02/26/a-return-to-science-evidence-based-estimates-of-the-benefits-of-reducing-climate-pollution/.*

final rule are discussed in the following sections, and the results of DOE's analyses estimating the benefits of the reductions in emissions of these GHGs are presented in section V.B.6 of this document.

The Attorney General of TN asserted that the standards improperly rely on faulty social-cost-of-carbon estimate. (Attorney General of TN, No. 1149 at p. 2) In response, DOE noted that the Interagency Working Group's (IWG) Social Costs of Greenhouse Gas (SC–GHG) estimates were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. The IWG's 2016 TSD[168] and the 2017 National Academies report provide detailed discussions of the ways in which the modeling underlying the development of the SC–GHG estimates addressed quantified sources of uncertainty.[169] In the February 2021 SC–GHG TSD, the IWG stated that the models used to produce the interim estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature. In the judgment of the IWG, these and other limitations suggest that the range of four interim SC–GHG estimates presented in the TSD likely underestimate societal damages from GHG emissions.

DOE is aware that in December 2023, EPA issued a new set of SC–GHG estimates in connection with a final rulemaking under the Clean Air Act. [170] As DOE had used the IWG interim values in proposing this rule and is currently reviewing the updated 2023 SC–GHG values, for this final rule, DOE used these updated 2023 SC–GHG values to conduct a sensitivity analysis of the value of GHG emissions reductions. DOE notes that because EPA's estimates are considerably higher than the IWG's interim SC–GHG values applied for this final rule, an analysis that uses the EPA's estimates results in significantly greater climate-related benefits. However, such results would not affect DOE's decision in this final rule. As stated elsewhere in this document, DOE would reach the same conclusion regarding the economic justification of the standards presented in this final rule without considering the IWG's interim SC–GHG values, which DOE agrees are conservative estimates. For the same reason, if DOE were to use EPA's higher SC–GHG estimates, they would not change DOE's conclusion that the standards are economically justified.

a. Social Cost of Carbon

The SC–CO_2 values used for this final rule were based on the values developed for the February 2021 SC–GHG TSD, which are shown in Table IV.30 in 5-year increments from 2020 to 2050. The set of annual values that DOE used, which was adapted from estimates published by EPA,[171] is presented in appendix 14A of the final rule TSD. These estimates are based on methods, assumptions, and parameters identical to the estimates published by the IWG (which were based on EPA modeling) and include values for 2051 to 2070. DOE expects additional climate benefits to accrue for products still operating after 2070, but a lack of available SC–CO_2 estimates for emissions years beyond 2070 prevents DOE from monetizing these potential benefits in this analysis.

Table IV.30. Annual SC-CO_2 Values from 2021 Interagency Update, 2020–2050 (2020$ per Metric Ton CO_2)

Year	Discount Rate and Statistic			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. DOE adjusted the values to 2022$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case.

b. Social Cost of Methane and Nitrous Oxide

The SC–CH_4 and SC–N_2O values used for this final rule were based on the values developed for the February 2021 SC–GHG TSD. Table IV.31 shows the updated sets of SC–CH_4 and SC–N_2O estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in appendix 14A of the final rule TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC- N_2O values, as recommended by the IWG. DOE derived values after 2050 using the approach described above for the SC–CO_2.

[168] Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Technical Update on the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. August 2016. (Last accessed January 18, 2022.) *www.epa.gov/sites/default/files/2016–12/documents/sc_co2_tsd_august_2016.pdf.*

[169] An overview is presented in section 4.1 of the February 2021 SC–GHG TSD.

[170] See *www.epa.gov/environmental-economics/scghg.*

[171] *See* EPA, *Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis,* Washington, DC, December 2021. Available at *nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1013ORN.pdf* (last accessed Dec. 1, 2023).

Table IV.31. Annual SC-CH_4 and SC-N_2O Values from 2021 Interagency Update, 2020–2050 (2020$ per Metric Ton)

Year	SC-CH_4				SC-N_2O			
	Discount Rate and Statistic				Discount Rate and Statistic			
	5%	3%	2.5%	3%	5%	3%	2.5 %	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1500	2000	3900	5800	18000	27000	48000
2025	800	1700	2200	4500	6800	21000	30000	54000
2030	940	2000	2500	5200	7800	23000	33000	60000
2035	1100	2200	2800	6000	9000	25000	36000	67000
2040	1300	2500	3100	6700	10000	28000	39000	74000
2045	1500	2800	3500	7500	12000	30000	42000	81000
2050	1700	3100	3800	8200	13000	33000	45000	88000

DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. DOE adjusted the values to 2022$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case.

c. Sensitivity Analysis Using Updated SC–GHG Estimates

In December 2023, EPA issued an updated set of SC–GHG estimates (2023 SC–GHG) in connection with a final rulemaking under the Clean Air Act.[172] These estimates incorporate recent research and address recommendations of the National Academies (2017) and comments from a 2023 external peer review of the accompanying technical report. For this rulemaking, DOE used these updated 2023 SC–GHG values to conduct a sensitivity analysis of the value of GHG emissions reductions associated with alternative standards for consumer water heaters. This sensitivity analysis provides an expanded range of potential climate benefits associated with amended standards. The final year of EPA's new 2023 SC–GHG estimates is 2080; therefore, DOE did not monetize the climate benefits of GHG emissions reductions occurring after 2080.

The overall climate benefits are greater when using the higher, updated 2023 SC–GHG estimates, compared to the climate benefits using the older IWG SC–GHG estimates. The results of the sensitivity analysis are presented in appendix 14C of the final rule TSD.

[172] *See www.epa.gov/environmental-economics/scghg.*

2. Monetization of Other Emissions Impacts

For the final rule, DOE estimated the monetized value of NO_X and SO_2 emissions reductions from electricity generation using benefit-per-ton estimates for that sector from the EPA's Benefits Mapping and Analysis Program.[173] DOE used EPA's values for $PM_{2.5}$-related benefits associated with NO_X and SO_2 and for ozone-related benefits associated with NO_X for 2025 and 2030, and 2040, calculated with discount rates of 3 percent and 7 percent. DOE used linear interpolation to define values for the years not given in the 2025 to 2040 period; for years beyond 2040, the values are held constant. DOE combined the EPA regional benefit-per-ton estimates with regional information on electricity consumption and emissions from *AEO2023* to define weighted-average national values for NO_X and SO_2 (*see* appendix 14B of the final rule TSD).

DOE also estimated the monetized value of NO_X and SO_2 emissions reductions from site use of natural gas in consumer water heaters using benefit per ton estimates from the EPA's Benefits Mapping and Analysis Program. Although none of the sectors covered by EPA refers specifically to residential and commercial buildings, the sector called ''area sources'' would be a reasonable proxy for residential and commercial buildings.[174] The EPA document provides high and low estimates for 2025 and 2030 at 3- and 7-percent discount rates.[175] DOE used the same linear interpolation and extrapolation as it did with the values for electricity generation.

DOE multiplied the site emissions reduction (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

M. Utility Impact Analysis

The utility impact analysis estimates the changes in installed electrical capacity and generation projected to result for each considered TSL. The analysis is based on published output from the NEMS associated with *AEO2023*. NEMS produces the *AEO* Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. For the current analysis, impacts are quantified by comparing the levels of electricity sector generation, installed capacity, fuel consumption and emissions in the *AEO2023* Reference case and various side cases. Details of the methodology are provided in the appendices to chapter 15 of the final rule TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation, primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of potential new or amended energy conservation standards. The utility

[173] U.S. Environmental Protection Agency. Estimating the Benefit per Ton of Reducing Directly-Emitted $PM_{2.5}$, $PM_{2.5}$ Precursors and Ozone Precursors from 21 Sectors. Available at *www.epa.gov/benmap/estimating-benefit-ton-reducing-directly-emitted-pm25-pm25-precursors-and-ozone-precursors* (last accessed Dec. 1, 2023).

[174] ''Area sources'' represents all emission sources for which states do not have exact (point) locations in their emissions inventories. Because exact locations would tend to be associated with larger sources, ''area sources'' would be fairly representative of small dispersed sources like homes and businesses.

[175] ''Area sources'' are a category in the 2018 document from EPA but are not used in the 2021 document cited above. *See: www.epa.gov/sites/default/files/2018-02/documents/source apportionmentbpttsd_2018.pdf.*

analysis also estimates the impact on gas utilities in terms of projected changes in natural gas deliveries to consumers for each TSL.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the products subject to standards. The MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more-efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by consumers on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on the products to which the new standards apply and other goods and services, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (''BLS''). BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[176] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.,* the utility sector) to more labor-intensive sectors (*e.g.,* the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this final rule using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 4 (''ImSET'').[177] ImSET is a special-purpose version of the ''U.S. Benchmark National Input-Output'' (''I–O'') model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and that there are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may over-estimate actual job impacts over the long run for this rule. Therefore, DOE used ImSET only to generate results for near-term timeframes (2030–2034), where these uncertainties are reduced. For more details on the employment impact analysis, see chapter 16 of the final rule TSD.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for consumer water heaters. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for consumer water heaters, and the standards levels that DOE is adopting in this final rule. Additional details regarding DOE's analyses are contained in the final rule TSD supporting this document.

A. Trial Standard Levels

In general, DOE typically evaluates potential new or amended standards for products and equipment by grouping individual efficiency levels for each class into TSLs. Use of TSLs allows DOE to identify and consider manufacturer cost interactions between the product classes, to the extent that there are such interactions, and price elasticity of consumer purchasing decisions that may change when different standard levels are set. The changes to the shipments model will drive differential national impacts both on the consumer and manufacturer side that are more realistic of how the market may change in response to amended DOE standards.

In the analysis conducted for this final rule, DOE analyzed the benefits and burdens of six TSLs for consumer water heaters. DOE developed TSLs that combine efficiency levels for each analyzed product class. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the final rule TSD.

Table V.1 presents the TSLs and the corresponding efficiency levels that DOE has identified for potential amended energy conservation standards for consumer water heaters. TSL 6 represents the maximum technologically feasible (''max-tech'') energy efficiency for all product classes. TSL 5 represents the highest efficiency level for each product class with a positive NPV at the 7-percent discount rate for all product classes. For gas-fired gas storage water heater, the NPV at the 7-percent discount rate is negative from EL 3 to EL 5. Therefore, TSL 5 is constructed by reducing the efficiency level for gas-fired storage water heaters (*i.e.,* EL 2) and with the same efficiency level for all other product classes compared to the max-tech. TSL 4 represents the highest efficiency level for each product class with the maximum NPV at the 7-percent discount rate for all product classes. Therefore, TSL 4 is constructed by reducing the efficiency level for electric storage water heaters (*i.e.,* EL 2). TSL 3 represents an interim energy efficiency level between the Joint Stakeholder Recommendation (*i.e.,* TSL 2) and TSL 4. TSL 2 represents the Joint Stakeholder Recommendation. Finally, because EL 1 is the lowest analyzed efficiency level above baseline, TSL 1 is constructed with EL 1 for all product classes, except for electric storage water heaters (20 gal $\leq V_{eff} \leq$ 55 gal) which is set equal to the current standard level.

[176] *See* U.S. Department of Commerce—Bureau of Economic Analysis. *Regional Input-Output Modeling System (RIMS II) User's Guide.* Available at: *www.bea.gov/resources/methodologies/RIMSII-user-guide* (last accessed Jan. 18, 2024).

[177] Livingston, O.V., S.R. Bender, M.J. Scott, and R.W. Schultz. *ImSET 4.0: Impact of Sector Energy Technologies Model Description and User's Guide.* 2015. Pacific Northwest National Laboratory: Richland, WA. PNNL–24563.

Table V.1 Trial Standard Levels for Consumer Water Heaters

Product Class	Trial Standard Level					
	1	2	3	4	5	6
	Efficiency Level					
Gas-fired Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal)	1	2	2	2	2	5
Oil-fired Storage Water Heaters (V_{eff} ≤ 50 gal)	1	2	2	2	2	2
Small electric storage water heaters (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)	0	0	1	1	1	1
Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal, excluding small electric storage water heaters)	0	1	1	2	3	3
Electric Storage Water Heaters (55 gal < V_{eff} ≤ 120 gal)	1	1	1	2	3	3

DOE constructed the TSLs for this final rule to include ELs representative of ELs with similar characteristics (*i.e.,* using similar technologies and/or efficiencies, and having roughly comparable equipment availability). The use of representative ELs provided for greater distinction between the TSLs. While representative ELs were included in the TSLs, DOE considered all efficiency levels as part of its analysis.[178]

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on consumer water heater consumers by looking at the effects that potential new and amended standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on selected consumer subgroups. These analyses are discussed in the following sections.

a. Life-Cycle Cost and Payback Period

In general, higher-efficiency products affect consumers in two ways: (1) purchase price increases and (2) annual operating costs decrease. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* product price plus installation costs), and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter 8 of the final rule TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.11 show the LCC and PBP results for the TSLs considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product. In the second table, the impacts are measured relative to the efficiency distribution in the in the no-new-standards case in the compliance year (see section IV.F.8 of this document). Because some consumers purchase products with higher efficiency in the no-new-standards case, the average savings are less than the difference between the average LCC of the baseline product and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

Table V.2 Average LCC and PBP Results for Gas-fired Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal)

TSL	Efficiency Level	Average Costs *2022$*				Simple Payback *years*	Average Lifetime *years*
		Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	0	1,432	242	2,868	4,300	NA	14.5
1	1	1,470	237	2,815	4,285	8.4	14.5
2,3,4,5	2	1,578	226	2,689	4,267	9.1	14.5
6	5	2,241	198	2,410	4,651	18.5	14.5

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

[178] Efficiency levels that were analyzed for this final rule are discussed in section IV.C of this document. Results by efficiency level are presented in TSD chapters 8, 10, and 12.

Table V.3 Average LCC Savings Relative to the No-New-Standards Case for Gas-fired Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal)

TSL	Efficiency Level	Life-Cycle Cost Savings	
		Average LCC Savings* *2022$*	Percent of Consumers that Experience Net Cost
1	1	15	20.3
2,3,4,5	2	29	40.5
6	5	(285)	69.8

* The savings represent the average LCC for affected consumers. Numbers in parentheses denote negative values.

Table V.4 Average LCC and PBP Results for Oil-fired Storage Water Heaters (V_{eff} ≤ 50 gal)

TSL	Efficiency Level	Average Costs *2022$*				Simple Payback *years*	Average Lifetime *years*
		Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	0	3,934	794	8,441	12,375	NA	15.5
1	1	4,029	773	8,222	12,251	4.7	15.5
2,3,4,5,6	2	4,189	755	8,017	12,206	6.5	15.5

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.5 Average LCC Savings Relative to the No-New-Standards Case for Oil-fired Storage Water Heaters (V_{eff} ≤ 50 gal)

TSL	Efficiency Level	Life-Cycle Cost Savings	
		Average LCC Savings* *2022$*	Percent of Consumers that Experience Net Cost
1	1	123	10.8
2,3,4,5,6	2	141	26.8

* The savings represent the average LCC for affected consumers. Numbers in parentheses denote negative values.

Table V.6 Average LCC and PBP Results for Small Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)

TSL	Efficiency Level	Average Costs *2022$*				Simple Payback *years*	Average Lifetime *years*
		Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
1,2	0	780	314	3,623	4,403	NA	15.1
3,4,5,6	1	3,015	178	2,138	5,153	16.5	15.1

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.7 Average LCC Savings Relative to the No-New-Standards Case for Small Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)

TSL	Efficiency Level	Life-Cycle Cost Savings	
		Average LCC Savings* *2022$*	Percent of Consumers that Experience Net Cost
1,2	0	NA	0.0
3,4,5,6	1	(750)	76.5

* The savings represent the average LCC for affected consumers. Numbers in parentheses denote negative values.

Table V.8 Average LCC and PBP Results for Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal, excluding Small Electric Storage Water Heaters)

TSL	Efficiency Level	Average Costs *2022$*				Simple Payback *years*	Average Lifetime *years*
		Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
1	0	902	340	3,891	4,793	NA	15.1
2,3	1	1,855	171	2,047	3,902	5.6	15.1
4	2	1,903	139	1,700	3,602	5.0	15.1
5,6	3	1,995	130	1,600	3,594	5.2	15.1

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.9 Average LCC Savings Relative to the No-New-Standards Case for Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal, excluding Small Electric Storage Water Heaters)

TSL	Efficiency Level	Life-Cycle Cost Savings	
		Average LCC Savings* *2022$*	Percent of Consumers that Experience Net Cost
1,2	0	NA	0.0
2,3	1	859	34.7
4	2	1,146	32.7
5,6	3	1,067	38.2

* The savings represent the average LCC for affected consumers. Numbers in parentheses denote negative values.

Table V.10 Average LCC and PBP Results for Electric Storage Water Heaters (55 gal < V_{eff} ≤ 120 gal)

TSL	Efficiency Level	Average Costs *2022$*				Simple Payback *years*	Average Lifetime *years*
		Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	0	2,019	290	3,368	5,387	NA	15.1
1,2,3	1	2,028	244	2,857	4,885	0.2	15.1
4	2	2,064	194	2,303	4,367	0.5	15.1
5,6	3	2,180	176	2,101	4,282	1.4	15.1

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.11 Average LCC Savings Relative to the No-New-Standards Case for Electric Storage Water Heaters (55 gal < V_{eff} ≤ 120 gal)

TSL	Efficiency Level	Life-Cycle Cost Savings	
		Average LCC Savings* *2022$*	Percent of Consumers that Experience Net Cost
1,2,3	1	458	0.3
4	2	613	1.4
5,6	3	190	38.8

* The savings represent the average LCC for affected consumers. Numbers in parentheses denote negative values.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households, senior-only households, and small businesses. Table V.12 through Table V.16 compare the average LCC savings and PBP at each efficiency level for the consumer subgroups with

similar metrics for the entire consumer sample for each consumer water heater product class analyzed. In most cases, the average LCC savings and PBP for low-income households and senior-only households at the considered efficiency levels are not substantially different from the average for all households. Chapter 11 of the final rule TSD presents the complete LCC and PBP results for the subgroups.

Table V.12 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households; Gas-fired Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal)

TSL	Low-Income Households	Senior-Only Households	Small Businesses	All Households
Average LCC Savings (2022$)				
1	31	25	(11)	15
2,3,4,5	81	47	(39)	29
6	71	(282)	(372)	(285)
Simple Payback Period (years)				
1	4.0	7.2	9.6	8.4
2,3,4,5	4.6	8.1	9.9	9.1
6	9.3	20.1	15.3	18.5
Consumers with Net Cost (%)				
1	11.4	15.1	37.4	20.3
2,3,4,5	26.1	37.8	61.3	40.5
6	37.7	66.0	76.2	69.8
Consumers with Net Benefit (%)				
1	41.4	39.9	21.2	36.4
2,3,4,5	50.7	40.7	17.9	38.2
6	57.3	31.3	23.8	29.3

Table V.13 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households; Oil-fired Storage Water Heaters (V_{eff} ≤ 50 gal)

TSL	Low-Income Households	Senior-Only Households	Small Businesses	All Households
Average LCC Savings (2022$)				
1	159	134	33	123
2,3,4,5,6	236	158	(10)	141
Simple Payback Period (years)				
1	2.5	4.5	5.3	4.7
2,3,4,5,6	3.4	6.3	7.4	6.5
Consumers with Net Cost (%)				
1	5.3	7.7	19.5	10.8
2,3,4,5,6	8.9	23.9	48.3	26.8
Consumers with Net Benefit (%)				
1	58.3	57.0	47.4	55.7
2,3,4,5,6	74.3	59.6	36.2	56.7

Table V.14 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households; Small Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)

TSL	Low-Income Households	Senior-Only Households	Small Businesses	All Households
Average LCC Savings (2022$)				
1,2*	NA	NA	NA	NA
3,4,5,6	788	(321)	(1662)	(750)
Simple Payback Period (years)				
1,2*	NA	NA	NA	NA
3,4,5,6	6.0	15.1	28.0	16.5
Consumers with Net Cost (%)				
1,2*	NA	NA	NA	NA
3,4,5,6	29.5	57.0	88.8	76.5
Consumers with Net Benefit (%)				
1,2*	NA	NA	NA	NA
3,4,5,6	65.0	39.2	9.9	22.5

* TSLs 1 and 2 represent no new amended standards for small electric storage water heaters.

Table V.15 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households; Electric Storage Water Heaters (20 gal ≤ V_{eff} ≤ 55 gal, Except Small Electric Storage Water Heaters)

TSL	Low-Income Households	Senior-Only Households	Small Businesses	All Households
Average LCC Savings (2022$)				
1*	NA	NA	NA	NA
2,3	1579	433	295	859
4	1934	610	453	1146
5,6	1858	555	374	1067
Simple Payback Period (years)				
1*	NA	NA	NA	NA
2,3	2.8	6.9	4.8	5.6
4	2.5	6.1	4.3	5.0
5,6	2.5	6.4	4.6	5.2
Consumers with Net Cost (%)				
1*	NA	NA	NA	NA
2,3	16.2	32.7	63.9	34.7
4	14.6	31.0	63.7	32.7
5,6	16.2	36.1	70.1	38.2
Consumers with Net Benefit (%)				
1*	NA	NA	NA	NA
2,3	69.2	53.0	24.1	53.4
4	71.6	55.6	24.9	56.4
5,6	77.0	57.5	26.7	58.1

* TSL 1 represents no new amended standards for electric storage water heaters (20 gal ≤ V_{eff} ≤ 55 gal, except small electric storage water heaters).

Table V.16 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households; Electric Storage Water Heaters (55 gal < V_{eff} ≤ 120 gal)

TSL	Low-Income Households	Senior-Only Households	Small Businesses	All Households
Average LCC Savings (2022$)				
1,2,3	464	372	398	458
4	674	432	419	613
5,6	279	97	84	190
Simple Payback Period (years)				
1,2,3	0.1	0.3	0.2	0.2
4	0.2	0.7	0.4	0.5
5,6	0.7	2.1	1.3	1.4
Consumers with Net Cost (%)				
1,2,3	0.1	0.2	0.7	0.3
4	0.4	1.0	4.8	1.4
5,6	16.5	36.0	66.2	38.8
Consumers with Net Benefit (%)				
1,2,3	4.4	3.9	2.8	3.4
4	14.8	13.6	9.1	13.9
5,6	69.7	47.1	24.0	50.5

c. Rebuttable Presumption Payback

As discussed in section III.F.2 of this document, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedures for consumer water heaters. In contrast, the PBPs presented in section V.B.1.a of this document were calculated using distributions that reflect the range of energy use in the field.

Table V.17 presents the rebuttable-presumption payback periods for the considered TSLs for consumer water heaters. While DOE examined the rebuttable-presumption criterion, it considered whether the standard levels considered for this rule are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to definitively evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

Table V.17 Comparison of Rebuttable-Presumption Payback Periods

TSL	1	2	3	4	5	6
GSWH	5.8	7.4	7.4	7.4	7.4	12.4
OSWH	4.1	5.7	5.7	5.7	5.7	5.7
ESWH (20 gal ≤ V_{eff} ≤ 35 gal, FHR < 51 gal)	NA	NA	12.4	12.4	12.4	12.4
ESWH (20 gal ≤ V_{eff} ≤ 55 gal, excluding Small ESWH)	NA	3.7	3.7	3.2	3.4	3.4
ESWH (55 gal < V_{eff} ≤ 120 gal)	0.3	0.3	0.3	0.6	1.5	1.5

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of amended energy conservation standards on manufacturers of consumer water heaters. The next section describes the expected impacts on manufacturers at each considered TSL. Chapter 12 of the final rule TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

In this section, DOE provides GRIM results from the analysis, which examines changes in the industry that would result from a standard. The following tables summarize the estimated financial impacts (represented by changes in INPV) of potential amended energy conservation standards on manufacturers of consumer water heaters, as well as the conversion costs that DOE estimates manufacturers of consumer water heaters would incur at each TSL.

As discussed in section IV.J.2.d of this document, DOE modeled two scenarios to evaluate a range of cash flow impacts on the consumer water heater industry: (1) the preservation of gross margin percentage scenario and (2) the preservation of operating profit. Under the preservation of gross margin percentage scenario, DOE applied a single uniform ''gross margin percentage'' across all efficiency levels. As MPCs increase with efficiency, this scenario implies that the per-unit dollar profit would also increase. DOE assumed a ''gross margin percentage'' of 31 percent for gas-fired storage water heaters, 30 percent for oil-fired storage

water heaters, and 28 percent for all electric storage water heaters. These gross margin percentages (and corresponding manufacturer markups) are the same as the ones DOE assumed in the engineering analysis and the no-new-standards case of the GRIM. Because this scenario assumes that a manufacturer's absolute dollar markup would increase as MPCs increase in the standards cases, it represents the upper bound to industry profitability under potential new energy conservation standards.

The preservation of operating profit scenario reflects manufacturers' concerns about their inability to maintain margins as MPCs increase to reach more stringent efficiency levels. In this scenario, while manufacturers make the necessary investments required to convert their facilities to produce compliant products, operating profit does not change in absolute dollars and decreases as a percentage of revenue.

Each of the modeled manufacturer markup scenarios results in a unique set of cash flows and corresponding industry values at each TSL. In the following discussion, the INPV results refer to the difference in industry value between the no-new-standards case and each standards case resulting from the sum of discounted cash flows from 2023 through 2059. To provide perspective on the short-run cash flow impact, DOE includes in the discussion of results a comparison of free cash flow between the no-new-standards case and the standards case at each TSL in the year before new standards are required.

Table V.18 Manufacturer Impact Analysis for Consumer Water Heaters under the Preservation of Gross Margin Scenario

	Units	No-New-Standards Case	Trial Standard Level					
			1	2	3	4	5	6
INPV	*2022$ millions*	1,478.8	1,484.2	1,506.9	1,438.9	1,447.6	1,447.5	1,473.5
Change in INPV*	*2022$ millions*	-	5.5	28.2	(39.8)	(31.2)	(31.3)	(5.2)
	%	-	0.4	1.9	(2,7)	(2.1)	(2.1)	(0.4)
Free Cash Flow (2029)	*2022$ millions*	124.0	121.0	17.3	(24.1)	(29.3)	(48.8)	(155.0)
Change in Free Cash Flow (2029)	*2022$ millions*	-	(3.0)	(106.7)	(148.1)	(153.3)	(172.8)	(279.0)
	%	-	(2.4)	(86.0)	(119.4)	(123.6)	(139.4)	(225.0)
Product Conversion Costs	*2022$ millions*	-	3.5	11.1	13.3	13.6	14.6	25.1
Capital Conversion Costs	*2022$ millions*	-	4.0	228.7	319.0	330.4	373.1	601.1
Total Investment Required**	*2022$ millions*	-	7.5	239.8	332.4	344.0	387.6	626.2

* Numbers in parentheses indicate a negative number.

**Numbers may not sum exactly due to rounding.

Table V.19 Manufacturer Impact Analysis for Consumer Water Heaters under the Preservation of Operating Profit Scenario

	Units	No-New-Standards Case	Trial Standard Level*					
			1	2	3	4	5	6
INPV	*2022$ millions*	1,478.8	1,470.3	1,203.4	1,087.2	1,058.6	1,000.7	769.2
Change in INPV	*2022$ millions*	-	(8.4)	(275.3)	(391.5)	(420.1)	(478.1)	(709.5)
	%	-	(0.6)	(18.6)	(26.5)	(28.4)	(32.3)	(48.0)
Free Cash Flow (2029)	*2022$ millions*	124.0	121.0	17.3	(24.1)	(29.3)	(48.8)	(155.0)
Change in Free Cash Flow (2029)	*2022$ millions*	-	(3.0)	(106.7)	(148.1)	(153.3)	(172.8)	(279.0)
	%	-	(2.4)	(86.0)	(119.4)	(123.6)	(139.4)	(225.0)
Product Conversion Costs	*2022$ millions*	-	3.5	11.1	13.3	13.6	14.6	25.1
Capital Conversion Costs	*2022$ millions*	-	4.0	228.7	319.0	330.4	373.1	601.1
Total Investment Required**	*2022$ millions*	-	7.5	239.8	332.4	344.0	387.6	626.2

* Numbers in parentheses indicate a negative number.
**Numbers may not sum exactly due to rounding.

At TSL 1, DOE estimates that impacts on INPV would range from −$8.4 million to $5.5 million, or a change in INPV of −0.6 percent to 0.4 percent. At TSL 1, industry free cash flow is $121.0 million, which is a decrease of $3.0 million, or a drop of 2.4 percent, compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $7.5 million. At TSL 1, approximately 73 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 1 would set the energy conservation standard for gas-fired storage water heaters at EL 1, oil-fired storage water heaters at EL 1, small electric storage water heaters at baseline efficiency level (*i.e.,* EL 0), electric storage water heaters with an effective storage volume of at least 20 gallons and less than or equal to 55 gallons (excluding small electric storage water heaters) at baseline, and electric storage water heaters with effective storage volumes above 55 gallons at EL 1. At TSL 1, DOE estimates that manufacturers would incur approximately $3.5 million in product conversion costs, as some gas-fired storage water heaters and electric storage water heaters would need to be redesigned to comply with the standard. DOE also estimates that manufacturers would incur approximately $4.0 million in capital conversion costs at TSL 1 to accommodate the need for increased capacity for gas-fired and electric storage water heaters.

At TSL 1, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 1.6 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Given the relatively small increase in production costs, DOE does not project a notable drop in shipments in the year the standard takes effect. In the preservation of gross margin scenario, manufacturers are able to fully pass on this slight cost increase to consumers. In the preservation of gross margin percentage scenario, the slight increase in cashflow from the higher MSP outweighs the $7.5 million in conversion costs, causing a slightly positive change in INPV at TSL 1 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup and the $7.5 million in conversion costs incurred by manufacturers cause a slightly negative change in INPV at TSL 1 under the preservation of operating profit scenario.

At TSL 2, DOE estimates that impacts on INPV would range from −$275.3 million to $28.2 million, or a change in INPV of −18.6 percent to 1.9 percent. At TSL 2, industry free cash flow is $17.3 million, which is a decrease of $106.7 million, or a drop of 86.0 percent compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $239.8 million. At TSL 2, approximately 24 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 2 would set the energy conservation standard for gas-fired storage water heaters at EL 2, oil-fired storage water heaters at EL 2, small electric storage water heaters at baseline, electric storage water heaters with an effective storage volume of at least 20 gallons and less than 55 gallons (excluding small electric storage water heaters) at EL 1, and electric storage water heaters with an effective storage

volume of above 55 gallons at EL 1. At TSL 2, DOE estimates that manufacturers would incur approximately $11.1 million in product conversion costs, as some gas-fired storage water heaters and electric storage water heaters would need to be redesigned to comply with the standard. While small electric storage water heaters could remain reliant on electric resistance technology, most electric storage water heaters would need to transition to heat pump technology. In 2023, heat pump electric storage water heaters comprise approximately 3 percent of the electric storage water heater market. At TSL 2, heat pump water heaters are expected to comprise approximately 61 percent of the electric storage water heater market in 2030 since all electric storage water heaters (except for small electric storage) would need to meet heat pump levels, driving large investments to expand production capacity of heat exchangers and to optimize production costs. Driven by the need for increased heat exchanger production capacity, DOE estimates that manufacturers would incur approximately $207.6 million in capital conversion costs for electric storage water heaters (and $228.7 million in capital conversion costs for all product classes) at TSL 2.

At TSL 2, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 36.6 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Despite an increase in production costs, DOE does not project a notable drop in shipments in the year the standard takes effect. In the preservation of gross margin scenario, manufacturers are able to fully pass on this cost increase to consumers. In the preservation of gross margin percentage scenario, the increase in cashflow from the higher MSP outweighs the $239.8 in conversion costs, causing a slightly positive change in INPV at TSL 2 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup and the $239.8 million in conversion costs incurred by manufacturers cause a negative change in INPV at TSL 2 under the preservation of operating profit scenario.

At TSL 3, DOE estimates that impacts on INPV would range from −$391.5 million to −$39.8 million, or a change in INPV of −26.5 percent to −2.7 percent. At TSL 3, industry free cash flow is −$24.1 million, which is a decrease of $148.1 million, or a drop of 119.4 percent, compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $332.4 million. At TSL 3, approximately 17 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 3 would set the energy conservation standard for gas-fired storage water heaters at EL 2, oil-fired storage water heaters at EL 2, small electric storage water heaters at EL 1, electric storage water heaters with an effective storage volume of at least 20 gallons and less than 55 gallons (excluding small electric storage water heaters) at EL 1, and electric storage water heaters with an effective storage volume of above 55 gallons at EL 1. At TSL 3, DOE estimates that manufacturers would incur approximately $13.3 million in product conversion costs, as some gas-fired storage water heaters and electric storage water heaters with an effective storage volume of between 20 and 55 gallons would need to be redesigned to comply with the standard. In 2023, heat pump electric storage water heaters comprise approximately 3 percent of the electric storage water heater market. In 2030 (the analyzed compliance year), heat pump electric storage water heaters would comprise 100 percent of the electric storage water heater market, driving large investments in product redesign and expanding heat exchanger manufacturing capacity. This would necessitate small electric storage water heater manufacturers developing split-system heat pump designs. Driven by the need for increased heat exchanger production capacity, DOE estimates that the industry would incur approximately $297.9 million in capital conversion costs for electric storage water heaters (and $319.0 million in capital conversion costs for all product classes) at TSL 3.

At TSL 3, the large conversion costs result in a free cash flow dropping below zero in the years before the standards year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At TSL 3, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 54.7 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Given the projected increase in production costs, DOE expects an estimated 15.4 percent drop in shipments in the year the standard takes effect relative to the no-new-standards case. The increase in cashflow from the higher MSP is outweighed by the $332.4 million in conversion costs and the drop in annual shipments, causing a slightly negative change in INPV at TSL 3 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup, $332.4 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a large negative change in INPV at TSL 3 under the preservation of operating profit scenario.

At TSL 4, DOE estimates that impacts on INPV would range from −$420.1 million to −$31.2 million, or a change in INPV of −28.4 percent to −2.1 percent. At TSL 4, industry free cash flow is −$29.3 million, which is a decrease of −$153.3 million, or a drop of 123.6 percent, compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $344.0 million. At TSL 4, approximately 17 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 4 would set the energy conservation standard for gas-fired storage water heaters at EL 2, oil-fired storage water heaters at EL 2, small electric storage water heaters at EL 1, electric storage water heaters with an effective storage volume of at least 20 gallons and less than 55 gallons (excluding small electric storage water heaters) at EL 2, and electric storage water heaters with an effective storage volume of above 55 gallons at EL 2. At TSL 4, DOE estimates that manufacturers would incur approximately $13.6 million in product conversion costs, as some gas-fired storage water heaters, electric storage water heaters with an effective storage volume of between 20 and 55 gallons, and electric storage water heaters with an effective storage volume of above 55 gallons would need to be redesigned to comply with the standard. In 2023, heat

pump electric storage water heaters comprise approximately 3 percent of the electric storage water heater market. In 2030 (the analyzed compliance year), heat pump electric storage water heaters would comprise 100 percent of the electric storage water heater market, driving large investments in product redesign and expanding heat exchanger manufacturing capacity. This would necessitate small electric storage water heater manufacturers developing split-system heat pump designs. Driven by the need for increased heat exchanger production capacity, DOE estimates that the industry would incur approximately $309.3 million in capital conversion costs for electric storage water heaters (and $330.4 million in capital conversion costs for all product classes) at TSL 4.

At TSL 4, the large conversion costs result in a free cash flow dropping below zero in the years before the standards year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At TSL 4, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 58.7 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Given the projected increase in production costs, DOE expects an estimated 15.2 percent drop in shipments in the year the standard takes effect relative to the no-new-standards case. The increase in cashflow from the higher MSP is outweighed by the $344.0 million in conversion costs and the drop in annual shipments, causing a slightly negative change in INPV at TSL 4 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup, $344.0 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a large negative change in INPV at TSL 4 under the preservation of operating profit scenario.

At TSL 5, DOE estimates that impacts on INPV would range from −$478.1 million to −$31.3 million, or a change in INPV of −32.3 percent to −2.1 percent. At TSL 5, industry free cash flow is −$48.8 million, which is a decrease of $172.8 million, or a drop of 139.4 percent compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $387.6 million. At TSL 5, approximately 14 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 5 would set the energy conservation standard for gas-fired storage water heaters at EL 2, oil-fired storage water heaters at EL 2, small electric storage water heaters at EL 1, electric storage water heaters with an effective storage volume of less than 55 gallons (excluding small electric storage water heaters) at EL 3, and electric storage water heaters with effective an volume of above 55 gallons at EL 3. At TSL 5, DOE estimates that manufacturers would incur approximately $14.6 million in product conversion costs, as some gas-fired storage water heaters, electric storage water heaters with an effective storage volume of between 20 and 55 gallons, and electric storage water heaters with an effective storage volume above 55 gallons would need to be redesigned to comply with the standard. In 2023, heat pump electric storage water heaters comprise approximately 3 percent of the electric storage water heater market. At TSL 5, 100 percent of electric storage water heaters would need to meet heat pump levels, driving large investments in product redesign and expanding heat exchanger manufacturing capacity. This would necessitate small electric storage water heater manufacturers developing split-system heat pump designs. Additionally, requiring larger condensers for gas-fired storage water heaters would require significant investments in capacity. Driven by the need for increased heat exchanger production capacity for electric storage water heaters and increased production capacity for larger condensers for gas-fired storage water heaters, DOE estimates that the industry would incur approximately $373.1 million in capital conversion costs at TSL 5.

At TSL 5, the large conversion costs result in a free cash flow dropping below zero in the years before the standards year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At TSL 5, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 66.6 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Given the projected increase in production costs, DOE expects an estimated 16.0 percent drop in shipments in the year the standard takes effect relative to the no-new-standards case. The increase in cashflow from the higher MSP is outweighed by the $387.6 million in conversion costs and the drop in annual shipments, causing a slightly negative change in INPV at TSL 5 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup, the $387.6 million in conversion costs incurred by manufacturers, and the drop in annual shipments cause a large negative change in INPV at TSL 5 under the preservation of operating profit scenario.

At TSL 6, DOE estimates that impacts on INPV would range from −$709.5 million to −$5.2 million, or a change in INPV of −48.0 percent to −0.4 percent. At TSL 6, industry free cash flow is −$155.0 million, which is a decrease of $279.0 million, or a drop of 225.0 percent, compared to the no-new-standards case value of $124.0 million in 2029, the year leading up to the standards year. Industry conversion costs total $626.2 million. At TSL 6, approximately 2 percent of consumer water heater shipments are expected to meet the required efficiency levels by the analyzed 2030 compliance date.

TSL 6 would set the energy conservation standard for gas-fired storage water heaters at EL 5, oil-fired storage water heaters at EL 2, small electric storage water heaters at EL 1, electric storage water heaters with an effective storage volume of less than 55 gallons (excluding small electric storage water heaters) at EL 3, and electric storage water heaters with an effective storage volume of above 55 gallons at EL 3. At TSL 6, DOE estimates that manufacturers would incur approximately $25.1 million in product conversion costs, as some gas-fired storage water heaters and electric storage water heaters with an effective storage volume of between 20 and 55 gallons would need to be redesigned to comply with the standard. In 2023, heat pump electric storage water heaters comprise approximately 3 percent of the electric storage water heater market. At TSL 6, 100 percent of electric storage water heaters would need to meet heat pump levels, driving large investments in product redesign and expanding heat

exchanger manufacturing capacity. This would necessitate small electric storage water heater manufacturers developing split-system heat pump designs. Additionally, requiring larger condensers, electronic ignition, power venting, and larger heat exchangers for gas-fired storage water heaters would require significant investments in capacity. Driven by the need for increased heat exchanger production capacity for electric storage water heaters and increased production capacity for electronic ignition, power venting, larger heat exchangers, and larger condensers for gas-fired storage water heaters, DOE estimates that the industry would incur approximately $601.1 million in capital conversion costs at TSL 6.

At TSL 6, the large conversion costs result in a free cash flow dropping below zero in the years before the standards year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

At TSL 6, the shipment-weighted average MPC for consumer water heaters covered by this rulemaking increases by 101.6 percent relative to the no-new-standards case shipment-weighted average MPC for all water heaters in 2030. Given the projected increase in production costs, DOE expects an estimated 19.4 percent drop in shipments in the year the standard takes effect relative to the no-new-standards case. In this scenario, the increase in cashflow from the higher MSP is outweighed by the $626.2 million in conversion costs and the drop in annual shipments, causing a slightly negative change in INPV at TSL 6 under this scenario.

Under the preservation of operating profit scenario, manufacturers earn the same per-unit operating profit as would be earned in the no-new-standards case in 2031 (a year after the analyzed compliance year), but manufacturers do not earn additional profit from their investments. In this scenario, the manufacturer markup decreases in 2031. This reduction in the manufacturer markup, the $626.2 million in conversion costs, and the drop in annual shipments incurred by manufacturers cause a significant negative change in INPV at TSL 6 under the preservation of operating profit scenario.

b. Direct Impacts on Employment

To quantitatively assess the potential impacts of amended energy conservation standards on direct employment in the consumer water heater industry, DOE used the GRIM to estimate the domestic labor expenditures and number of direct employees in the no-new-standards case and in each of the standards cases during the analysis period.

Labor expenditures related to product manufacturing depend on the labor intensity of the product, the sales volume, and an assumption that wages remain fixed in real terms over time. The total labor expenditures in each year are calculated by multiplying the total MPCs by the labor percentage of MPCs. The total labor expenditures in the GRIM were then converted to total production employment levels by dividing production labor expenditures by the average fully burdened wage multiplied by the average number of hours worked per year per production worker. To do this, DOE relied on hourly wages from the engineering analysis and the *ASM* inputs: [179] Production Workers' Annual Hours, Production Workers for Pay Period, and Number of Employees. DOE also relied on the BLS employee compensation data [180] to determine the fully burdened wage ratio. The fully burdened wage ratio factors in paid leave, supplemental pay, insurance, retirement and savings, and legally required benefits.

The number of production employees is then multiplied by the U.S. labor percentage to convert total production employment to total domestic production employment. The U.S. labor percentage represents the industry fraction of domestic manufacturing production capacity for the covered product. This value is derived from manufacturer interviews, product database analysis, and publicly available information. DOE estimates that 80 percent of consumer water heaters analyzed in this final rule are produced domestically.

The domestic production employees estimate covers production line workers, including line supervisors, who are directly involved in fabricating and assembling products within the OEM facility. Workers performing services that are closely associated with production operations, such as materials handling tasks using forklifts, are also included as production labor. DOE's estimates only account for production workers who manufacture the specific products covered by this final rule.

Non-production employees account for the remainder of the direct employment figure. The non-production employees estimate covers domestic workers who are not directly involved in the production process, such as sales, engineering, human resources, and management. Using the amount of domestic production workers calculated above, non-production domestic employees are extrapolated by multiplying the ratio of non-production workers in the industry compared to production employees. DOE assumes that this employee distribution ratio remains constant between the no-new-standards case and standards cases.

Direct employment is the sum of domestic production employees and non-production employees. Using the GRIM, DOE estimates in the absence of new energy conservation standards there would be 4,110 domestic production and non-production employees for consumer water heaters in 2030. Table V.20 shows the range of the impacts of energy conservation standards on U.S. manufacturing employment in the consumer water heaters industry. The following discussion provides a qualitative evaluation of the range of potential impacts presented in Table V.20.

[179] U.S. Census Bureau's Annual Survey of Manufactures: 2018–2021 (Available at: *www.census.gov/programs-surveys/asm/data/tables.html*) (last accessed January 18, 2024).

[180] U.S. Bureau of Labor Statistics. *Employer Costs for Employee Compensation.* (September 2023) (Dec. 15, 2023) Available at *www.bls.gov/news.release/archives/ecec_12152023.pdf* (last accessed Jan. 1, 2024).

Table V.20 Domestic Direct Employment Impacts for Consumer Water Heater Manufacturers in 2030

	No-New-Standards Case	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Direct Employment in 2030 (Production workers + Non-Production Workers)	4,110	4,110 to 4,120	2,941 to 5,544	2,393 to 5,480	2,393 to 5,504	2,393 to 5,760	441 to 7,350
Potential Changes in Direct Employment Workers in 2030*	-	0 to 10	(1,168) to 1,434	(1,716) to 1,370	(1,716) to 1,394	(1,716) to 1,650	(3,669) to 3,240

*DOE presents a range of potential employment impacts. Numbers in parentheses denote negative values.

The direct employment impacts shown in Table V.20 represent the potential domestic employment changes that could result following the compliance date for the consumer water heater product classes analyzed in this final rule. Manufacturing employment could increase or decrease due to the labor content of the various products being manufactured domestically or if manufacturers decided to move production facilities abroad because of the amended standards. The upper-bound estimate corresponds to an increase in the number of domestic workers that would result from amended energy conservation standards if manufacturers continue to produce the same scope of covered products within the United States after compliance takes effect. The lower-bound estimate reflects the risk of manufacturers re-evaluating production siting decisions in response to amended energy conservation standards. This conservative lower bound of domestic direct employment varies by TSL and product class. For this final rule, DOE reassessed and adjusted its conservative lower bound of potential domestic direct employment impacts to account for the potential that gas-fired storage water heater OEMs may re-evaluate domestic manufacturing locations at certain analyzed TSLs.

For electric storage water heaters (which account for approximately 51 percent of shipments in 2030), the lower end of the domestic employment range represents the potential decrease in production workers if manufacturing of heat pump electric storage water heaters moves to lower labor-cost countries in response to the large investments necessary to expand heat exchanger production capacity. To establish the estimated change in domestic direct employment for electric storage water heaters, the direct employment analysis assumed a reduction in domestic employment commensurate with the percentage of electric storage water heater shipments that transition to heat pump designs. For gas-fired storage water heaters (which account for approximately 49 percent of shipments in 2030), the lower bound represents a shift of all domestic production workers to foreign production locations at max-tech (TSL 6). At max-tech, it is possible that manufacturers would revisit their siting decisions based on the need for increased production capacity for larger condensers. DOE applied this conservative assumption to establish a lower bound that avoids underestimating the potential direct employment impacts.

Additional detail on the analysis of direct employment can be found in chapter 12 of the final rule TSD. Additionally, the employment impacts discussed in this section are independent of the employment impacts from the broader U.S. economy, which are documented in chapter 16 of the final rule TSD.

c. Impacts on Manufacturing Capacity

Industry concerns around manufacturing capacity were driven by potential technology transitions. In particular, manufacturers focused on the transition to heat pump technology for electric storage water heaters with rated storage volumes of between 20 and 55 gallons. The vast majority of sales today in this product class are electric resistance water heaters. DOE estimates that approximately 3 percent of current electric storage consumer water heater sales are heat pump units. At the final rule level, all electric storage water heaters, excluding small electric storage water heaters, would need to incorporate heat pump technology. Industry would need to add capacity to produce an additional three to four million heat pump electric storage water heater units per year. In interviews, manufacturers noted that heat pump electric storage water heaters are more complex to manufacture than electric resistance water heaters. DOE estimated conversion costs based on both industry feedback and estimates of capital investment from the engineering analysis. DOE's analysis indicated significant investment in additional production floor space and in production capacity for heat exchangers. At TSL 2, conversion costs total $239.8 million, presuming all OEMs of electric storage water heaters, excluding small electric storage water heaters, invest in the transition to heat pump models.

d. Impacts on Subgroups of Manufacturers

As discussed in section IV.J.1 of this document, using average cost assumptions to develop an industry cash flow estimate may not be adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche manufacturers, and manufacturers exhibiting a cost structure substantially different from the industry average could be affected disproportionately. DOE used the results of the industry characterization to group manufacturers exhibiting similar characteristics. Consequently, DOE identified small business manufacturers as a subgroup for a separate impact analysis.

For the small business subgroup analysis, DOE applied the small business size standards published by the U.S. Small Business Administration (''SBA'') to determine whether a company is considered a small business. The size standards are codified at 13 CFR part 121. To be categorized as a small business under North American Industry Classification System (''NAICS'') code 335220, ''Major Household Appliance Manufacturing,'' a consumer water heater manufacturer and its affiliates may employ a

maximum of 1,500 employees. The 1,500-employee threshold includes all employees in a business's parent company and any other subsidiaries. Based on this classification, DOE identified three manufacturers that qualify as domestic small businesses.

The small business subgroup analysis is discussed in more detail in chapter 12 of the final rule TSD. DOE examines the potential impacts of this final rule on small business manufacturers in section VI.B of this document.

e. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the regulatory actions of other Federal agencies and States that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency.

For the cumulative regulatory burden analysis, DOE examined Federal, product-specific regulations that could affect consumer water heater manufacturers and that take effect approximately 3 years before or after the estimated compliance date (2030). This information is presented in Table V.21.

BILLING CODE 6450–01–P

Table V.21 Compliance Dates and Expected Conversion Expenses of Federal Energy Conservation Standards Affecting Consumer Water Heater Original Equipment Manufacturers

Federal Energy Conservation Standard	Number of OEMs*	Number of OEMs Affected by Today's Rule**	Approx. Standards Compliance Year	Industry Conversion Costs *(millions)*	Industry Conversion Costs / Equipment Revenue***
Miscellaneous Refrigeration Products† 88 FR 19382 (March 31, 2023)	38	2	2029	$126.9 (2021$)	3.1%
Dishwashers† 88 FR 32514 (May 19, 2023)	22	3	2027	$125.6 (2021$)	2.1%
Room Air Conditioners 88 FR 34298 (May 26, 2023)	8	3	2026	$24.8 (2021$)	0.4%
Consumer Pool Heaters 88 FR 34624 (May 30, 2023)	20	3	2028	$48.4 (2021$)	1.5%
Microwave Ovens 88 FR 39912 (June 20, 2023)	18	3	2026	$46.1 (2021$)	0.7%
Consumer Boilers† 88 FR 55128 (August 14, 2023)	24	5	2030	$98.0 (2022$)	3.6%
Walk-in Coolers and Freezers† 88 FR 60746 (September 5, 2023)	79	2	2027	$89.0 (2022$)	0.8%
Commercial Water Heating Equipment 88 FR 69686 (October 6, 2023)	15	5	2026	$42.7 (2022$)	5.3%
Commercial Refrigerators, Refrigerator-Freezers, and Freezers† 88 FR 70196 (October 10, 2023)	83	1	2028	$226.4 (2022$)	1.6%
Dehumidifiers† 88 FR 76510 (November 6, 2023)	20	2	2028	$6.9 (2022$)	0.4%
Consumer Furnaces 88 FR 87502 (December 18, 2023)	15	3	2029	$162.0 (2022$)	1.8%

Refrigerators, Refrigerator-Freezers, and Freezers 89 FR 3026 (January 17, 2024)	63	3	2029 and 2030‡	$830.3 (2022$)	1.3%
Consumer Conventional Cooking Products 89 FR 11434 (February 14, 2024)	35	3	2028	$66.7 (2022$)	0.3%
Consumer Clothes Dryers 89 FR 18164 (March 12, 2024)	19	3	2028	$180.7 (2022$)	1.4%
Residential Clothes Washers 89 FR 19026 (March 15, 2024)	22	3	2028	$320.0 (2022$)	1.8%

* This column presents the total number of OEMs identified in the energy conservation standard rule that is contributing to cumulative regulatory burden.

** This column presents the number of OEMs producing consumer water heaters that are also listed as OEMs in the identified energy conservation standard that is contributing to cumulative regulatory burden.

*** This column presents industry conversion costs as a percentage of product revenue during the conversion period. Industry conversion costs are the upfront investments manufacturers must make to sell compliant products/equipment. The revenue used for this calculation is the revenue from just the covered product/equipment associated with each row. The conversion period is the timeframe over which conversion costs are made and lasts from the publication year of the final rule to the compliance year of the energy conservation standard. The conversion period typically ranges from 3 to 5 years, depending on the rulemaking.

† These rulemakings are at the NOPR stage, and all values are subject to change until finalized through publication of a final rule.

‡ For the refrigerators, refrigerator-freezers, and freezers energy conservation standards direct final rule, the compliance year (2029 or 2030) varies by product class.

BILLING CODE 6450–01–C

DOE received several comments in response to the July 2023 NOPR about cumulative regulatory burden. DOE addresses those comments in section IV.J.3.b of this document.

3. National Impact Analysis

This section presents DOE's estimates of the national energy savings and the NPV of consumer benefits that would result from each of the TSLs considered as potential amended standards.

a. National Energy Savings

To estimate the energy savings attributable to potential amended standards for consumer water heaters, DOE compared their energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2030–2059). Table V.22 presents DOE's projections of the national energy savings for each TSL considered for consumer water heaters. The savings were calculated using the approach described in section IV.H.2 of this document.

Table V.22 Cumulative National Energy Savings for Consumer Water Heaters; 30 Years of Shipments (2030–2059)

	Trial Standard Level					
	1	2	3	4	5	6
	quads					
Primary Energy						
GSWH	0.37	1.71	1.71	1.71	1.71	6.93
OSWH	0.000	0.001	0.001	0.001	0.001	0.001
Small ESWH	0.00	0.00	0.75	0.75	0.75	0.75
Medium ESWH	0.00	15.33	17.91	21.12	21.73	21.73
Large ESWH	0.001	0.001	0.001	0.005	0.013	0.013
Total Primary Energy	0.4	17.0	20.4	23.6	24.2	29.4
FFC Energy						
GSWH	0.42	1.91	1.91	1.91	1.91	7.80
OSWH	0.000	0.001	0.001	0.001	0.001	0.001
Small ESWH	0.00	0.00	0.77	0.77	0.77	0.77
Medium ESWH	0.00	15.65	18.29	21.61	22.24	22.24
Large ESWH	0.001	0.001	0.001	0.005	0.014	0.014
Total FFC Energy	0.4	17.6	21.0	24.3	24.9	30.8

OMB Circular A–4 [181] requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using 9 years, rather than 30 years, of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[182] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to consumer water heaters. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.23. The impacts are counted over the lifetime of consumer water heaters purchased during the period 2030–2038.

Table V.23 Cumulative National Energy Savings for Consumer Water Heaters; 9 Years of Shipments (2030–2038)

	Trial Standard Level					
	1	2	3	4	5	6
	quads					
Primary Energy						
GSWH	0.12	0.55	0.55	0.55	0.55	2.13
OSWH	0.000	0.000	0.000	0.000	0.000	0.000
Small ESWH	0.00	0.00	0.17	0.17	0.17	0.17
Medium ESWH	0.00	4.57	5.26	6.20	6.35	6.35
Large ESWH	0.000	0.000	0.000	0.001	0.004	0.004
Total Primary Energy	0.1	5.1	6.0	6.9	7.1	8.7
FFC Energy						
GSWH	0.13	0.61	0.61	0.61	0.61	2.39
OSWH	0.000	0.001	0.001	0.001	0.001	0.001
Small ESWH	0.00	0.00	0.18	0.18	0.18	0.18
Medium ESWH	0.00	4.67	5.38	6.34	6.51	6.51
Large ESWH	0.000	0.000	0.000	0.001	0.004	0.004
Total FFC Energy	0.1	5.3	6.2	7.1	7.3	9.1

[181] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* Available at *www.whitehouse.gov/omb/information-for-agencies/circulars* (last accessed Jan. 18. 2024). DOE used the prior version of Circular A–4 (September 17, 2003) in accordance with the effective date of the November 9, 2023 version.

[182] EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. (42 U.S.C. 6295(m)) While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6-year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for consumer water heaters. In accordance with OMB's guidelines on regulatory analysis,[183] DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.24 shows the consumer NPV results with impacts counted over the lifetime of products purchased during the period 2030–2059.

Table V.24 Cumulative Net Present Value of Consumer Benefits for Consumer Water Heaters; 30 Years of Shipments (2030–2059)

Discount Rate	Trial Standard Level					
	1	2	3	4	5	6
	billion 2022$					
3 percent discount rate						
GSWH	1.53	6.08	6.08	6.08	6.08	9.31
OSWH	0.006	0.011	0.011	0.011	0.011	0.011
Small ESWH	0.00	0.00	(2.81)	(2.81)	(2.81)	(2.81)
Medium ESWH	0.00	75.66	84.69	107.68	108.09	108.09
Large ESWH	0.005	0.005	0.005	0.031	0.068	0.068
Total 3 percent	1.5	82	88	111	111	115
7 percent discount rate						
GSWH	0.43	1.54	1.54	1.54	1.54	(1.74)
OSWH	0.002	0.004	0.004	0.004	0.004	0.004
Small ESWH	0.00	0.00	(2.15)	(2.15)	(2.15)	(2.15)
Medium ESWH	0.00	23.53	25.63	33.99	33.58	33.58
Large ESWH	0.002	0.002	0.002	0.011	0.022	0.022
Total 7 percent	0.4	25	25	33	33	30

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.25. The impacts are counted over the lifetime of products purchased during the period 2030–2038. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

Table V.25 Cumulative Net Present Value of Consumer Benefits for Consumer Water Heaters; 9 Years of Shipments (2030–2038)

Discount Rate	Trial Standard Level					
	1	2	3	4	5	6
	billion 2022$					
3 percent discount rate						
GSWH	0.58	2.27	2.27	2.27	2.27	0.64
OSWH	0.004	0.007	0.007	0.007	0.007	0.007
Small ESWH	0.00	0.00	(1.51)	(1.51)	(1.51)	(1.51)
Medium ESWH	0.00	27.08	30.09	38.65	38.73	38.73
Large ESWH	0.002	0.002	0.002	0.011	0.024	0.024
Total 3 percent	0.6	29	31	39	40	38
7 percent discount rate						
GSWH	0.21	0.74	0.74	0.74	0.74	(2.31)
OSWH	0.002	0.003	0.003	0.003	0.003	0.003
Small ESWH	0.00	0.00	(1.25)	(1.25)	(1.25)	(1.25)
Medium ESWH	0.00	11.09	12.02	16.18	15.95	15.95
Large ESWH	0.001	0.001	0.001	0.005	0.010	0.010
Total 7 percent	0.2	12	12	16	15	12

The previous results reflect the use of a default trend to estimate the change in price for consumer water heaters over the analysis period (*see* section IV.F.1 of this document). DOE also conducted a sensitivity analysis that considered one

[183] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf* (last accessed July 1, 2021).

scenario with a price decline compared to the reference case and one scenario with a price increase compared to the reference case. The results of these alternative cases are presented in appendix 10C of the final rule TSD. In the price-decline case, the NPV of consumer benefits is higher than in the default case. In the price increase case, the NPV of consumer benefits is lower than in the default case.

c. Indirect Impacts on Employment

DOE estimates that amended energy conservation standards for consumer water heaters will reduce energy expenditures for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered. There are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2030–2034), where these uncertainties are reduced.

The results suggest that the adopted standards are likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the final rule TSD presents detailed results regarding anticipated indirect employment impacts.

4. Impact on Utility or Performance of Products

As discussed in section III.F.1.d of this document, DOE has concluded that the standards adopted in this final rule will not lessen the utility or performance of the consumer water heaters under consideration in this rulemaking. Manufacturers of these products currently offer units that meet or exceed the adopted standards.

5. Impact of Any Lessening of Competition

DOE considered any lessening of competition that would be likely to result from new or amended standards. As discussed in section III.F.1.e of this document, EPCA directs the Attorney General of the United States (''Attorney General'') to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination in writing to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. To assist the Attorney General in making this determination, DOE provided the Department of Justice (''DOJ'') with copies of the NOPR and the TSD for review. In its assessment letter responding to DOE, DOJ concluded that the proposed energy conservation standards for consumer water heaters are unlikely to have a significant adverse impact on competition. DOE is publishing the Attorney General's assessment at the end of this final rule.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. Chapter 15 in the final rule TSD presents the estimated impacts on electricity-generating capacity, relative to the no-new-standards case, for the TSLs that DOE considered in this rulemaking.

Energy conservation resulting from potential energy conservation standards for consumer water heaters is expected to yield environmental benefits in the form of reduced emissions of certain air pollutants and greenhouse gases. Table V.26 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The emissions were calculated using the multipliers discussed in section IV.K of this document. DOE reports annual emissions reductions for each TSL in chapter 13 of the final rule TSD.

BILLING CODE 6450–01–P

Table V.26 Cumulative Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

	Trial Standard Level					
	1	2	3	4	5	6
Electric Power Sector and Site Emissions						
CO_2 (*million metric tons*)	20	299	342	404	417	716
CH_4 (*thousand tons*)	0.4	20	24	28	29	34
N_2O (*thousand tons*)	0.0	2.8	3.3	3.8	3.9	4.5
SO_2 (*thousand tons*)	0.1	88	107	123	126	124
NO_X (*thousand tons*)	17	153	166	201	209	475
Hg (*tons*)	0.0	0.6	0.7	0.9	0.9	0.9
Upstream Emissions						
CO_2 (*million metric tons*)	2.7	33	37	44	45	87
CH_4 (*thousand tons*)	280	3,038	3,389	4,050	4,199	8,500
N_2O (*thousand tons*)	0.0	0.1	0.2	0.2	0.2	0.3
SO_2 (*thousand tons*)	0.0	1.6	2.0	2.3	2.3	2.5
NO_X (*thousand tons*)	43	512	576	685	710	1,375
Hg (*tons*)	0.000	0.002	0.003	0.003	0.003	0.003
Total FFC Emissions						
CO_2 (*million metric tons*)	22	332	379	448	462	803
CH_4 (*thousand tons*)	280	3,058	3,413	4,078	4,228	8,534
N_2O (*thousand tons*)	0.0	2.9	3.5	4.0	4.1	4.7
SO_2 (*thousand tons*)	0.1	90	109	126	128	127
NO_X (*thousand tons*)	61	665	742	886	919	1,851
Hg (*tons*)	0.0	0.6	0.8	0.9	0.9	0.9

Note: Totals may not equal sums due to rounding.

As part of the analysis for this rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 that DOE estimated for each of the considered TSLs for consumer water heaters. Section IV.L of this document discusses the estimated SC–CO_2 values that DOE used. Table V.27 presents the value of CO_2 emissions reduction at each TSL for each of the SC–CO_2 cases. The time-series of annual values is presented for the selected TSL in chapter 14 of the final rule TSD.

Table V.27 Present Value of CO_2 Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

TSL	SC-CO_2 Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	billion 2022$			
1	0.2	0.9	1.4	2.8
2	3.0	13	21	40
3	3.4	15	24	46
4	4.0	18	28	54
5	4.1	18	29	56
6	7.2	32	51	97

BILLING CODE 6450–01–C

As discussed in section IV.L.2, DOE estimated the climate benefits likely to result from the reduced emissions of methane and N_2O that DOE estimated for each of the considered TSLs for consumer water heaters. Table V.28 presents the value of the CH_4 emissions reduction at each TSL, and Table V.29 presents the value of the N_2O emissions reduction at each TSL. The time-series of annual values is presented for the selected TSL in chapter 14 of the final rule TSD.

Table V.28 Present Value of Methane Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

TSL	SC-CH_4 Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	billion 2022$			
1	0.1	0.4	0.5	1.0
2	1.3	4.0	5.6	11
3	1.4	4.4	6.2	12
4	1.7	5.3	7.4	14
5	1.8	5.5	7.7	14
6	3.6	11	16	30

Table V.29 Present Value of Nitrous Oxide Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

TSL	SC-N_2O Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	billion 2022$			
1	0.00	0.00	0.00	0.00
2	0.01	0.04	0.06	0.11
3	0.01	0.05	0.08	0.13
4	0.01	0.06	0.09	0.15
5	0.01	0.06	0.09	0.16
6	0.02	0.07	0.10	0.18

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the global and U.S. economy continues to evolve rapidly. DOE, together with other Federal agencies, will continue to review methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. DOE notes, however, that the adopted standards are economically justified even without inclusion of monetized benefits of reduced GHG emissions.

DOE also estimated the monetary value of the economic benefits associated with NO_X and SO_2 emissions reductions anticipated to result from the considered TSLs for consumer water heaters. The dollar-per-ton values that DOE used are discussed in section IV.L of this document. Table V.30 presents the present value for NO_X emissions reduction for each TSL calculated using 7-percent and 3-percent discount rates, and Table V.31 presents similar results for SO_2 emissions reductions. The results in these tables reflect application of EPA's low dollar-per-ton values, which DOE used to be conservative. The time-series of annual values is presented for the selected TSL in chapter 14 of the final rule TSD.

Table V.30 Present Value of NO_X Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

TSL	7% Discount Rate	3% Discount Rate
	million 2022$	
1	710	2,020
2	9,781	27,898
3	11,061	31,658
4	13,023	37,373
5	13,430	38,594
6	23,946	69,019

Table V.31 Present Value of SO_2 Emissions Reduction for Consumer Water Heaters Shipped in 2030–2059

TSL	7% Discount Rate	3% Discount Rate
	million 2022$	
1	2.0	5.6
2	1,926	5,477
3	2,324	6,648
4	2,666	7,626
5	2,723	7,796
6	2,667	7,642

Not all the public health and environmental benefits from the reduction of greenhouse gases, NO_X, and SO_2 are captured in the values above, and additional unquantified benefits from the reductions of those pollutants as well as from the reduction of direct PM and other co-pollutants may be significant. DOE has not included monetary benefits of the reduction of Hg emissions because the amount of reduction is very small.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of Economic Impacts

Table V.32 presents the NPV values that result from adding the estimates of the economic benefits resulting from reduced GHG and NO_X and SO_2 emissions to the NPV of consumer benefits calculated for each TSL considered in this rulemaking. The consumer benefits are domestic U.S. monetary savings that occur as a result of purchasing the covered products, and are measured for the lifetime of products shipped during the period 2030–2059. The climate benefits associated with reduced GHG emissions resulting from the adopted standards are global benefits, and are also calculated based on the lifetime of consumer water heaters shipped during the period 2030–2059.

Table V.32 Consumer NPV Combined with Present Value of Climate Benefits and Health Benefits

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Using 3% Discount Rate for Consumer NPV and Health Benefits (billion 2022$)						
5% Average SC-GHG case	3.9	119	131	162	164	202
3% Average SC-GHG case	4.8	132	146	179	182	235
2.5% Average SC-GHG case	5.5	142	156	192	195	258
3% 95th percentile SC-GHG case	7.3	166	184	224	228	318
Using 7% Discount Rate for Consumer NPV and Health Benefits (billion 2022$)						
5% Average SC-GHG case	1.5	41	43	55	55	67
3% Average SC-GHG case	2.4	54	58	72	73	100
2.5% Average SC-GHG case	3.1	63	69	85	86	123
3% 95th percentile SC-GHG case	4.9	88	96	117	119	183

C. Conclusion

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this final rule, DOE considered the impacts of new and amended

standards for consumer water heaters at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off up-front costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information; (2) a lack of sufficient salience of the long-term or aggregate benefits; (3) a lack of sufficient savings to warrant delaying or altering purchases; (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments; (5) computational or other difficulties associated with the evaluation of relevant tradeoffs; and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a standard decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the final rule TSD. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[184]

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.[185] DOE welcomes comments on how to more fully assess the potential impact of energy conservation standards on consumer choice and how to quantify this impact in its regulatory analysis in future rulemakings.

1. Benefits and Burdens of TSLs Considered for Consumer Water Heater Standards

Table V.33 and Table V.34 summarize the quantitative impacts estimated for each TSL for consumer water heaters. The national impacts are measured over the lifetime of consumer water heaters purchased in the 30-year period that begins in the anticipated year of compliance with amended standards (2030–2059). The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. DOE is presenting monetized benefits of GHG emissions reductions in accordance with the applicable Executive orders, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the Interim Estimates presented by the Interagency Working Group because the consumer benefits alone outweigh the costs of the adopted rule (as described in section V.C of this document). The efficiency levels contained in each TSL are described in section V.A of this document.

BILLING CODE 6450–01–P

[184] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp. 853–883. doi: *10.1111/0034–6527.00354.*

[185] Sanstad, A.H. *Notes on the Economics of Household Energy Consumption and Technology Choice.* 2010. Lawrence Berkeley National Laboratory. *www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf* (last accessed July 1, 2021).

Table V.33 Summary of Analytical Results for Consumer Water Heater TSLs: National Impacts

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Cumulative FFC National Energy Savings						
Quads	0.4	17.6	21.0	24.3	24.9	30.8
Cumulative FFC Emissions Reduction						
CO_2 (*million metric tons*)	22	332	379	448	462	803
CH_4 (*thousand tons*)	280	3,058	3,413	4,078	4,228	8,534
N_2O (*thousand tons*)	0.0	2.9	3.5	4.0	4.1	4.7
SO_2 (*thousand tons*)	0.1	90	109	126	128	127
NO_X (*thousand tons*)	61	665	742	886	919	1,851
Hg (*tons*)	0.0	0.6	0.8	0.9	0.9	0.9
Present Value of Benefits and Costs (*3% discount rate, billion 2022$*)						
Consumer Operating Cost Savings	2.9	124	148	173	179	212
Climate Benefits*	1.3	17	20	23	24	43
Health Benefits**	2.0	33	38	45	46	77
Total Benefits†	6.2	175	206	241	249	332
Consumer Incremental Product Costs‡	1.3	42	60	62	67	97
Consumer Net Benefits	1.5	82	88	111	111	115
Total Net Benefits	4.8	132	146	179	182	235
Present Value of Benefits and Costs (*7% discount rate, billion 2022$*)						
Consumer Operating Cost Savings	1.1	47	56	65	67	80
Climate Benefits*	1.3	17	20	23	24	43
Health Benefits**	0.7	12	13	16	16	27
Total Benefits†	3.1	76	88	104	107	149
Consumer Incremental Product Costs‡	0.7	22	30	32	34	50
Consumer Net Benefits	0.4	25	25	33	33	30
Total Net Benefits	2.4	54	58	72	73	100

Note: This table presents the costs and benefits associated with consumer water heaters shipped during the period 2030−2059. These results include benefits to consumers which accrue after 2059 from the products shipped during the period 2030−2059.

* Climate benefits are calculated using four different estimates of the SC-CO_2, SC-CH_4, and SC-N_2O. Together, these represent the global SC-GHG. For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3-percent discount rate are shown; however, DOE emphasizes the value of considering the benefits calculated using all four sets of SC-GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for NO_X and SO_2) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. *See* section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate.

‡ Costs include incremental equipment costs as well as installation costs.

Table V.34 Summary of Analytical Results for Consumer Water Heater TSLs: Manufacturer and Consumer Impacts

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5	TSL 6
Manufacturer Impacts						
Industry NPV (*million 2022*$) (No-new-standards case INPV = $1,478.8)	1,470.3 to 1,484.2	1,203.4 to 1,506.9	1,087.2 to 1,438.9	1,058.6 to 1,447.6	1,000.7 to 1,447.5	769.2 to 1,473.5
Industry NPV *(% change)*	(0.6) to 0.4	(18.6) to 1.9	(26.5) to (2.7)	(28.4) to (2.1)	(32.3) to (2.1)	(48.0) to (0.4)
Consumer Average LCC Savings (2022$)						
GSWH	15	29	29	29	29	(285)
OSWH	123	141	141	141	141	141
Small ESWH (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)	NA	NA	(750)	(750)	(750)	(750)
ESWH (20 gal ≤ V_{eff} ≤ 55 gal excluding Small ESWH)	NA	859	859	1,146	1,067	1,067
ESWH (55 gal < V_{eff} ≤ 120 gal)	458	458	458	613	190	190
Shipment-Weighted Average*	15	429	340	472	458	251
Consumer Simple PBP (years)						
GSWH	8.4	9.1	9.1	9.1	9.1	18.5
OSWH	4.7	6.5	6.5	6.5	6.5	6.5
Small ESWH (20 gal ≤ V_{eff} ≤ 35 gal and FHR < 51 gal)	NA	NA	16.5	16.5	16.5	16.5
ESWH (≥20 gal and ≤55 gal excluding Small ESWH)	NA	5.6	5.6	5.0	5.2	5.2
ESWH (>55 gal and ≤120 gal)	0.2	0.2	0.2	0.5	1.4	1.4
Shipment-Weighted Average*	3.3	6.9	8.5	8.3	8.5	14.3
Percent of Consumers that Experience a Net Cost						
GSWH	20	41	41	41	41	70
OSWH	11	27	27	27	27	27
Small ESWH	0	0	77	77	77	77
ESWH (≥20 gal and ≤55 gal excluding Small ESWH)	0	35	35	33	38	38
ESWH (>55 gal and ≤120 gal)	0	0	0	1	39	39
Shipment-Weighted Average*	10	35	40	39	42	57

*Weighted by market share in start year of 2030.

BILLING CODE 6450–01–C

DOE first considered TSL 6, which represents the max-tech efficiency levels for all product classes. At TSL 6, the design options for GSWHs include condensing technology; the design options for ESWHs include heat pump technology; and the design options for oil-fired storage water heaters (''OSWHs'') include extra insulation and multi-flue heat exchangers. TSL 6 would require extensive changes to the way manufacturers currently produce water heaters. At TSL 6, approximately 2 percent of consumer water heater

shipments are expected to meet the required efficiency levels by the 2030 compliance date. This includes approximately 0.2 percent of shipments for GSWHs, 17 percent of shipments for OSWHs, 1 percent of small ESWH, 5 percent of ESWH with an effective storage volume of less than 55 gallons (excluding small ESWH) shipments, and 11 percent of ESWHs with an effective storage volume greater than or equal to 55 gallons shipments. There would be a significant ramp up in manufacturing capacity, especially for gas storage and electric storage water heaters, needed to support the market due to the transition to accommodate these advanced technologies.

TSL 6 would save an estimated 30.8 quads of energy, an amount DOE considers significant. Under TSL 6, the NPV of consumer benefit would be $30 billion using a discount rate of 7 percent, and $115 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 6 are 803 Mt of CO_2, 8,534 thousand tons of CH_4, 4.7 thousand tons of N_2O, 1,851 thousand tons of NO_X, 127 thousand tons of SO_2, and 0.9 tons of Hg. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 6 is $43 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 6 is $27 billion using a 7-percent discount rate and $77 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 6 is $100 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 6 is $235 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

At TSL 6, consumers will experience an average LCC cost of $285 for GSWHs, which is primarily driven by the total installed cost increases for gas condensing technology. For OSWHs, consumers will experience an average LCC savings of $141. For electric storage water heaters 20 to 35 gallons, consumers will experience an LCC cost of $750. For GSWHs, the consumers experiencing a net LCC cost is 70 percent, and for small ESWHs, the consumers experiencing a net LCC cost is 77 percent.

At TSL 6, the projected change in INPV ranges from a decrease of $709.5 million to a decrease of $5.2 million, which corresponds to a decrease of 48.0 percent and a decrease of 0.4 percent, respectively. The range of the impacts is driven primarily by the ability of manufacturers to recover their compliance costs. DOE estimates that industry must invest $626.2 million to comply with standards set at TSL 6. DOE understands that manufacturers would need to significantly upgrade their facilities to accommodate heat pump technology for ESWHs. Upgrades to produce heat pump electric storage water heaters include expansion of heat exchanger facilities and inclusion of refrigeration charging systems. In addition, manufacturers would need to expand their component sourcing of compressors and more sophisticated controls to produce these more advanced technology products. DOE estimates that manufacturers would need to scale up production of heat pump electric storage water heaters from approximately 3 percent of ESWH sales today (0.14 million units in 2023) to 100 percent of ESWH units in 2030. DOE believes significant research and development efforts would also be needed to support the introduction of a wider variety of heat pump water heater models in the market to meet the various needs of consumers, especially split-system heat pump water heaters that would be needed to support the replacement of small electric storage water heaters. Currently, there are very limited split-system heat pump water heater models commercially available in the United States, which are produced by only a few manufacturers and are sold in low quantities. DOE is concerned that sufficient products may not be available to support the small electric storage water heaters market, and new products may not be introduced by a large majority of water heater manufacturers by the compliance date of this final rule. In sum, DOE is concerned that industry will not be able to transition to 100 percent of electric storage water heaters to heat pump designs within a 5-year compliance window, as would be necessary to comply with TSL 6.

DOE is also concerned about training the workforce that would be needed to install and service the heat pump water heater market by the compliance date of the standards. ESWHs are typically installed by plumbers. Advanced-technology water heaters require the ability to work with refrigerants similar to that of heating, ventilation, and air conditioning servicing contractors. DOE hopes that the emergence of workforce programs supported by the Inflation Reduction Act and the Bipartisan Infrastructure Law will begin to support the training and education of the workforce needed to support the clean energy transition. However, DOE understands this transition will take time and the workforce may not be ready at the scale necessary to support TSL 6.

The Secretary concludes that at TSL 6 for consumer water heaters, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and estimated monetary value of the emissions reductions would be outweighed by economic impacts to manufacturers, primarily driven by the ramp up in scale and offerings needed to support both ESWH and GWSH efficiencies at TSL 6, the economic costs for small ESWH consumers (many of whom are low income), and the distinct impact of high initial costs for low-income consumers purchasing replacement water heaters in emergency circumstances. Approximately 0.2 percent of gas storage water heater shipments and approximately 4 percent of all electric storage water heaters shipments would meet TSL 6 efficiencies by 2030. DOE also notes that new technologies have recently been introduced into the heat pump water heater market, such as 120-volt water heaters, whose efficiencies are lower than TSL 6. Such 120-volt water heaters can be more readily adopted by more households, lowering installation costs. While DOE expects continued innovation in the heat pump water heater market at this time, DOE is worried that prematurely requiring TSL 6 efficiency levels will remove these new products from the market prematurely. The Secretary is also concerned about the uncertainty in the market to ensure GSWHs and ESWHs will continue to be available to all consumers, including small ESWH replacements. Consequently, the Secretary has concluded that TSL 6 is not economically justified.

DOE then considered TSL 5, which represents the max-tech efficiency levels for all product classes except for GSWHs, which includes a lower non-condensing efficiency level. At TSL 5, the design options for GSWHs include either gas-actuated or electric flue dampers instead of condensing technologies. For the remainder of the product classes, the efficiency levels and technologies are the same as in TSL 6: that is, for ESWHs, TSL 5 includes max-technology efficiency levels for heat pump water heaters across all

ESWH product classes, including small ESWHs. Approximately 14 percent of consumer water heater shipments are expected to meet the TSL 5 efficiency levels by the 2030 compliance date. The percentage of shipments expected to meet or exceed the efficiency levels in TSL 5 is the same as TSL 6 for all product classes except for GSWH. For GSWHs, approximately 23 percent of shipments are expected to meet TSL 5 efficiencies by the compliance date of the amended standards. At TSL 5, the standard would transition all consumer electric storage water heaters to heat pump technology across all effective storage volumes, delivery capacity offerings, and sizes in the market.

TSL 5 would save an estimated 24.9 quads of energy, an amount DOE considers significant. Under TSL 5, the NPV of consumer benefit would be $33 billion using a discount rate of 7 percent, and $111 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 5 are 462 Mt of CO_2, 4,228 thousand tons of CH_4, 4.1 thousand tons of N_2O, 919 thousand tons of NO_X, 128 thousand tons of SO_2, and 0.9 tons of Hg. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 5 is $24 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 5 is $16 billion using a 7-percent discount rate and $46 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 5 is $73 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 5 is $182 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

At TSL 5, DOE estimates that consumers will see a life-cycle cost savings for all product classes, except for small ESWH. At TSL 5, the average LCC savings is $29 for GSWH consumers, which is driven by the lower installed costs as compared to the TSL 6 condensing level. While the LCC savings are positive for a majority of consumers across TSL 5 product classes, 77 percent of small ESWH consumers will experience a net cost when installing a split-system heat pump water heater.

At TSL 5, the projected change in INPV ranges from a decrease of $478.1 million to a decrease of $31.3 million, which corresponds to a decrease of 32.3 percent and a decrease of 2.1 percent, respectively. DOE estimates that industry must invest $387.6 million to comply with standards set at TSL 5. The primary driver of high conversion costs is the industry's investment to meet market demand for heat pump electric storage water heaters. DOE estimates that manufacturers would need to scale up production of heat pump electric storage water heaters from approximately 3 percent of all ESWH units (0.14 million units in 2023) to 100 percent of units in 2030. As a part of this scale-up, manufacturers would need to develop new split-system heat pumps for the small electric storage water heater market. Manufacturers would likely need to invest in cost optimization of existing designs, in new designs, and in additional manufacturing capacity for heat pump water heaters.

Similar to the discussion at TSL 6, DOE's concerns continue to be driven by the ramp up in manufacturing, research, and development that would be needed to support the heat pump water heater market to continue today's volumes. TSL 5 would require the expansion of heat pump lines and the introduction of new products to support the entire market, especially small ESWHs.

The Secretary concludes that at TSL 5 for consumer water heaters, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and estimated monetary value of the emissions reductions would be outweighed by the impacts on manufacturers, driven by the uncertainty in the ramp up needed to support a full transition of all volumes to heat pump water heaters for ESWHs, the impacts on consumers of small ESWHs, and the increase in initial costs. While the LCC savings are positive for a majority of consumers across TSL 5 product classes, 56 percent of small ESWH consumers would experience net costs when installing a split-system heat pump water heater. DOE is concerned about the increase in first costs for consumers forced to purchase a replacement water heater when their existing water heater fails and the inability for the market to introduce cost-optimized heat pump water heaters as an offering to consumers to help mitigate the initial first cost increase. As at TSL 5, DOE is also concerned about the workforce being ready to service and install at the volumes necessary to support such a transition in 5 years. Consequently, the Secretary has concluded that TSL 5 is not economically justified.

DOE then considered TSL 4, which represents a lower efficiency level for ESWHs and maintains the same efficiency levels for OSWHs and GSWHs as at TSL 5. At TSL 4, the design options for GSWHs include either gas-actuated or electric flue dampers; the design options for OSWHs include extra insulation and multi-flue heat exchangers; and the design options for ESWHs include heat pump technology. Approximately 17 percent of consumer water heater shipments are expected to meet the TSL 4 efficiency levels by the 2030 compliance date. The percentage of shipments in 2030 expected to meet the analyzed level in TSL 4 for ESWHs is approximately 11 percent, which is a significant increase from the max-tech efficiency levels required at TSL 5 and TSL 6. However, for small ESWH, the percentage of shipments expected to meet TSL 4 remains at approximately 1 percent. At TSL 4, the standard would transition all consumer electric storage water heaters to heat pump technology, but at a more moderate efficiency level for ESWHs except for small ESWHs. DOE still expects this transition to be significant, but DOE notes that manufacturers have more experience producing ESWHs, excluding small ESWHs, at these efficiency levels due to the prevalence of the ENERGY STAR program. DOE also expects the programs from the Inflation Reduction Act, including the appliance rebates and tax credits, would help support the expansion of this market.

TSL 4 would save an estimated 24.3 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be $33 billion using a discount rate of 7 percent, and $111 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 448 Mt of CO_2, 4,078 thousand tons of CH_4, 4.0 thousand tons of N_2O, 886 thousand tons of NO_X, 126 thousand tons of SO_2, and 0.9 tons of Hg. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 4 is $23 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 4 is $16 billion using a 7-percent discount rate and $45 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health

benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 4 is $72 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 4 is $179 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

The average LCC across all product classes is positive, except for the small ESWH. DOE continues to be concerned about the development of new models that would need to be introduced into the split-system heat pump water heater market to support the small ESWH replacements. As DOE noted in discussing TSL 6, only a few manufacturers produce consumer water heaters today in very small volumes and would not be able to support the entire small ESWH market today. Similar to TSLs 5 and 6, 77 percent of small ESWH consumers will experience a net cost when installing a split-system heat pump water heater.

At TSL 4, the projected change in INPV ranges from a decrease of $420.1 million to a decrease of $31.2 million, which corresponds to a decrease of 28.4 percent and a decrease of 2.1 percent, respectively. DOE estimates that industry must invest $344.0 million to comply with standards set at TSL 4. For ESWH manufacturers, stepping down from max-tech provides greater flexibility in the design process and reduces the level of model-specific optimization. This results in lower conversion costs. However, manufacturers would still need to develop new split-system heat pumps for the small ESWH market and scale up production capacity for integrated heat pump water heaters. As previously discussed, DOE estimates that manufacturers would need to scale up production of heat pump electric storage water heaters from approximately 3 percent of ESWH sales in 2023 to 100 percent of units in 2030.

The Secretary concludes that at TSL 4 for consumer water heaters, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and estimated monetary value of the emissions reductions would be outweighed by the manufacturing concerns and by the uncertainty associated with the industry's ability to ramp up production at the levels necessary to meet a standard at TSL 4 within a 5-year period. Given TSL 4 represents a lower efficiency level that would require less model-specific optimization, DOE expects the research and development efforts to be smaller and DOE does expect significant ramp-up of this greater efficiency market segment in response to the incentive programs. However, DOE continues to be concerned about industry's ability to produce more than three million heat pump water heater units a year, while introducing new innovative products to meet consumers' needs and optimizing to produce lower-cost products. As at TSLs 6 and 5, DOE is concerned that the efficiency level required by TSL 4 may preclude the introduction of 120-volt water heaters into the broader market, which DOE considered as a qualitative factor and has considered in its decision-making. Adopting a standard level at TSL 4 would prevent innovation around these technologies (such as reducing their costs). Consequently, the Secretary has concluded that TSL 4 is not economically justified.

DOE then considered TSL 3, which represents the same levels as TSL 4 except includes a lower efficiency level for ESWHs. For those ESWHs less than 55 gallons of effective storage volume (including small ESWHs), TSL 3 includes an ''entry'' level heat pump efficiency level to accommodate some of the new product innovations that have been recently introduced into the market. At TSL 3, currently available 120–V heat pump water heaters would be able to comply with the required efficiencies. For ESWHs greater than 55 gallons of effective storage volume, TSL 3 includes an incremental increase in heat pump efficiency over the current standards. At TSL 3, the standard would still transition all consumer electric storage water heaters to heat pump technology. As previously noted, heat pump technology currently comprises approximately 3 percent of the electric storage water heater market. TSL 3 would shift 100 percent of electric storage water heaters to heat pumps, driving large investments in design of new heat pump offerings and new product capacity. Approximately 17 percent of consumer water heater shipments are expected to meet the TSL 3 efficiency levels by the 2030 compliance date. The percentage of shipments expected to meet or exceed the efficiency levels at TSL 3 is the same as TSL 4 for all product classes except for ESWHs. The percentage of shipments in 2030 expected to meet the analyzed level in TSL 3 for ESWHs is approximately 11 percent. However, for small ESWHs, the percentage of shipments expected to meet TSL 3 remains at approximately 1 percent in 2030.

TSL 3 would save an estimated 21.0 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefit would be $25 billion using a discount rate of 7 percent and $88 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 379 Mt of CO_2, 3,413 thousand tons of CH_4, 3.5 thousand tons of N_2O, 742 thousand tons of NO_X, 109 thousand tons of SO_2, and 0.8 tons of Hg. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 is $20 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 3 is $13 billion using a 7-percent discount rate and $38 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 3 is $58 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 3 is $146 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

At TSL 3, the average LCC impact is a savings across all product classes, except for the small ESWH. Similar to TSLs 4, 5, and 6, 77 percent of small ESWH consumers will experience a net cost when installing a split-system heat pump water heater.

At TSL 3, the projected change in INPV ranges from a decrease of $391.5 million to a decrease of $39.8 million, which corresponds to a decrease of 26.5 percent and a decrease of 2.7 percent, respectively. DOE estimates that industry must invest $332.4 million to comply with standards set at TSL 3. Manufacturers would need to develop new split-system heat pumps for the small ESWH market. They would also need to scale up production capacity for integrated heat pump water heaters.

The Secretary concludes that at TSL 3 for consumer water heaters, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and estimated monetary value of the emissions reductions would be outweighed by the uncertainty associated with the ability for industry to meet the demand necessary to

support the entire market for ESWHs, including the workforce transition needed to service and install all of these heat pump water heaters. For small ESWHs, DOE estimates that the fraction of consumers experiencing a net cost is 56 percent. Based on those costs to small ESWH consumers and the possible difficulty of meeting the market needs within the compliance timeframe, the Secretary has concluded that TSL 3 is not economically justified.

DOE then considered TSL 2, which represents the baseline efficiency level for small ESWHs and heat pump efficiency levels for all other ESWHs. TSL 2 also includes max-tech efficiency levels for OSWHs and a moderate increase in efficiency for GSWHs. TSL 2 also aligns most closely with the Joint Stakeholder Recommendation efficiency levels, with minor differences to the small ESWH product class as discussed in section IV.C of this document. Approximately 24 percent of consumer water heater shipments are expected to meet the TSL 2 efficiency levels by the 2030 compliance date. The percentage of shipments expected to meet or exceed the efficiency levels at TSL 2 is the same as TSL 3 for all product classes except for small ESWHs. The percentage of shipments in 2030 expected to meet the TSL 2 efficiency levels for ESWHs is approximately 24 percent. However, since TSL 2 for small ESWHs represents the baseline efficiency level, all small ESWHs are expected to meet TSL 2 levels, compared to only 1 percent of small ESWH shipments at TSL 3. While DOE recognizes that TSL 2 is not the TSL that maximizes net monetized benefits, DOE has determined that TSL 2 is designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified.

TSL 2 would save an estimated 17.6 quads of energy, an amount DOE considers significant. Under TSL 2, the NPV of consumer benefit would be $25 billion using a discount rate of 7 percent and $82 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 2 are 332 Mt of CO_2, 3,058 thousand tons of CH_4, 2.9 thousand tons of N_2O, 665 thousand tons of NO_X, 90 thousand tons of SO_2, and 0.6 ton of Hg. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 is $17 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 2 is $12 billion using a 7-percent discount rate and $33 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated total NPV at TSL 2 is $54 billion. Using a 3-percent discount rate for all benefits and costs, the estimated total NPV at TSL 2 is $132 billion. The estimated total NPV is provided for additional information; however, DOE primarily relies upon the NPV of consumer benefits when determining whether a proposed standard level is economically justified.

At TSL 2, the average LCC impact is a savings for all product classes. The average LCC impact is a savings of $29 for GSWHs, savings of $141 for OSWHs, savings of $859 for ESWHs (20 gal $\leq V_{eff} \leq$ 55 gal) excluding small ESWHs, and savings of $458 for ESWHs (55 gal $< V_{eff} \leq$ 120 gal). The fraction of consumers experiencing a net LCC cost is 41 percent for GSWHs, 27 percent for OSWHs, 35 percent for ESWHs (20 gal $\leq V_{eff} \leq$ 55 gal) excluding small ESWHs, and 0 percent for ESWHs (55 gal $< V_{eff} \leq$ 120 gal). Consumers of small ESWH (20 gal $\leq V_{eff} \leq$ 35 gal) are not impacted at TSL 2, as the standard is not proposed to be amended.

At TSL 2, the projected change in INPV ranges from a decrease of $275.3 million to an increase of $28.2 million, which corresponds to a decrease of 18.6 percent and an increase of 1.9 percent, respectively. DOE estimates that industry must invest $239.8 million to comply with standards set at TSL 2.

At higher TSLs, the primary driver of high conversion costs is the industry's investment to meet market demand for heat pump electric storage water heaters. TSL 2 preserves the existing market for small ESWHs, allowing small ESWHs utilizing only electric resistance technology (*i.e.,* that do not utilize a heat pump) to remain in the market. In turn, this reduces the level of investment needed to meet market demand for heat pump water heaters. DOE estimates industry would need to scale up production of heat pump electric storage water heaters from approximately 3 percent of ESWHs today to 61 percent of ESWHs in 2030, a significant reduction from higher TSLs. This approach, while still requiring a significant ramp up in manufacturing capacity for heat pump water heaters, allows for a more incremental transition to heat pump technology. It limits the investment required of manufacturers relative to higher TSLs that would require transitioning the entire ESWH market to heat pump technology and recognizes the benefits of providing additional time for small electric storage water heater designs using heat pump technology to mature. DOE believes that having a major manufacturer sign on to the Joint Stakeholder Recommendation is a testament to industry's ability to ramp up capacity to produce the volumes necessary to support the heat pump water heater market that will be required by TSL 2 by the compliance date of the amended standards.[186]

After considering the analysis and weighing the benefits and burdens, the Secretary has concluded that standards set at TSL 2 for consumer water heaters would be economically justified. At this TSL, the average LCC savings for consumers of all product classes are expected to be positive. The average LCC savings across all ESWH, excluding small ESWHs, consumers is $1,867. At TSL 2, the efficiency levels for ESWHs allow for continued development and innovation with 120–V heat pump ESWHs as well as split-system heat pump ESWHs. The efficiency levels at TSL 2 also allow for existing small ESWHs to remain on the market, providing an important option for a subset of consumers. The FFC national energy savings are significant and the NPV of consumer benefits is positive using both a 3-percent and 7-percent discount rate. These national benefits vastly outweigh the costs. The positive LCC savings—a different way of quantifying consumer benefits—reinforces this conclusion. The standard levels at TSL 2 are economically justified even without weighing the estimated monetary value of emissions reductions. When those emissions reductions are included—representing $17 billion in climate benefits (associated with the average SC–GHG at a 3-percent discount rate), and $12 billion (using a 7-percent discount rate) or $33 billion (using a 3-percent discount rate) in health benefits—the rationale becomes stronger still.

In addition, DOE considered that the efficiency levels across TSL 2 are generally representative of the Joint Stakeholder Recommendation. More specifically, DOE believes the Joint Stakeholder agreement from a cross section group of stakeholders provides DOE with a good indication of stakeholder views on this rulemaking

[186] As detailed in II.B.2 of this document, Rheem is a signatory to the Joint Stakeholder Recommendation. BWC was an original signatory to the Joint Stakeholder Recommendation, which included a recommendation of heat pump levels for ESWHs with rated storage volumes greater than 35 gallons, but subsequently removed itself as a signatory after the July 2023 NOPR after raising concerns about how DOE proposed to align with the Joint Stakeholder Recommendation.

and with some assurance that industry can transition to these levels and the market will see significant benefits, as indicated by DOE's analysis.

Accordingly, the Secretary has concluded that TSL 2 would offer the maximum improvement in efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy. Although results are presented here in terms of TSLs, DOE analyzes and evaluates all possible ELs for each product class in its analysis. TSL 2 comprises efficiency levels that offer significant LCC savings while keeping the percentage of consumers experiencing a net cost at a modest level. In particular, lower-income homeowners who currently use small ESWHs are significantly less likely to be disproportionately impacted at TSL 2 than at higher TSLs. TSL 2 also reduces the percentage of the market that would be transitioning to heat pump water heaters within a 5-year period. While DOE understands the ramp up to accommodate heat pump water heaters at TSL 2 is still significant, DOE believes manufacturers can leverage their existing operations, knowledge, workforce networks, and R&D to scale at a level needed to support an amended standard at TSL 2. Lastly, TSL 2 most closely represents the recommended standard levels submitted by Joint Stakeholders to DOE, providing further support for standard levels set at TSL 2, a factor the Secretary considers significant.

As discussed in section IV.F.9 of this document, DOE does not expect any significant amount of switching across product classes as a result of the adopted standards, with the exception of ESWHs and small ESWHs. There are a number of significant additional costs involved in switching from electric equipment to gas equipment and vice versa, such as replacing an electrical panel or installing new gas lines (both inside and outside of the home) and new venting. These additional costs can possibly exceed $1,000 on top of the installed costs estimated in this final rule, making product switching as a result of standards very likely to be a minimal effect at most.

Therefore, based on the above considerations, DOE adopts the conservation standards for consumer water heaters at TSL 2 for those product classes where there are existing applicable UEF standards. For the remaining product classes, DOE adopts converted standards in the UEF metric based on the amended appendix E test procedure. Altogether, the new and amended energy conservation standards for consumer water heaters, which are expressed as UEF, are shown in Table V.35. Note that this table does not show product classes for which standards remain unchanged by this final rule.

BILLING CODE 6450–01–P

Table V.35 New and Amended Energy Conservation Standards for Consumer Water Heaters

Product Class	Effective Storage Volume and Input Rating* *(if applicable)*	Draw Pattern	Uniform Energy Factor
Gas-fired Storage Water Heater	< 20 gal	Very Small	$0.2062 - (0.0020 \times V_{eff})$
		Low	$0.4893 - (0.0027 \times V_{eff})$
		Medium	$0.5758 - (0.0023 \times V_{eff})$
		High	$0.6586 - (0.0020 \times V_{eff})$
	≥20 gal and ≤55 gal	Very Small	$0.3925 - (0.0020 \times V_{eff})$
		Low	$0.6451 - (0.0019 \times V_{eff})$
		Medium	$0.7046 - (0.0017 \times V_{eff})$
		High	$0.7424 - (0.0013 \times V_{eff})$
	> 100 gal	Very Small	$0.1482 - (0.0007 \times V_{eff})$
		Low	$0.4342 - (0.0017 \times V_{eff})$
		Medium	$0.5596 - (0.0020 \times V_{eff})$
		High	$0.6658 - (0.0019 \times V_{eff})$
Oil-fired Storage Water Heater	≤50 gal	Very Small	$0.2909 - (0.0012 \times V_{eff})$
		Low	$0.5730 - (0.0016 \times V_{eff})$
		Medium	$0.6478 - (0.0016 \times V_{eff})$
		High	$0.7215 - (0.0014 \times V_{eff})$
	> 50 gal	Very Small	$0.1580 - (0.0009 \times V_{eff})$
		Low	$0.4390 - (0.0020 \times V_{eff})$
		Medium	$0.5389 - (0.0021 \times V_{eff})$
		High	$0.6172 - (0.0018 \times V_{eff})$
Very Small Electric Storage Water Heater	< 20 gal	Very Small	$0.5925 - (0.0059 \times V_{eff})$
		Low	$0.8642 - (0.0030 \times V_{eff})$
		Medium	$0.9096 - (0.0020 \times V_{eff})$
		High	$0.9430 - (0.0012 \times V_{eff})$
Small Electric Storage Water Heater	≥20 gal and ≤35 gal	Very Small	$0.8808 - (0.0008 \times V_{eff})$
		Low	$0.9254 - (0.0003 \times V_{eff})$
Electric Storage Water Heaters	≥20 and ≤ 55 gal (excluding small electric storage water heaters)	Very Small	2.30
		Low	2.30
		Medium	2.30
		High	2.30
	>55 gal and ≤120 gal	Very Small	2.50
		Low	2.50
		Medium	2.50
		High	2.50
	>120 gal	Very Small	$0.3574 - (0.0012 \times V_{eff})$
		Low	$0.7897 - (0.0019 \times V_{eff})$
		Medium	$0.8884 - (0.0017 \times V_{eff})$
		High	$0.9575 - (0.0013 \times V_{eff})$
Tabletop Water Heater	<20 gal	Very Small	$0.5925 - (0.0059 \times V_{eff})$
		Low	$0.8642 - (0.0030 \times V_{eff})$
	≥20 gal	Very Small	$0.6323 - (0.0058 \times V_{eff})$
		Low	$0.9188 - (0.0031 \times V_{eff})$
Instantaneous Oil-fired Water Heater	<2 gal and ≤210,000 Btu/h	Very Small	0.61
		Low	0.61
		Medium	0.61
		High	0.61
	≥2 gal and ≤210,000 Btu/h	Very Small	$0.2780 - (0.0022 \times V_{eff})$
		Low	$0.5151 - (0.0023 \times V_{eff})$
		Medium	$0.5687 - (0.0021 \times V_{eff})$
		High	$0.6147 - (0.0017 \times V_{eff})$
Instantaneous Electric Water Heater	≥2 gal	Very Small	$0.8086 - (0.0050 \times V_{eff})$
		Low	$0.9123 - (0.0020 \times V_{eff})$
		Medium	$0.9252 - (0.0015 \times V_{eff})$
		High	$0.9350 - (0.0011 \times V_{eff})$

BILLING CODE 6450–01–C

2. Annualized Benefits and Costs of the Adopted Standards

The benefits and costs of the adopted standards can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2022$) of the benefits from operating products that meet the adopted standards (consisting primarily of operating cost savings from using less energy), minus increases in product purchase costs, and (2) the annualized monetary value of the climate and health benefits.

Table V.36 shows the annualized values for consumer water heaters under TSL 2, expressed in 2022$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced NO_X and SO_2 emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the standards adopted in this rule is $2,623 million per year in increased equipment costs, while the estimated annual benefits are $5,655 million in reduced equipment operating costs, $1,051 in monetized climate benefits, and 1,416 in monetized health benefits. In this case, the net benefit would amount to $5,499 per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the standards is $2,586 million per year in increased equipment costs, while the estimated annual benefits are $7,566 million in reduced operating costs, $1,051 million in monetized climate benefits, and $2,033 million in monetized health benefits. In this case, the net benefit would amount to $8,065 million per year.

BILLING CODE 6450–01–P

Table V.36 Annualized Benefits and Costs of Adopted Standards (TSL 2) for Consumer Water Heaters

	Million 2022$/year		
	Primary Estimate	Low-Net-Benefits Estimate	High-Net-Benefits Estimate
3% discount rate			
Consumer Operating Cost Savings	7,566	7,078	8,065
Climate Benefits*	1,051	1,039	1,063
Health Benefits**	2,033	2,009	2,058
Total Benefits†	10,650	10,125	11,186
Consumer Incremental Product Costs‡	2,586	3,023	2,398
Net Benefits	8,065	7,102	8,788
Change in Producer Cashflow (INPV)‡‡	(28) - 3	(28) - 3	(28) - 3
7% discount rate			
Consumer Operating Cost Savings	5,655	5,294	6,024
Climate Benefits* (3% discount rate)	1,051	1,039	1,063
Health Benefits**	1,416	1,400	1,432
Total Benefits†	8,122	7,732	8,519
Consumer Incremental Product Costs‡	2,623	2,984	2,467
Net Benefits	5,499	4,748	6,052
Change in Producer Cashflow (INPV)‡‡	(28) – 3	(28) - 3	(28) - 3

Note: This table presents the costs and benefits associated with consumer water heaters shipped during the period 2030−2059. These results include consumer, climate, and health benefits that accrue after 2059 from the products shipped during the period 2030−2059. The Primary, Low Net Benefits, and High Net Benefits Estimates utilize projections of energy prices from the *AEO2023* Reference case, Low Economic Growth case, and High Economic Growth case, respectively. In addition, incremental equipment costs reflect a medium decline rate in the Primary Estimate, a low decline rate in the Low Net Benefits Estimate, and a high decline rate in the High Net Benefits Estimate. The methods used to derive projected price trends are explained in sections IV.F.1 and IV.F.4 of this document. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

* Climate benefits are calculated using four different estimates of the global SC-GHG (see section IV.L of this document). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown; however, DOE emphasizes the value of considering the benefits calculated using all four sets of SC-GHG estimates. To monetize the benefits of reducing GHG emissions, this analysis uses the interim estimates presented in the *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates Under Executive Order 13990* published in February 2021 by the IWG.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health

benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. *See* section IV.L of this document for more details.
† Total benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate.
‡ Costs include incremental equipment costs as well as installation costs.
‡‡ Operating Cost Savings are calculated based on the life cycle costs analysis and national impact analysis as discussed in detail below. *See* sections IV.F and IV.H of this document. DOE's national impacts analysis includes all impacts (both costs and benefits) along the distribution chain beginning with the increased costs to the manufacturer to manufacture the product and ending with the increase in price experienced by the consumer. DOE also separately conducts a detailed analysis on the impacts on manufacturers (*i.e.*, manufacturer impact analysis, or "MIA"). *See* section IV.J of this document. In the detailed MIA, DOE models manufacturers' pricing decisions based on assumptions regarding investments, conversion costs, cashflow, and margins. The MIA produces a range of impacts, which is the rule's expected impact on the INPV. The change in INPV is the present value of all changes in industry cash flow, including changes in production costs, capital expenditures, and manufacturer profit margins. The annualized change in INPV is calculated using the industry weighted average cost of capital value of 9.6 percent that is estimated in the manufacturer impact analysis (*see* chapter 12 of the final rule TSD for a complete description of the industry weighted average cost of capital). For consumer water heaters, the annualized change in INPV ranges from -$28 million to $3 million. DOE accounts for that range of likely impacts in analyzing whether a trial standard level is economically justified. *See* section V.C of this document. DOE is presenting the range of impacts to the INPV under two scenarios: the Preservation of Gross Margin scenario, which is the manufacturer markup scenario used in the calculation of Consumer Operating Cost Savings in this table; and the Preservation of Operating Profit scenario, where DOE assumed manufacturers would not be able to increase per-unit operating profit in proportion to increases in manufacturer production costs. DOE includes the range of estimated annualized change in INPV in the above table, drawing on the MIA explained further in section IV.J of this document to provide additional context for assessing the estimated impacts of this final rule to society, including potential changes in production and consumption, which is consistent with OMB's Circular A-4 and E.O. 12866. If DOE were to include the INPV into the annualized net benefit calculation for this final rule, the annualized net benefits would range from $8,037 million to $8,068 million at 3-percent discount rate and would range from $5,471 million to $5,502 million at 7-percent discount rate.

BILLING CODE 6450–01–C

3. Conversion Factor Final Rule Enforcement Policy

As discussed in section II.B.1 of this document, the currently applicable standards were established by the December 2016 Conversion Factor Final Rule, which utilized mathematical conversion equations to translate EF-based standards to the UEF metric for products that were on the market at the time. 81 FR 96204.

In that final rule, DOE issued an enforcement policy to ensure that individual models manufactured prior to July 13, 2015 that complied with the existing EF standards and remained unchanged in design would be tested to the EF metric and not be harmed by the transition to the UEF metric. 81 FR 96204, 96226–96227. This was done to prevent ''overrating'' to the minimum UEF standard; manufacturers are required to disclose the actual performance in the same metric as all other products. *Id.* The Department stated that these models will continue to remain subject to the enforcement policy until compliance with amended energy conservation standards is required. *Id.*

As a result, today's market continues to offer consumer water heaters that do not meet the current UEF-based standards (this is depicted in appendix 3A to the TSD). This final rule adopts amended energy conservation standards for consumer water heaters. Upon the compliance date of this final rule, the 2016 enforcement policy is terminated for all water heaters.

4. Severability

Finally, DOE added a new paragraph to 10 CFR 430.32 to make explicit the agency's intent that each energy conservation standard for each product class is separate and severable from one another, and that if any energy conservation standard for any product class is stayed or determined to be invalid by a court of competent jurisdiction, the remaining energy conservation standards for the other product classes shall continue in effect. Because this is an expression of DOE's intent, public comment on this paragraph is not relevant. This severability clause is intended to clearly express the Department's intent that should an energy conservation standard for any product class be stayed or invalidated, energy conservation standards for the other product classes shall continue in effect. In the event a court were to stay or invalidate one or more energy conservation standards for any product class as finalized, the Department would want the remaining energy conservation standards for the other product classes as finalized to remain in full force and legal effect.

D. Test Procedure Applicability

Manufacturers, including importers, must use product-specific certification templates to certify compliance to DOE. For consumer water heaters, the certification template reflects the general certification requirements specified at 10 CFR 429.12 and the product-specific requirements specified at 10 CFR 429.17. DOE has not proposed to amend the product-specific certification requirements for these products in this standards rulemaking. These requirements will be addressed in a separate rulemaking.

As discussed in section III.C of this document, DOE most recently amended the test procedure for these products at appendix E in the June 2023 TP Final Rule.

In light of the new and amended standards being adopted by this final rule, DOE is creating new provisions to specify how the appendix E test procedure should be applied. DOE is providing further clarifications around certain aspects of the appendix E test procedure to account for the products which would use this test procedure to determine UEF ratings. These amendments to the test procedure and related provisions are discussed in the following sections.

1. High-Temperature Testing

The current DOE test procedure calls for an outlet water temperature of 125 °F ± 5 °F. 88 FR 40406, 40422. This temperature is consistent with data DOE has on water heater thermostat settings in the field. For example, as discussed in chapter 7 of the final rule TSD, a 2015 study of 127 homes with electric resistance water heaters in central Florida showed that audited hot water setpoint temperatures averaged 127 °F (52.8 °C) (Std. Dev: 11.5 °F (6.4 °C)) and field measurement studies in California showed the median setpoint temperature to be 123 °F (50.6 °C). Additionally, as of 2017, survey data show that over 75% of contractors usually or always set the tank thermostat to 120 °F (*see* chapter 7 of the final rule TSD).[187] Further, the energy use analysis in this rulemaking uses water heater thermostat settings that are based on a 2006–2020 contractor survey conducted by Clear Seas.[188] [189] This annual survey of more than 300 plumbing/hydronic heating contractor firms indicated that 41 percent of responding contractors *always* install a water heater with a setpoint temperature of 120 °F, 20 percent always install with a setpoint temperature higher than 120 °F, and 39 percent *usually* install with a setpoint of 120 °F. DOE assumed that half of the latter portion installed the water heater at 120 °F, resulting in an overall distribution of 61 percent of water heaters set to 120 °F, and 39 percent with setpoints uniformly distributed between 120 °F and 140 °F, resulting in an average setpoint of approximately 124 °F. In the July 2014 UEF TP Final Rule, DOE cited data that found the average set point temperature for consumer water heaters in the field is 124.2 °F (51.2 °C). 79 FR 40542, 40554. A compilation of field data across the United States and southern Ontario by Lawrence Berkeley National Laboratory had also found a median daily outlet water temperature of 122.7 °F (50.4 °C). *Id.* Taken together, these data indicate that the outlet water temperature of 125 °F ± 5 °F used in the DOE test procedure is representative of average water heater temperature settings in the field, with 120 °F being the most common setting.

However, after the December 2016 Conversion Factor Final Rule issued amended standards for electric storage water heaters with rated storage volumes above 55 gallons that could only be met through the use of heat pump technology, DOE observed a market shift towards smaller electric storage water heater sizes where the standards could be met through electric resistance heating. These smaller water heaters have a setting or mode that continuously stores water at a higher temperature then uses a mixing valve to deliver water at the temperature setpoint. As a result, a new market began to emerge for consumers who still desired effective storage volumes above 55 gallons but did not want to install heat pump water heaters: electric resistance storage water heaters with rated storage volumes less than 55 gallons but with significantly higher effective storage volumes due to higher storage tank temperatures. 88 FR 40406, 40446. DOE anticipates a similar market shift in response to this final rule as the new standards for electric storage water heaters with capacities greater than or equal to 20 gallons and less than or equal to 55 gallons are met through the use of heat pump technology, while the standards for small electric storage water heaters (capacities greater than or equal to 20 gallons and less than or equal to 35 gallons) can be met by electric resistance heating technology.

As stated in the July 2022 TP SNOPR and the June 2023 TP Final Rule, consumers would be expected to use the high-temperature mode on these small electric storage water heaters as part of the regular operation of their water heater because consumers are electing to purchase an undersized water heater based on its capacity-boosting ability. Accordingly, for such products, a representative average use cycle must encompass the ''capacity boosting'' capability, as this is the mode that the consumer will likely be using once the water heater is installed in the field. 88 FR 49058, 49164. However, before the June 2023 TP Final Rule, the DOE test procedure did not have a provision for measuring energy use of water heaters that continuously store water at a higher temperature to boost capacity. The June 2023 TP Final Rule established a high-temperature test method that would allow consumers to compare the energy efficiency of water heaters that increase capacity through elevated storage temperatures with water heaters that use larger tank volumes to achieve the same capacity. However, DOE deferred the implementation of high-temperature testing provisions to this energy conservation standards rulemaking. 88 FR 40406, 40448. This has allowed DOE to consider details of the implementation to best suit the needs of the market in a standards-case-scenario.

Whereas the June 2023 TP Final Rule established how to conduct a high-temperature test, this standards rulemaking establishes which products must use the high-temperature test method. In this final rule, DOE is adopting the proposed provisions for the application of the high-temperature test method, clarifying how the maximum tank temperature can be verified, adopting additional exemptions for very small and large electric storage water heaters, and permitting optional representations for heat pump water heaters using the high-temperature test method.

DOE received the following general comments in response to the July 2023 NOPR and December 2023 SNOPR regarding general support, applicability, and potential concerns around high-temperature testing and the use of effective storage volume. DOE also addresses information received regarding impacts associated with high-temperature testing.

The Joint Advocacy Groups supported DOE's proposed implementation of the effective storage volume and high temperature testing provisions, stating their agreement with DOE's determination that high-temperature testing is representative of the average use cycle for electric storage water heaters that offer consumers the ability to increase storage tank temperature. The Joint Advocacy Groups added that this proposal would also help ensure the expected savings from the proposed standards are realized. (Joint Advocacy Groups, No. 1165 at p. 7) NEEA supported DOE's proposed use of effective storage volume and high-temperature testing, asserting that it would effectively inhibit the use of small, overheated tanks installed with mixing valves as a means of circumventing heat pump-level standards, and would ensure the energy savings projected in the NOPR are

[187] Clear Seas Research. 2017 Water Heater Study. *clearseasresearch.com* (Last accessed: Dec. 1, 2023).

[188] Clear Seas Research. Water Heater Study. 2006. Plumbing and Mechanical.

[189] Clear Seas Research. 2020 Water Heater Study, available online at: *clearseasresearch.com.* (Last accessed: May 1, 2023).

realized. (NEEA, No. 1199 at pp. 7–8) CEC supported DOE's proposed high-temperature testing provisions, stating that they would close a significant loophole that would allow smaller, less-efficient storage water heaters to operate with higher effective storage volumes. (CEC, No. 1173 at p. 12) The Joint Stakeholders stated their support of the effective storage volume provisions, conditional on their narrow application to certain electric resistance storage water heaters, to aid in ensuring the expected savings from the proposed standards are realized.

The CA IOUs agreed that rated storage volume is no longer an appropriate measure for hot water service and supported the transition to using the effective storage volume metric, stating that such an approach is consistent with comments that they and others have provided previously in this rulemaking. The CA IOUs noted that only certain electric resistance storage water heaters would be subject to the high-temperature test method, and the effective storage volume would be equivalent to the rated storage volume for all other consumer water heaters. The CA IOUs recommended that DOE plainly state that high-temperature testing is applicable only for those electric storage water heaters with a maximum set point temperature above 135 °F, and that the effective storage volume for all other consumer water heaters is equal to the rated volume. (CA IOUs, No. 1175 at p. 2) The Joint Stakeholders also requested that DOE clarify the application of high-temperature testing and effective storage volume requirements with regards to product classes other than electric storage water heaters. (Joint Stakeholders, No. 1156 at pp. 1–2)

Rheem requested clarification on whether high-temperature testing is intended for electric instantaneous water heaters with rated storage volumes greater than or equal to 2 gallons. Rheem recommended that the high-temperature test method not apply to these products, as they are not direct replacements for heat pump water heaters. (Rheem, No. 1177 at p. 3)

To clarify, the high-temperature test method is applicable only to electric storage water heaters. It is not applicable to electric instantaneous water heaters. Consumer electric instantaneous water heaters, like consumer electric storage water heaters, are statutorily limited to an input rate of 12 kW (which corresponds to the typical household circuit limitations in residential buildings). (42 U.S.C. 6291(27)(A)–(B)) Instantaneous-type water heaters have at least 4,000 Btu/h of input per gallon of water stored. (42 U.S.C. 6291(27)(B)) Considering these two limitations, the maximum volume that a consumer electric instantaneous water heater could have is approximately 10 gallons. For the reasons detailed in section V.D.1.c of this document, products of this size are unlikely to use elevated temperatures to directly replace the consumer utility of a water heater with a larger stored volume of water. And, in response to the CA IOUs' request, DOE clarifies the verification of the maximum tank temperature in section V.D.1.b of this document, which does more than simply state the applicability of the high-temperature test method is based on a maximum setpoint.

NYSERDA supported the use of the effective storage volume and the high-temperature test method, but noted that, although the high-temperature test applies only to certain electric storage water heaters, the appendix E test procedure would also result in an effective storage volume greater than rated storage volume for all other water heaters when $T_{max,1}$ is greater than 130 °F and also more than 5 °F higher than the delivery temperature, $T_{del,2}$.[190] NYSERDA therefore asked for clarification on how the effective storage volume metric is applied to different water heaters. (NYSERDA, No. 1192 at pp. 5–6, 7)

DOE is maintaining the provisions in appendix E, which result in a higher effective storage volume to products that have an internal tank temperature five degrees above the delivery set point temperature in order to assess products on an equivalent effective storage volume basis. As discussed in the June 2023 TP Final Rule, this would typically only apply if the product has a built-in mixing valve and normally operates in a manner that elevates the storage tank temperature in its default mode. Therefore, the increased effective storage volume is representative of the actual performance of such a model in its default mode. In the June 2023 TP Final Rule, DOE presented test data which demonstrated that only models with this specific design had effective storage volumes greater than rated storage volumes, and that all other traditional models of storage water heaters were unaffected.

GEA expressed support for DOE's proposals regarding high-temperature testing and the scope of products to which it would apply. GEA stated that DOE's proposed rule appropriately recognizes the importance of integrated mixing valves and accounts for them. However, GEA concurred with AHRI's comments regarding needed clarifications to the test procedure and standard and to the appropriate temperature limits for high-temperature testing (which are discussed in more detail later in this section). (GEA, No. 1203 at pp. 1–2)

Rheem agreed that the transition from electric resistance to heat pump storage water heaters presents an incentive to increase the temperature of an electric resistance storage water heater to increase the amount of hot water it can deliver. Rheem also stated that high-temperature testing should only be valid for products that operate with a stored volume of water (*i.e.,* storage-type or circulating). (Rheem, No. 1177 at p. 2) Relatedly, Rheem supported the application of the high-temperature test method to tabletop water heaters because these products can be used to replace heat pump water heaters. (Rheem, No. 1177 at p. 3)

Other commenters provided feedback for DOE to consider additional potential impacts of the high-temperature test method on the market. BWC stated that elements of the test procedure, such as the method for circulating water heaters and the application of high-temperature testing, appeared to be incomplete in the June 2023 TP Final Rule, and that DOE has continued to revise these aspects of the test procedure in the July 2023 NOPR. (BWC, No. 1164 at p. 7) AHRI raised concerns with the high-temperature test provisions for electric storage water heaters, stating that these provisions and their implications should have been fully addressed in the recent test procedure rulemaking because manufacturers require additional time to understand the proposal and how it would be implemented. AHRI stated that DOE has not provided clear direction in the July 2023 NOPR as to how the high-temperature test will be applied and enforced. (AHRI, No. 1167 at p. 2) AHRI and its members asserted that DOE has not provided sufficient test data for stakeholders to understand the impacts of the high-temperature test method on electric resistance storage water heaters. (AHRI, No. 1167 at p. 2)

A.O. Smith commented that the purpose of the high-temperature test method was to prevent circumvention of heat pump-level standards for larger electric storage water heaters by means of using a smaller electric resistance storage water heater operating at a higher temperature. A.O. Smith also

[190] $T_{max,1}$ is the maximum measured mean tank temperature after cut-out following the first draw of the 24-hour simulated-use test. $T_{del,2}$ is the average outlet water temperature during the 2nd draw of the 24-hour simulated-use test. See section 1.15 of appendix E.

noted that there may be additional avenues by which industry could avoid transitioning the market to heat pump water heaters. A.O. Smith recommended addressing these concerns in a supplemental NOPR prior to finalizing this rulemaking. A.O. Smith commented that understanding the relationship between maximum temperature offering, effective storage volume, FHR, and UEF is a prerequisite for evaluating the proposed efficiency levels for the electric storage water heater product classes. (A.O. Smith, No. 1182 at pp. 3–4)

A.O. Smith also asserted that DOE has not provided justification nor testing data to demonstrate that the direct substitution of effective storage volume instead of rated storage volume will make up for the known negative impact that testing at higher temperatures will have on UEF. Citing EPCA, A.O. Smith noted that DOE must account for the change in efficiency resulting from an amended test procedure and recommended that DOE test baseline very small and small electric storage water heaters according to the new test procedure to ensure that the proposed standards do not result in a stringency increase. To this end, A.O. Smith also provided its own test data, which demonstrate the reduction in UEF as a result of the high-temperature test method. A.O. Smith recommended that DOE adjust the standards to allow for these reduced ratings to remain compliant and minimize manufacturer redesign burden. (A.O. Smith, No. 1182 at pp. 3–4)

Rheem and A.O. Smith provided data that demonstrate the impact of high-temperature testing on these rated values for very small and small electric storage water heaters, while NEEA provided insights from its own testing regarding the relationship between temperature and FHR. (Rheem, No. 1177 at p. 21; A.O. Smith, No. 1182 at pp. 6–7) NEEA stated that the FHR increases by 2.5 gallons for every 5 °F increase in tank temperature from 125 °F. (NEEA, No. 1199 at pp. 7–8) Rheem stated that the boost in FHR from the high temperature will occur only for the first draw of the FHR test, and then afterwards the recovery rate will be the same, and the commenter provided an equation to estimate the increased FHR. (Rheem, No. 1177 at p. 21)

DOE reviewed the information from Rheem, A.O. Smith, and NEEA in addition to its own test data to evaluate the impact of the high-temperature test. For example, in the process of developing the June 2023 TP Final Rule, DOE collected data on one 50-gallon electric storage water heater set to three different tank temperature set points (one of them being the maximum setting that would be used for the high-temperature test method). 88 FR 40406, 40447.

The results of DOE's assessments on very small electric storage water heaters follow in section V.D.1.c of this document. DOE's calculations and data from stakeholders have led DOE to conclude that the high-temperature test method should not be required for very small electric storage water heaters.

In its own modeling analysis, Rheem identified that electric storage water heaters with rated storage volumes between 20 and 35 gallons would be noncompliant with the proposed standards if tested to the high-temperature test method, and therefore, all such products would have to be redesigned to use an exemption. (Rheem, No. 1177 at p. 2)

DOE has identified 35 certified basic models of small electric storage water heaters in its market assessment (*see* appendix 3A to the final rule TSD) and determined that all of these models heat water using electric resistance elements and, as currently designed, do not meet any of the criteria for an exemption to the requirement to determine UEF according to the high temperature test method. For example, most of these products are likely capable of heating and storing water at or above the temperature threshold criterion that would, if they were capable of only heating and storing water at that temperature or less, exempt them from high temperature testing (the temperature criterion is discussed in more detail in the following section of this document). (Heat pump small electric storage water heaters, discussed later in this paragraph, were not certified to DOE.) Based on the calculations provided by Rheem and NEEA, DOE has determined that the vast majority of these small electric storage water heaters are capable of achieving an FHR of more than 51 gallons when set to the highest temperature set point (as would be required under high-temperature testing), and thus these products would qualify for the medium draw pattern when tested to the high-temperature test method. As such, these products would be subject to the standards for electric storage water heaters under 55 gallons generally and not the standards for small electric storage water heaters, which are applicable only for products in the very small and low draw patterns. Further, the models that would remain in the low draw pattern (having an FHR less than 51 gallons) would have an effective storage volume greater than 35 gallons, such that they would not be considered small electric storage water heaters, either. Therefore, these specific small electric storage water heaters would be subject to standards being adopted for electric storage water heaters with 20–55 gallons of storage volume generally (*i.e.*, the standards for small electric storage water heaters would not apply), which are met through use of heat pump technology, unless they are redesigned to be eligible for one of the exemptions from high-temperature testing. If a product were redesigned to become eligible for an exemption, then the high-temperature test method would not be required, and thus these electric resistance products would remain as small electric storage water heaters and be subject to the standards being adopted for small electric storage water heaters, which can be met using electric resistance heating.

Additionally, in response to A.O. Smith's concern regarding the potential need to adjust small electric storage water heater standards to account for the impact of the high-temperature test, DOE notes that redesigns to the thermostat capabilities of electric storage water heaters are expected to be relatively low-cost for manufacturers, and products redesigned in such a manner would still be able to serve the majority of the market based on consumer field usage data (as described above). In a final rule amending test procedures for commercial water-heating equipment, DOE evaluated the implications of removing a temperature criterion of 180 °F that previously was part of the definition of a commercial water heater. 81 FR 79261, 79285 (Nov. 10, 2016). In that final rule, it was discussed that redesigning water heaters to account for the 180 °F temperature threshold can be achieved through replacement of a single part, the thermostat, which can be very easily and inexpensively changed to allow for heating water to greater than 180 °F. *Id.* In 2016 A.O. Smith commented that a thermostat designed to deliver water temperatures in excess of 180 °F can be installed at no additional cost on products that are consumer water heaters in all other respects. *Id.* (*See also* A.O. Smith, Docket No. EERE–2014–BT–TP–0008, No. 27 at pp. 6–7). In light of these previous stakeholder comments there is no reason to believe that, for small electric storage water heaters, redesigning models to limit the temperature to 135 °F would increase the price of the product. Hence, DOE expects thermostat redesigns to become a common strategy for manufacturers to offer small electric storage water heaters

after the compliance date of this final rule.

However, this does not mean that all small electric storage water heaters available today would require redesign to be compliant with the amended standards set forth in this final rule. As discussed in section V.D.1.d of this document, the high-temperature test method is not required for heat pump water heaters; therefore, the high-temperature test method would not affect heat pump configurations on the market today. For example, consumers can continue to use circulating heat pump water heaters in small electric storage water heater configurations (*i.e.,* with small separate tanks) for cases where a small electric storage water heater is desired but without the specific design exemptions that electric resistance products would require. DOE has identified four recent models on the market—two of which have been marked for sale in the United States—which offer this capability.[191]

Consequently, DOE concludes that no compliant products on the market today will be required to use the high-temperature test method in order to demonstrate compliance with the standards being adopted in this final rule. Therefore, DOE is not establishing any specific enforcement provisions beyond the requirements of the appendix E test procedure with regards to the high temperature test method.

DOE recognizes that there may be additional ways for industry to develop alternatives to heat pump water heaters for consumers; however, DOE aims to have all products that offer the same performance, capacity, and consumer utility be treated equally under standards. The development and implementation of the high-temperature test method is one way to assure this for products that vary temperature to accomplish these ends. In addition to this, DOE is amending the definitions of the product classes to more accurately capture the branches of the market under which performance, capacity, and consumer utility can be grouped. This is discussed in section IV.A.1.e of this document.

PHCC commented that the storage temperature cannot be raised beyond the ability of a mixing valve to safely regulate the outlet water temperature, and that mixing valves are not inexpensive. PHCC asserted that the device itself can be 25 percent to 30 percent of the cost of the water heater itself, and along with additional labor, material, maintenance, and operational costs, which the commenter suggested would result in mixing valves not being a commonly used solution today. PHCC also warned that installation of water heaters at elevated temperatures without a mixing valve causes a serious safety risk in addition to increased standby losses. In its comment, PHCC stated that the creation of the limited capacity will almost ensure that the high-temperature outcomes will happen, and if so, DOE should consider mandating mixing valves to ensure safety for consumers. (PHCC, No. 1151 at p. 2)

The price of a mixing valve and its installation would vary depending on whether the mixing valve is shipped with the water heater, built into the water heater, or part of a standard installation kit. DOE understands the estimate of a mixing valve being 25 to 30 percent of the water heater's material price may reflect a separately purchased mixing valve. However, as discussed throughout this rulemaking and the most recent test procedure rulemaking, water heaters with built-in mixing valves or with mixing valves in the water heater's installation kit could become more common. Based on DOE's teardown analyses (as described in section IV.C.1.c of this document and chapter 5 of the final rule TSD), mixing valves that are provided by the water heater manufacturer could be significantly less expensive than ones purchased separately due to the volume in which water heater manufacturers can supply these. In the LCC analysis, DOE uses an estimate of approximately $75 per unit material price (before markup) based on the aforementioned teardown analyses assuming that the mixing valve can likely be provided by the water heater manufacturer in a scenario with amended standards.

While DOE agrees with PHCC that mixing valves are a safety feature and should be used to temper extra-hot water to a degree that does not pose such a high scalding risk, the Department notes that EPCA does not delegate DOE the authority to issue regulations mandating such a consumer safety feature. Instead, DOE is statutorily obligated to ensure that its energy conservation standards can be met by products that are safe for consumers (see the screening analysis criteria in section IV.B). In its analysis of amended standards for consumer water heaters in this final rule, DOE has determined that the standards for small electric storage water heaters can be met by products that either limit the high temperature capability or are compatible with mixing valves in order to protect consumers from scalding.

Therefore, as stated earlier, in this final rule, DOE is adopting the proposed provisions for the high-temperature test method, clarifying how the maximum tank temperature can be verified, adopting additional exemptions for very small and large electric storage water heaters, and permitting optional representations for heat pump water heaters using the high-temperature test method.

a. Maximum Tank Temperature

In the July 2023 NOPR, DOE proposed that certain water heaters that have a maximum setpoint temperature capable of heating and storing water above 135 °F would be required to conduct the high temperature test, while water heaters that can only heat and store water at or below 135 °F would not be required to undergo such testing. 88 FR 49058, 49165. In arriving at the 135 °F setpoint, DOE considered: (1) the effective storage volume of a small electric storage water heater with a rated storage volume of 35 gallons for various mean tank temperatures; and (2) potential consumer uses for higher storage tank temperatures. *Id.* The effective storage volume at various temperatures provides insight into the likelihood a small electric storage water heater would operate in a capacity-boosting mode, and in the July 2023 NOPR the Department provided a table that showed the effective storage volume for various tank temperature settings. Table V.37 from the July 2023 NOPR is reproduced here also. *Id.*

[191] Product literature for models of heat pump small electric storage water heaters can be found docketed at *www.regulations.gov/docket/EERE-2017-BT-STD-0019.* In the December 2023 SNOPR the Department had erroneously stated that there are no longer heat pump circulating water heaters available on the market (*see* 88 FR 89330, 89333) due to changes in a manufacturer's website.

Table V.37 Effective Storage Volume of a Water Heater with a 35-gallon Rated Storage Volume at Various Mean Tank Temperatures

Mean Tank Temperature (°F)	V_{eff} of Water Heater with 35-gallon V_r (gallons)
125	35
130	38
135	41
140	44
145	47
150	50
155	53
160	56
165	59
170	62

For instance, it is unlikely a consumer would purchase a 35-gallon small electric storage water heater and set the tank temperature to 130 °F to increase the effective storage volume to 38 gallons, which is less than a 9 percent increase in effective storage volume. On the other hand, at a maximum setpoint of 140 °F, a 35-gallon small electric storage water heater could replace up to a 44-gallon heat pump water heater, which represents more than a 25 percent increase in effective capacity. *Id.* The market share of medium electric storage water heaters around 40 gallons is approximately 40 percent. As a result, DOE proposed a maximum temperature setpoint of 135 °F.

However, DOE also recognizes that increased capacity is not the only reason a consumer may want a higher tank storage temperature. Higher temperature setpoints can allow consumers to pair water heaters with clothes washers or dishwashers that lack heating elements and can be used to reduce bacterial growth. While the data shows that only a small percentage of consumers are utilizing tank temperature setpoints greater than 135 °F, DOE notes that the 135 °F maximum temperature setpoint is not a temperature limit. There are heat pump models of small electric water heaters available on the market that are exempt from the high temperature testing provisions and have temperature setpoints of 140 °F or higher.[192] Additionally, DOE proposed that units capable of storing water at a setpoint above 135 °F only through a temporary, consumer-initiated mode lasting no longer than 120 hours would not be subject to high temperature testing. This would allow consumers to initiate the temporary, high-heat mode prior to using a clothes washer or dishwasher that lacks a heating element for special cleaning loads, *e.g.,* when dust mites or norovirus may be of particular concern. This temporary mode would also allow consumers to periodically raise the temperature of the tank past 135 °F to quickly eliminate any bacteria growth in the tank. For instance, if a consumer shuts their water heater off or puts it into a low-temperature vacation mode to conserve energy while not in use, they can use the temporary, high-heat mode to quickly eliminate any bacteria in the tank. Finally, DOE also notes that a setpoint of 135 °F is well within the range of many recommendations for controlling bacteria growth in storage water heaters.[193]

In response to the July 2023 NOPR, the Joint Advocacy Groups supported the proposed 135 °F threshold for high temperature testing provisions, adding that a threshold of 140 °F could significantly undermine the intent of the proposed standards by allowing 35-gallon water heaters to reach an effective storage volume of 44 gallons without being tested in a representative manner. The Joint Advocacy Groups also agreed with DOE's tentative determination that the proposed 135 °F threshold would not compromise the utility of the water heater for consumers who desire hotter water for certain situations. (Joint Advocacy Groups, No. 1165 at pp. 7–8) NEEA also urged DOE not to set the limit to require high-temperature testing any higher than 135 °F. (NEEA, No. 1199 at pp. 7–8)

BWC, on the other hand, urged DOE to consider increasing the temperature criterion for the high-temperature test exemption from 135 °F to 140 °F because residential electric storage water heaters that heat water to 140 °F serve a distinct health and safety function, as the Centers for Disease Control (''CDC'') recommends maintaining this temperature to mitigate the formation or presence of legionella bacteria. (BWC, No. 1164 at p. 9) AHRI also suggested that the temperature criterion for the high-temperature test exemptions be increased to 140 °F because setting the internal tank temperature to 140 °F may produce significant health and safety benefits to consumers (*i.e.,* killing legionella, norovirus, and dust mites). AHRI provided information that showed that washing clothes and bedding at 140 °F is one of the suggested guidelines that healthcare agencies provide to kill dust mites and norovirus. Additionally, AHRI cited information from the CDC, which recommends storing hot water above 140 °F to control for legionella. (AHRI, No. 1167 at p. 3–4)

A.O. Smith similarly commented that a temperature of 140 °F is recommended to wash bedding and linens to kill dust mites and norovirus. The commenter also referenced DOE's website, which recommends that people with suppressed immune systems may want

[192] Product literature for models of heat pump small electric storage water heaters can be found docketed at *www.regulations.gov/docket/EERE-2017-BT-STD–0019.* See, for example, models marketed to reach up to 145 °F: *www.nyle.com/wp-content/uploads/2023/01/SB-E008T-010323.pdf* and *www.heatwater.com/wp-content/uploads/2021/09/SB-C6-112923.pdf* (Last accessed Jan. 18, 2024).

[193] According to the CDC, legionella generally grow well between 77 °F and 113 °F, but growth slows between 113 °F and 120 °F, and legionella begin to die above 120 °F. See the CDC's Legionella Environmental Assessment Form. Centers for Disease Control and Prevention. Available online at *www.cdc.gov/legionella/downloads/legionella-environmental-assessment-p.pdf.* (Last accessed: Jan. 18, 2024).

to keep their tank temperature at 140 °F and install limited devices on taps and baths. A.O. Smith stated that several codes, including the National Plumbing Code of Canada,[194] require electric resistance storage water heaters to be shipped at a 140 °F set point; therefore, allowing a 140 °F set point would reduce manufacturer burden from having to produce separate model lines for the United States and Canada. (A.O. Smith, No. 1182 at p. 6) A.O. Smith collected data on water heater temperatures from a survey of 500 homeowners. The data, A.O. Smith stated, showed that 63 percent of respondents adjusted the water heater set point from the factory-shipped temperature.[195] Of those who adjusted the set point, 45 percent increased the set point, 38 percent decreased the set point, and 17 percent had done both. A.O. Smith also gathered data from 40-gallon ''connected'' water heaters [196] which showed that a total of 10 percent of customers have set the temperature higher than 135 °F, whereas 5 percent of customers have the temperature higher than 140 °F. A.O. Smith argued that it believes a threshold of 140 °F for exemption from high-temperature testing better maintains consumer utility. (A.O. Smith, No. 1182 at p. 6)

Rheem noted that the EF test procedure, which had been in use for over 25 years, had a representative nominal tank temperature between 130 and 140 °F, so a temperature of 140 °F is representative for a subset of water heaters in the field today. Rheem stated that, in addition to requirements in Canada, the CDC also recommends temperature control limits that store hot water above 140 °F. (Rheem, No. 1177 at p. 4)

Finally, the CA IOUs strongly recommended that the temperature criterion for the high-temperature test method exemptions be reduced to no more than 130 °F. The CA IOUs expressed concern that a temperature as high as 135 °F would still enable small electric storage water heaters to directly compete with a larger heat pump water heaters and erode the anticipated savings from heat pump-level standards. The CA IOUs calculated that if a lowboy water heater with 35 gallons of rated storage volume and a 51-gallon FHR were to operate at 135 °F with a thermostatic mixing valve, it would have an effective storage volume of 42 gallons and a new FHR of 56 gallons—which would appear to be in the range of the 20–55 gallon electric storage water heater class. Therefore, the CA IOUs stated that the high-temperature test should be required for electric storage water heaters that have a permanent mode or setting in which the water heater is capable of heating and storing water above the test procedure design temperature of 125 °F. (CA IOUs, No. 1175 at pp. 3–4)

First, in response to A.O. Smith's concern about manufacturer burden, DOE notes that harmonizing the factory-shipped setpoint temperature between the United States and Canada may not eliminate manufacturer burden. Specifically, the current minimum efficiency requirements for electric resistance storage water heaters are different in Canada, and several manufacturers currently offer distinct models in Canada to meet these requirements. *See* chapter 3 of the final rule TSD for more details on Canada's minimum efficiency requirements.

With respect to the comments on both raising and lowering the maximum setpoint temperature proposed in the July 2023 NOPR, DOE first notes that the maximum setpoint temperature is based on the expected use for these products. Data show that consumers do not generally use very high temperature setpoints even in light of CDC guidance, so the ''upper limit'' of temperatures found in normal installations appears to be lower than the 140 °F suggested by some stakeholders.

In the July 2023 NOPR, DOE tentatively determined that small electric storage water heaters that can heat and store water above 135 °F will be substantially more likely to be used permanently at higher temperatures to increase capacity (as discussed in section V.D.1 of this document). Commenters advocating for a higher maximum setpoint temperature of 140 °F do not dispute DOE's determination that small electric storage water heaters that can heat and store water above 135 °F will be substantially more likely to be used permanently at higher temperatures to increase capacity. Instead, they focus on the health and safety benefits of setting the tank temperature to 140 °F. DOE recognizes that higher temperatures, *e.g.,* 140 °F, can more quickly control bacterial growth in storage water heaters. But, as discussed previously, DOE is not limiting the maximum temperature setpoint for small electric water heaters. Based on DOE's and A.O. Smith's data, approximately 10% of consumers use a setpoint temperature greater than 135 °F. For these consumers who prefer setpoint temperatures greater than 135 °F, there are small electric heat pump water heaters on the market today that have setpoint temperatures above 140 °F, and these models would not be affected by the high-temperature testing provision. Further, as noted earlier, the temporary mode exemption will allow owners of electric resistance storage water heaters to periodically increase the temperature above 135 °F, and for up to 120 hours (or five days) at a time, if desired for short-term disinfection applications.

With respect to the comment from the CA IOUs that DOE lower the temperature to 130 °F, DOE thinks it is unlikely that a consumer would purchase a 35 gallon small electric water heater and operate it at 130 °F to increase the capacity by 3 gallons. While Rheem suggested that DOE refer to the outdated EF test procedure to determine what temperatures are considered typical, the current UEF test procedure can provide more recent insight. The current test method is based on a normal delivery temperature of 125 °F ± 5 °F (as discussed previously), and within this normal range, consumer storage-type water heaters may sometimes contain water at 130 °F due to natural deviations from the setpoint temperature.

For example, commercially available electric storage water heaters that are marketed today to boost the capacity using higher storage tank temperatures all do so with temperatures above 135 °F. One product tested by DOE has a ''High'' setting that results in a tank temperature of about 140 °F, and the setting below that resulted in a tank temperature of 125 °F. There was no setting observed to boost capacity at a tank temperature of 135 °F. Another manufacturer offers a 55-gallon product with a variety of settings allowing the user to get ''performance equivalency'' of a 65-, 80-, or 100-gallon tank, stating that the tank raises the temperature safely up to 170 °F. 88 FR 40406, 40446.

---

[194] National Plumbing Code of Canada 2020, page 200. Available online at: *nrc-publications.canada.ca/eng/view/ft/?id=6e7cabf5-d83e-4efd-9a1c-6515fc7cdc71r.* (Last accessed: Oct. 31, 2023).

[195] DOE notes that clause 23.3 of UL Standard 174, ''Household Electric Storage Tank Water Heaters,'' was recently updated to require that the temperature-regulating control shall be set before leaving the factory to a control position corresponding to a water temperature no higher than 51.7 °C (125 °F). When the water heater is equipped with a thermostatic mixing valve in addition to the temperature regulating control, the factory setting of the water temperature mixing valve shall be no higher than 51.7 °C (125 °F), and the temperature-regulating control shall be factory set no higher than 60 °C (140 °F). These updates went into effect on October 14, 2023. This standard can be accessed online at:*www.shopulstandards.com/ProductDetail.aspx?productId=UL174_11_S_20040429.* (Last accessed: Nov. 30, 2023).

[196] A.O. Smith did not specify whether these units were connected to a utility demand-response program or were otherwise equipped with WiFi-enabled controls and monitoring.

At the lowest level of capacity boosting, this model is offering 18 percent additional effective storage volume (going from 55 gallons to 65 gallons), which would indicate a temperature around 140 °F as well. These designs demonstrate that storing water at 140 °F is a useful temperature for boosting capacity, whereas 135 °F may not be.

Crystal also recommended that DOE review the allowed usage of germicidal UV–C water treatment in recirculating hot- and warm-water lines to complement or substitute thermal disinfection cycles. According to Crystal, this is allowed under regulation in several countries around the world, and therefore products and research are available on the market as well as ongoing novel technology adoptions improving the sustainability and energy efficiency and maintenance of this field further. (Crystal, No. 577 at p. 1)

DOE has not found examples of consumer water heaters using UV treatment to disinfect hot water lines. However, to address issues like this, one manufacturer produces a point-of-use water heater that uses ozone generation to disinfect the water in the pipes and at the faucet while still delivering hot water at a temperature that is comfortable for hand-washing (the unit is advertised to have a maximum set point temperature of 120 °F).[197] Additionally, circulating water heaters (discussed more in section IV.A.1.a of this document) are a type of storage water heater that can maintain the water in the pipes at a high temperature so that all of the water in the system stays at a safe temperature and does not stagnate. The high temperature test will not impede the function of either of these types of products, as discussed later. Another manufacturer uses an antimicrobial enamel coating inside the water heater tank to prevent the growth of bacteria, mold, and mildew on the surface of the tank lining (though it is not advertised to specifically prevent legionella growth).[198]

b. Verification of Maximum Tank Temperature

As discussed in the previous section, in the July 2023 NOPR, DOE proposed that products that are unable to heat and store water at a set point above 135 °F would not be required to test using the high-temperature test method. 88 FR 49058, 49165. DOE received the following comments in response to the July 2023 NOPR requesting clarification on the maximum tank temperature, how it is measured, and specific tolerances around required values as well as criteria for products exempt of the high-temperature test method.

BWC asked for DOE to further clarify what design factors would constitute a product that is not capable of heating and storing water above 135 °F. Specifically, BWC sought additional information on whether the exemption criteria would be based on a direct user interface function which operates the product or, instead, a thermostat capable of being set above 135 °F. The commenter provided examples of configurations with surface-mount thermostats and electronic controls, with and without mixing valves, to inquire whether these configurations would be exempt from the high temperature test. (BWC, No. 1164 at pp. 7–8)

AHRI asked DOE to elaborate on how it would enforce the high-temperature test method. The commenter stated that most electric storage water heaters utilize a surface-mount thermostat, which is unsophisticated and has a large temperature tolerance—as a result, the mean tank temperature may vary appreciably from the temperature set point. AHRI stated that the mean tank temperature will typically be lower than the thermostat setting. As a result, AHRI requested feedback on whether the enforcement of the high-temperature test method would be based on thermostat set points or on test data (in the case that it is test data, AHRI recommended a temperature tolerance of ± 5 °F on $T_{max,1}$ prior to requiring high-temperature testing in appendix E). AHRI recommended that DOE measure the maximum tank temperature using the $T_{max,1}$ measurement in the simulated-use test because it is commonly used in the industry to evaluate the effective storage volume and is referenced in the regulations already (manufacturers and labs are familiar with how to test for $T_{max,1}$, and there would be minimal burden associated with determining the tank temperature based on this metric). (AHRI, No. 1167 at p. 4)

A.O. Smith also requested that DOE clarify how the temperature criterion for the high-temperature test is determined—whether it is a set point or whether it is a measurement. A.O. Smith stated that additional specificity is necessary because most electric resistance storage water heaters on the market use mechanical controls (*e.g.,* bi-metallic thermostats) which turn the elements on and off, resulting in larger temperature variation around the set point. A.O. Smith also requested that DOE clarify the enforcement provisions surrounding the level of external consumer intervention required to be exempt from the high-temperature test. (A.O. Smith, No. 1182 at p. 5)

Rheem requested clarification on how the maximum temperature a water heater is capable of storing water at is measured (whether it be the maximum temperature on the thermostat settings, the maximum temperature within the tank, the maximum mean tank temperature, or the maximum outlet temperature as measured by a test in section 29 of UL 174–2021.6.[199] Rheem recommended the use of $T_{max,1}$ to verify the temperature that a water heater can heat and store water to. (Rheem, No. 1177 at p. 5) Rheem recommended that DOE require certification and disclosure in product literature of the maximum temperature, FHR, and UEF when tested to the high-temperature requirements. Rheem also recommended that DOE establish enforcement provisions to ensure the maximum temperature aligns with the certified values. Rheem commented that a tolerance of ± 5 °F for the maximum tank temperature and ± 3 percent on the effective storage volume would be necessary due to variability in the test procedure and the imprecise operation of bi-metallic thermostat controllers. Rheem also asked for clarification on how DOE would conduct enforcement testing, and if DOE will run tests at both temperature conditions, then what steps must be taken between the two simulated-use tests. (Rheem, No. 1177 at p. 6)

In response to these requests for clarification, DOE clarifies that the exemption will be determined based on $T_{max,1}$, which is a measured parameter in the current test procedure that represents the maximum measured mean tank temperature after cut-out following the first draw of the 24-hour simulated-use test. In order to develop product-specific enforcement provisions for the high-temperature test method, DOE must first identify whether manufacturers should certify this value privately; as such, a certification was not suggested in the July 2023 NOPR. DOE is deferring this determination to a separate rulemaking addressing certification and enforcement provisions for consumer water heaters and is not codifying any specific requirements in this final rule.

In addition to this topic, Rheem suggested that, instead of conducting the high-temperature test at the

[197] For more information, see product literature available online at: *www.intellihot.com/wp-content/uploads/2023/01/Legionator-Product-Spec-Sheet-2.23.pdf.* (Last accessed: Nov. 28, 2023).

[198] For more information, see product press release available online at: *www.microban.com/bradford-white.* (Last accessed: Nov. 29, 2023).

[199] See UL 174–2021.6, UL Standard for Safety Household Electric Storage Tank Water Heaters.

maximum tank temperature, the high-temperature test should be conducted at a standardized temperature. Rheem recommended that the high-temperature test be performed at 160 °F ± 5 °F as a representative temperature for this type of water heater operation by 2029. Rheem stated that 160 °F is in between the 135 °F temperature criterion and the 180 °F maximum temperature (given that UL 174–2021 safety standard limits the maximum tank temperature to 185 °F). Rheem commented that future demand-response programs will also require operation at or above 160 °F. (Rheem, No. 1177 at p. 5)

In response to Rheem's request for a fixed set point temperature for high-temperature testing, DOE notes that not all water heaters with the capability to store water above 135 °F will necessarily have the capability to store water at 160 °F; hence, DOE is not adopting any changes to the set point requirements for the high-temperature test method. While the test may not be carried out at the exact temperature to which the water heater would be set in the field, it would be representative of the maximum temperature the water heater can sustain safely, which is important for consumer purchase decisions. UEF decreases with increased tank temperature; therefore, the water heater is expected to perform at least as well as a high-temperature rating evaluated at the highest tank temperature set point, all other environmental conditions the same. Should additional information become available regarding the set point temperatures of consumer electric resistance storage water heaters in the field, DOE may consider it in a future test procedure rulemaking.

c. Very Small and Large Electric Storage Water Heaters

In response to the July 2023 NOPR, some commenters stated that very small electric storage water heaters (*i.e.,* products with less than 20 gallons of rated storage volume) should not have to test to the high-temperature test method because these products are too small to reasonably substitute for larger heat pump water heaters, so it may be unlikely that these products are set to a high tank set point temperature.

Rheem suggested that the high-temperature test should be narrowly applied only to those electric storage water heaters which have potential to introduce a circumvention risk for heat pump water heater standards. In its comments, Rheem indicated that these products would be tabletop and electric storage water heaters with rated storage volumes greater than or equal to 20 gallons and less than or equal to 35 gallons. Rheem recommended that high-temperature testing should not apply to all other electric water heaters with storage volume. (Rheem, No. 1177 at p. 2) In its analysis, Rheem determined that a 19-gallon very small electric storage water heater would need to store water at 180 °F to achieve an FHR of approximately 51 gallons, which is much higher than is typically observed in consumer water heaters. On this basis, Rheem stated that very small electric storage water heaters cannot match the delivery capacities of 20–55 gallon electric storage water heaters, which would otherwise require heat pump technology. (Rheem, No. 1177 at pp. 2–3)

For electric resistance storage water heaters with rated storage volumes less than 20 gallons, AHRI recommended that high-temperature testing not be required because these units are unlikely to get into medium draw patterns at higher test temperatures. (AHRI, No. 1167 at p. 6)

A.O. Smith commented that, because small electric storage water heaters are the most likely to be operated at a higher temperature with a mixing valve to match the performance of larger water heaters, the high-temperature test method should be limited to small electric storage water heaters only. From its own testing of a 17-gallon very small electric storage water heater, A.O. Smith determined that increasing the set point from 125 °F to 150 °F resulted in a 43-percent increase in effective storage volume, but only a 4-percent increase in FHR, and thus A.O. Smith concluded that very small electric storage water heaters cannot match the performance of larger water heaters, even when operating at their highest set point temperatures. A.O. Smith recommended that DOE specify the high-temperature test only applies to 20–35 gallon products in order to maintain representativeness while reducing manufacturer testing burden. A.O. Smith commented that this would still ''close the loophole'' for heat pump water heater circumvention. (A.O. Smith, No. 1182 at pp. 6–7) Providing this information, A.O. Smith recommended that electric resistance storage water heaters of less than 20 gallons or greater than 55 gallons should be exempt from the high-temperature test method. (A.O. Smith, No. 1182 at p. 7)

To evaluate a potential exemption, DOE reviewed test data it had collected from very small electric storage water heaters in support of the proposed standards. These products, ranging in rated storage volume between 1.8 gallons and 19.9 gallons, all had delivery capacities in the very small or low draw patterns. Per its calculations, DOE also came to the same conclusion as commenters: no model would be capable of achieving an FHR high enough to place the water heater in the medium draw pattern at the highest tank temperature set point.

Based on DOE's data and information presented by commenters, DOE agrees that products with rated storage volumes of less than 20 gallons would not likely be set to higher temperatures to boost household delivery capacity as a substitute for a larger water heater. Therefore, DOE is exempting all very small electric storage water heaters from having to test to the high-temperature test method to demonstrate compliance with new UEF-based standards.

In addition to the previous suggestions provided by manufacturers, DOE received comments from NYSERDA and the CA IOUs suggesting that the high-temperature test method does not serve a purpose for larger electric resistance storage water heaters. NYSERDA stated that the high-temperature test method should not apply to larger-volume electric resistance storage water heaters that are already subject to heat pump-level standards. (NYSERDA, No. 1192 at p. 6) NYSERDA stated that exempting electric storage water heaters larger than 55 gallons of rated storage volume from the high-temperature test method (or potentially capping the effective storage volume) would reduce test burden and allow manufacturers to maintain the status quo for larger electric resistance storage water heaters. (NYSERDA, No. 1192 at p. 6) The CA IOUs suggested that DOE amend the calculations for effective storage volume such that products with rated storage volumes less than or equal to 120 gallons would be capped at an effective storage volume of 120 gallons. (CA IOUs, No. 1175 at pp. 3–4)

DOE agrees with NYSERDA and the CA IOUs that for products above a certain volume threshold, it is unlikely that testing according to the high-temperature method would provide more representative ratings. Specifically, the currently applicable standards for electric storage water heaters greater than 55 gallons of rated storage volume and less than or equal to 120 gallons of rated storage volume correspond to products with heat pump technology, such that all of these products on the market today are heat pump water heaters. (See 10 CFR 430.32(d)). Heat pump water heaters, discussed further in section V.D.1.d of this document, would already be exempt from the high-temperature test

method, as it is unlikely to be more representative for these products. Therefore, it is logical to exempt products that are 55–120 gallons of rated storage volume from the high-temperature test method, as this would be synonymous with the heat pump water heater exemption. Next, while DOE has not observed consumer electric storage water heaters on the market beyond 120 gallons of rated storage volume, it is unlikely that such very large products would rely on high-temperature operation to provide consumers with additional capacity: these products already contain rated storage volumes that are greater than those of products that have to comply with heat pump-level standards, such that the elevated temperature is not necessary to provide as much capacity as a heat pump water heater. Because of this, DOE has concluded that it is reasonable to exempt any electric storage water heater greater than 55 gallons of rated storage volume from the high-temperature test method.

This exemption for large electric storage water heaters additionally prevents potential backsliding from the standards of 55–120 gallon products, a concern brought up by multiple stakeholders and discussed in section IV.A.1.e of this document, because the rated storage volume and effective storage volume would thus be equal for any model greater than 55 gallons. An electric storage water heater between 55 and 120 gallons of rated storage volume would be required to demonstrate compliance with standards in accordance with the normal temperature test method, meaning that it cannot use the high temperature test method to increase its effective storage volume beyond 120 gallons and become subject to less-stringent standards.

d. Optional Representations for Heat Pump Water Heaters

In the July 2023 NOPR, DOE proposed that high-temperature testing would not apply to products that meet the definition of ''heat pump-type'' water heater at 10 CFR 430.2. 88 FR 49058, 49166.

CEC stated their appreciation of DOE's recognition for the significant non-efficiency grid benefit potential provided by maximizing the thermal storage of heat pump water heaters through the use of higher set point temperatures and thermostatic mixing valves. (CEC, No. 1173 at p. 12)

Rheem supported allowing optional high-temperature representations for certain heat pump water heaters because high-temperature operation might become more representative of heat pump water heater installations for three main reasons: (1) the increased need for demand-response water heaters that can perform advanced load-up and high-temperature energy storage, (2) the longer recovery time for heat pumps can be offset by storing water at a higher temperature to increase the amount of hot water immediately available, and (3) because a heat pump increases the size of the water heater, a comparable FHR can require elevated storage temperature. Rheem suggested that high-temperature operation for heat pump water heaters could cause even units with high UEF ratings to perform worse in the field. (Rheem, No. 1177 at pp. 2–4)

As noted in section V.D.1 of this document, if a water heater in its default mode of operation [200] has an internal tank temperature that significantly exceeds the delivery set point temperature, the calculation of effective storage volume captures this effect even without the high-temperature test method. (*See* section 6.3.1.1 of appendix E.) The FHR test would be carried out in this default mode and capture the increased delivery capacity. The 24-hour simulated-use test would be carried out in this default mode and would capture the increased standby losses from the higher-temperature operation. Therefore, if any heat pump water heater is designed to boost the tank temperature and incorporate a mixing valve as part of its normal operation, the effective storage volume, FHR, and UEF values resulting from the appendix E test procedure as written would be representative of this type of operation in the field.

DOE did not receive any other comments requesting that the high-temperature test method be made optional for voluntary representations of heat pump water heaters; however, DOE understands there is potential need to demonstrate storage and delivery capacity for heat pump water heaters representative of high-temperature operation that is not the default mode. Heat pump water heaters, unlike traditional electric resistance storage water heaters, can offer more modes to control the way the compressor and backup elements behave as a natural outcome of having more than one way to heat the water, and increasing storage tank temperature could be one potential way to increase delivery capacity when the compressor operates alone (*i.e.,* offers a slower recovery speed). In the June 2023 TP Final Rule, DOE adopted optional metrics for voluntary representations of heat pump water heaters to demonstrate performance in a variety of different environmental conditions because this information, DOE surmised, would be relevant for consumer information, and manufacturers already tested products to these alternate conditions. 88 FR 40406, 40437–40438. Similarly, DOE has determined that optional high-temperature representations would be relevant for consumer information as the market transitions towards this technology.

First, as discussed earlier, certain consumers using certain water heater configurations may desire higher set point temperatures, in which case the high-temperature test method could provide representative performance results. Second, as indicated by Rheem, future heat pump water heater control strategies could use variation of the storage tank temperature to compensate for slower compressor recovery periods when backup elements are either absent or disabled. A.O. Smith commented that consumers may be led to ''upsize'' when transitioning to a heat pump water heater (*see* section IV.C.1.b of this document for further discussion of this comment); however, as Rheem suggested, high-temperature performance data could enable consumers to purchase smaller, less expensive heat pump water heaters if the high-temperature performance data demonstrate equivalent performance to a larger product.

Unlike the mandatory requirement for electric resistance storage water heaters, the high-temperature test is optional for heat pump water heaters. This is because DOE expects the representativeness of this test method to depend on the designs of heat pump water heaters that emerge within the compliance period of this final rule. At this time, heat pump water heaters comprise a relatively small portion of the market; therefore, consumer preferences and usage are not yet as well understood (whereas, for electric resistance storage water heaters, several commenters indicated that the high-temperature test method would be representative of field applications). Should higher tank temperatures become more prevalent in field use as a result of a technology transition, DOE may revisit the implementation of the high-temperature test method in a future test procedure rulemaking.

e. Temporary Mode

Some electric resistance water heaters could offer high-temperature modes that

[200] Section 5.1.1 of appendix E outlines the determination of the operational mode for testing heat pump water heaters, which shall be the default mode unless otherwise specified.

allow for set points above the intended delivery temperature to boost delivery capacity, but only temporarily before automatically reverting to the normal temperature mode. This contrasts with several models that are currently available, which remain in the high-temperature setting until the consumer changes the mode or setting to deactivate the high-temperature mode. Temporary modes would be intended for occasional use in situations in which there is a short-term increased demand for hot water, while non-temporary modes would be more likely to be used long-term. In the June 2023 TP Final Rule, DOE discussed comments it received from stakeholders regarding water heaters with high-temperature modes. Specifically, stakeholders indicated that high-temperature modes are not intended to be the primary mode of operation and should not be used continuously, and that testing in these modes would not reflect their intended use. 88 FR 40406, 40449.

DOE understands that temporary high-temperature modes would be unlikely to be used long-term because they would automatically return the set point to a more typical temperature after a certain period of time has elapsed. Because these temporary modes cannot be used permanently, in the July 2023 NOPR DOE tentatively determined that units capable of storing water at a set point above 135 °F only through a temporary, consumer-initiated, high-temperature mode lasting no longer than 120 hours should not be subject to high-temperature testing. 88 FR 49058, 49165. DOE expects that such products would operate in non-high temperature modes for the majority of the time and, therefore, testing in the high-temperature mode would not be representative. Thus, DOE proposed to limit the high-temperature mode duration to 120 hours as a reasonable amount of time that demand may be temporarily higher than normal (such as when guests are visiting). Further, DOE expected that models with permanent high-temperature modes, whether shipped from the factory with that mode as the default mode or simply as a user-selectable mode, would be likely to be used continuously in the high-temperature mode. Therefore, DOE tentatively concluded it is representative to test such water heaters in the high-temperature modes and is proposing to require such testing. *Id.*

GEA commented that DOE's 120-hour limit without user intervention for extra demand is an appropriate approach for maintaining consumer utility and the energy-saving benefits of such features. (GEA, No. 1203 at pp. 1–2)

AHRI requested that DOE provide additional information on what meets the definition of a ''consumer-initiated'' high-temperature mode, which, if lasting less than 120 hours, would deem the product exempt from the high-temperature test method. AHRI also inquired as to the type of interaction by the user that is necessary to satisfy the requirement and whether the user can create a schedule. AHRI raised a concern that if products fail to meet the specific requirement for the temporary mode exemption, products tested to the high-temperature test method would not be able to comply with standards. (AHRI, No. 1167 at p. 4) BWC also asked for DOE to further clarify what a ''permanent mode or setting'' meant for the high-temperature test exemption. (BWC, No. 1164 at pp. 7–8)

Stanonik stated that the proposed addition of high-temperature testing provisions is confusing, and added that the provisions may be read to apply to most electric storage water heaters despite the fact that DOE explains the provisions are only meant to apply to a subset of them. Stanonik requested DOE clarify if the act of changing the thermostat on a consumer water heater would be considered an ''external consumer intervention'' that would then exclude the water heater from high-temperature testing. (Stanonik, No. 1197 at p. 1)

Rheem stated that it was generally supportive of the outlined exemptions from the high-temperature test, except for the temporary setting exemption. Although Rheem had suggested that DOE investigate temporary modes of operation in the test procedure rulemaking, Rheem indicated in its comments to the July 2023 NOPR that such an exemption would not be necessary if the test method were clarified and the temperature criterion were raised from 135 °F to 140 °F. (Rheem, No. 1177 at pp. 6–7)

In response to these requests from stakeholders, DOE is clarifying what would constitute consumer intervention for the purpose of the high-temperature test exemption. As discussed in section V.D.1.b of this document, a high-temperature mode would be one in which the water heater can achieve a $T_{max,1}$ greater than 135 °F during the 24-hour simulated-use test. If the water heater is set to such a mode, and the only time when it can achieve a $T_{max,1}$ greater than 135 °F is in the period of time that lasts 120 hours or less after the mode or setting is engaged by the user, then this would constitute a temporary high-temperature mode. To be exempt from the high-temperature test method, such a temporary high-temperature mode can only be activated via user intervention with the water heater. Once the temporary period of high-temperature operation has elapsed, the water heater must return to a lower tank temperature that would result in a $T_{max,1}$ less than or equal to 135 °F. If the user wishes to extend the period beyond 120 hours, they must reactivate the mode manually.

The purpose of this exemption is to allow products to increase capacity when there are limited times of high demand. Therefore, the consumer would have to manually activate the mode (*e.g.,* pushing a physical or digital button) if the high-temperature mode is required. If, instead, a product adheres to a regular schedule of high-temperature operation, a product would operate in a manner that demonstrates a consistent need for additional capacity, and in such a case the high-temperature test method would be more representative of the average daily use cycle of the product. For this reason, a scheduled setting would not be exempt from the high-temperature test method. For the normal-temperature test to remain representative of the ratings of the product, the water heater must permanently return to a mode in which the $T_{max,1}$ will not exceed 135 °F at any time after the temporary high-temperature operation has elapsed, and the only way in which the water heater would return to an elevated temperature is if the consumer interacts with the product manually again.

In response to Stanonik's question, the act of manually changing the set point temperature to achieve a mode in which the water heater can attain a $T_{max,1}$ beyond 135 °F is generally addressed in section V.D.1.b of this document. If the consumer can set the water heater to permanently heat and store water beyond 135 °F, then the water heater is not exempt from the high-temperature test. As outlined in section V.D.1.g of this document, such a model would not pass the second criterion for exemption.

f. Demand-Response Water Heaters

In the July 2023 NOPR, DOE proposed to exempt from high-temperature testing any water heaters that can only heat and store water at temperatures above 135 °F in response to instructions received from a utility or third-party demand-response program. DOE reasoned that the additional energy consumption from high-temperature water storage in demand-response water heaters is compensated for by periods of water heater inactivity (*i.e.,* a curtailment period) and, thus, demand-response water heaters do not engage in high-

temperature water storage in order to directly increase capacity over a representative average use cycle of 24 hours. 88 FR 49058, 49166.

AHRI stated that it appreciated the exemptions from the high-temperature test method, especially regarding demand-response water heaters; however, AHRI asserted the demand-response exemption was not clearly defined. AHRI requested DOE clarify the extent of this exemption for manufacturers. (AHRI, No. 1167 at p. 2) AHRI commented that setting an arbitrary maximum temperature for electric storage water heaters may create potential issues for consumers in jurisdictions with demand-response requirements. Specifically, AHRI stated that load-up events for demand-response water heaters allow products to store energy, and limiting the temperature of the water heater will limit its load-up capability. AHRI requested that DOE consider increasing the temperature criterion for the high-temperature test exemptions in order to accommodate this function of demand-response water heaters. (AHRI, No. 1167 at p. 3)

BWC expressed concerns with how DOE's high-temperature test method might impact demand-response electric resistance water heaters, suggesting that there could still be complications for these products even with the exemption from the high-temperature test method. BWC stated that the purpose of demand-response controls, as required in many states, is to heat the unit to a higher temperature during off-peak hours to store energy during times of peak electric grid demand, and that these controls can be activated by either the utility or the consumer themselves. BWC commented that water heaters would be incapable of storing water at or above 135 °F if the proposal were finalized, which would limit the load-shifting capabilities of demand-response water heaters. (BWC, No. 1164 at p. 8)

In response to commenters' concern about demand-response water heaters being limited to 135 °F, DOE is clarifying the meaning of its proposed exemption to the high-temperature test method. As noted previously, DOE proposed that electric storage water heaters capable of heating and storing water over 135 °F only in response to utility demand response signals would not be subject to high-temperature testing. This exemption was proposed so that water heaters intended for use in demand-response programs would not have to limit their temperature, provided that the ability to raise the temperature is initiated only as part of the water heater's use in a demand-response program. (This does not, however, preclude a demand-response water heater from also having a manual temporary high-heat mode as described in the previous section.)

In this final rule, DOE is adopting an exemption to the high-temperature test method that will allow demand-response programs to elevate the temperature of the water heater to any temperature that the unit is capable of achieving, so long as the unit can only achieve those temperatures as a result of the demand-response operation and not as a result of the user increasing the set point temperature. For example, a product with its maximum user-operable set point can store water at or below 135 °F during normal operation, but in response to utility signals requesting a load-up, the product can increase the temperature to 160 °F (as an example) would be exempt from the high-temperature test method because the user cannot set the water heater to continuously operate above 135 °F. Whereas continuous operation above 135 °F would increase the effective storage volume and FHR of the water heater, a load-up event that prompts the water heater to increase the temperature above this point does not. The load-up event only temporarily boosts the temperature so that the water heater can rely on stored energy throughout peak grid demand periods instead of relying on electricity from the grid; therefore, over the course of a representative average-use cycle (one day), the water heater does not provide extra capacity compared to when it is set to a lower temperature and allowed to recover the tank throughout the day.

Additionally, AHRI questioned whether grid-enabled water heaters are also exempt from the high-temperature testing method. (AHRI, No. 1167 at p. 3) BWC also requested clarification on whether the high-temperature test method would apply to grid-enabled water heaters, as this was not mentioned in either the June 2023 TP Final Rule or the July 2023 NOPR. (BWC, No. 1164 at pp. 8–9) Rheem argued that, because grid-enabled water heaters are intended for demand-response, they are not a direct replacement for heat pump water heaters to a great extent, and that the high-temperature test method need not apply to grid-enabled water heaters. (Rheem, No. 1177 at p. 3)

Grid-enabled water heaters, discussed in section IV.A.1.e, are defined as having rated storage volumes greater than 75 gallons (see 10 CFR 430.2). In section V.D.1.c of this final rule, DOE concluded that products with rated storage volumes greater than 55 gallons would be exempt from the high-temperature test method. As a result, all grid-enabled water heaters are exempt from the high-temperature test method. Grid-enabled water heaters are a specific subset of electric storage water heater products, which must be enrolled with a grid utility program and are designed for the purpose of demand-response control. As such, DOE expects that these products achieve higher storage temperatures as a result of utility signals and not as a result of a consumer's need for additional hot water. Therefore, DOE has concluded that it is representative for grid-enabled water heaters to test to a normal set point temperature and not the high-temperature test method.

g. Summary of the High-Temperature Test Method Applicability

As a result of the considerations discussed in the previous sections, DOE is establishing that the high-temperature test method must be conducted for all electric storage water heaters, except for those meeting the following exemptions.

The first exemption is for products that are not capable of heating the stored water beyond a $T_{max,1}$ temperature of 135 °F. If the product has a $T_{max,1}$ less than or equal to 135 °F when tested in the user-operable mode that results in its highest set point, the product is exempt. This temperature criterion allows the water heater to maintain its utility of providing hotter water for certain consumer needs without increasing the temperature so much that the water heater can be used as a direct substitute for a larger water heater that must comply with more stringent standards. Beyond this temperature, the high-temperature test method is more representative of the product's use in the field.

The second exemption is for heat pump water heaters. As discussed previously, heat pump water heaters are unlikely to be used to a significant extent at high temperatures. However, in the event that a heat pump water heater is designed for high-temperature operation, the heat pump water heaters are allowed to use the high-temperature test method optionally for voluntary representations, but normal set point operation (section 5.1.1 of appendix E) is the mode that must be used to demonstrate compliance with standards.

The third exemption is for demand-response water heaters, specifically those products which can only attain temperatures beyond 135 °F when requested to do so by a utility signal. If a product does not allow the consumer to operate it in a manner that would result in a $T_{max,1}$ beyond 135 °F but does allow the grid to increase the tank temperature above this point, it remains

exempt from the high-temperature test method.

The fourth exemption is for water heaters that allow the user to raise the temperature beyond 135 °F, but only for a maximum of 120 hours before automatically resetting to a temperature setting that results in $T_{max,1}$ at or below 135 °F. This allows water heaters to provide flexible-capacity modes for times when consumers may experience increased occupancy in the residence and thus a greater demand for hot water. The water heater must return to a mode that would result in a $T_{max,1}$ less than or equal to 135 °F after the 120-hour period elapses unless the user activates the boost mode again.

The fifth exemption is for water heaters of in-size categories where high-temperature operation is not expected to be representative of the product's function over an average daily use cycle. Very small electric storage water heaters (those with rated storage volumes less than 20 gallons) and large electric storage water heaters (those with rated storage volumes greater than 55 gallons) are not expected to use higher temperatures to boost capacity in order to be direct substitutes for products which have significantly more stringent standards.

This final rule adopts these five exemptions for section 5.1.2 of appendix E and 10 CFR 429.17.

2. Circulating Water Heaters

a. Separate Storage Tank Requirements

In response to the December 2023 SNOPR, NYSERDA encouraged DOE to review the test procedure to ensure that defining circulating water heaters as storage-type water heaters is consistent with the test method developed for these products. (NYSERDA, No. 1406 at p. 2)

The test method for circulating water heaters, as established by the June 2023 TP Final Rule, requires these products to be connected to a separate storage tank to serve as the volume of hot water that the circulating water heater requires for its function. *See* section 4.10 of the appendix E test procedure. As such, when a circulating water heater is tested per the appendix E test method, the test method will account for the stored volume of hot water and the standby losses that occur from it. This is analogous to how other traditional storage-type water heaters are tested.

When considering the potential impact of the proposed standards for electric storage water heaters on the availability of products to pair with heat pump circulating water heaters, DOE tentatively decided in the July 2023 NOPR that it would be more representative to pair such a product with an electric resistance storage water heater, surmising that is unlikely for consumers to pair a circulating heat pump water heater with an integrated heat pump water heater because they would already receive the energy-saving benefits of the integrated heat pump water heater. 88 FR 49058, 49167. Thus, in the July 2023 NOPR, DOE proposed to amend the separate storage tank requirement for a heat pump circulating water heater to reflect an electric resistance storage water heater that would be compliant with the proposed standards. Specifically, this proposed requirement was to pair a heat pump circulating water heater with a 30 gallon ± 5 gallon electric resistance storage water heater in the low draw pattern. *Id.*

In response to the July 2023 NOPR, some commenters indicated that heat pump circulating water heaters would be paired with a variety of tank sizes, meaning it would be impractical to base a rating for these products on just one tank pairing. Additionally, some commenters recommended alternative separate storage tank requirements to those proposed, or requested clarification.

A.O. Smith noted that gas-fired circulating water heaters present on the market today are only used in commercial applications, and the UFHWST tank pairing for these products is not common in residential applications, as it would result in a more expensive installation compared to a gas-fired storage water heater. (A.O. Smith, No. 1182 at p. 13)

BWC stated that it does not believe heat pump circulating water heaters should be coupled with 30 gallon ± 5 gallons electric storage water heaters in the appendix E test method for these products because this would not be realistic or representative of most real-world installations, which will typically rely on much larger tanks due to the slower recovery rate of a heat pump. BWC added that heat pump circulating water heaters are designed to meet a variety of unique residential applications in the field, which include different tank sizes and setups to provide adequate hot water, each of which would produce different efficiency ratings when tested; if forced to test to just one tank size, BWC stated that it would be compelled to cite to consumers an efficiency rating that is likely inflated and inaccurate compared to what the consumer will see in practice. BWC added further that a UFHWST, like that which is used for other types of circulating water heaters, would be a more representative pairing for heat pump circulating water heaters. (BWC, No. 1164 at pp. 12–13) Rheem suggested that heat pump circulating water heaters be certified with an UFHWST similar to other types of circulating water heaters because heat pump circulating water heaters may be developed to not rely on the use of backup electric resistance elements in an electric storage water heater tank. (Rheem, No. 1177 at pp. 14–15)

In section IV.A.1.a of this document, DOE discussed its decision to consider circulating water heaters as storage-type water heaters. Therefore, circulating electric heat pump water heaters would be classified as electric storage water heaters and subject to the applicable electric storage water heater standards. DOE does not intend to stifle innovation in or misinform consumers on the efficiency and performance characteristics of heat pump circulating water heaters, which could be used by consumers in lieu of traditional heat pump water heaters. In the test procedure rulemaking, DOE received an abundance of feedback indicating that these products are most likely to be paired with electric resistance storage water heaters, which was the basis for the proposed tank pairing in the July 2023 NOPR. Notwithstanding the recommendations from BWC and Rheem, there remains uncertainty regarding the sizes of UFHWSTs that could be paired with a heat pump circulating water heater should these products not be used with electric resistance storage water heaters. Products DOE has found on the market have demonstrated positive results from case studies while being paired up with nominal 40-gallon electric resistance storage water heaters,[201] so it is expected that the products available today would remain compatible with slightly smaller tanks as well. Therefore, in this final rule, DOE concludes that an electric resistance storage water heater that is 30 gallons ± 5 gallons and in the low draw pattern is still a representative pairing based on feedback received in the test procedure rulemaking.

In response to the December 2023 SNOPR, BWC commented that manufacturers will need to be able to test gas-fired circulating water heaters with a greater range of unfired hot water storage tank volumes than that which is specified in the June 2023 TP Final Rule. (BWC, No. 1413 at p. 2)

[201] A case study published by Nyle Water Heating Systems demonstrates the use of a circulating heat pump water heater with a nominal 40-gallon electric storage water heater. See online at: *www.nyle.com/wp-content/uploads/2021/09/Case-Study-3.2.pdf* (Last accessed: Jan. 5, 2024).

However, without consumer gas-fired circulating water heaters on the market, there is insufficient information (other than the feedback received during the test procedure rulemaking) to make a determination to amend the separate storage tank pairing for these products. The test method to pair gas-fired circulating water heaters with 80- to 120-gallon unfired hot water storage tanks was developed after careful consideration of numerous comments provided in that rulemaking. While finalizing the amendment as proposed, DOE will continue to assess the representativeness of the separate storage tank provisions in the appendix E test procedure and address these concerns in a future test procedure rulemaking if necessary.

Rheem stated its understanding that circulating water heaters would be tested with a manufacturer-specified storage tank, and that the storage tanks described in section 4.10 of appendix E would only be used if there was no manufacturer-specified storage tank. (Rheem, No. 1408 at p. 2) AHRI and A.O. Smith requested that DOE clarify whether a manufacturer would be able to make efficiency representations of circulating water heaters that are designed and specified (or shipped) for use with a storage tank that does not fall into the volume ranges outlined in the test procedure and enforcement provisions. (A.O. Smith, No. 1182 at p. 7; AHRI, No. 1167 at pp. 13–14)

The Department intends for the separate storage tank requirements in section 4.10 to apply to circulating water heaters, which are storage-type water heaters that are not sold with a tank. DOE understands that there may be some confusion based on the wording of section 1.19 of appendix E, which reads that a ''water heater requiring a storage tank'' means a water heater without a storage tank specified or supplied by the manufacturer that cannot meet the requirements of sections 2 and 5 of appendix E without the use of a storage water heater or unfired hot water storage tank. The current wording of section 1.19 in appendix E inadvertently conflates circulating water heaters with split-system water heaters—the distinctions between these two are discussed in section IV.A.1.f.i of this document. As such, DOE is making a minor amendment to section 1.19 of appendix E to resolve industry confusion around these distinctions after determining that it is clearer to define a ''water heater requiring a storage tank'' as a water heater without a storage tank supplied by the manufacturer that cannot meet the requirements of sections 2 and 5 of appendix E without the use of a storage water heater or unfired hot water storage tank. This edit removes the possibility that a water heater could have a manufacturer-specified tank pairing but would have to be tested with a different separate storage tank. Simultaneously DOE is clarifying in section 4.10 of appendix E that those setup provisions apply to water heaters requiring a storage tank—a term that is essentially synonymous with ''circulating water heater.''

In response to the questions from AHRI and A.O. Smith, representations of circulating water heaters must be made in accordance with the separate storage tank requirements in the appendix E test procedure. The compliance of the circulating water heater with the appropriate storage water heater standards would be determined based on the storage volume of the tank selected, which in turn determines the effective storage volume of the circulating water heater. For all types of circulating water heaters, should a manufacturer desire to report its performance to multiple tank sizes, each tank size would constitute a separate basic model.

Reporting requirements are not being established in this rulemaking addressing energy conservation standards for consumer water heaters, however, and DOE will propose these requirements in a separate rulemaking.

b. Product-Specific Enforcement Provisions

In the July 2023 NOPR, DOE proposed a series of steps it would take to ensure that the UFHWST used in assessment testing is as close as possible to the model that was used to determine the circulating water heater's rating. As stated earlier, reporting requirements are not being addressed in this rulemaking, but will be considered separately. 88 FR 49058, 49167. The intent of DOE's proposal was to create a procedure that would default to using the same tank that the circulating water heater manufacturer used, but in the extenuating circumstance wherein that tank is unavailable to DOE, the model could still be tested.

A.O. Smith recommended that DOE bolster the enforcement provisions and definitions outlining what would constitute a circulating water heater to prevent the emergence of electric resistance circulating water heater configurations. (A.O. Smith, No. 1182 at pp. 12–13) A.O. Smith also asked DOE to clarify certification requirements for circulating water heaters. (A.O. Smith, No. 1182 at p. 7) BWC stated that several provisions leave open the possibility that DOE could conduct enforcement testing with a significantly different UFHWST, including the possibility of testing with a different manufacturer's tank. BWC added that this could lead to unfair results, and that instead DOE should allow manufacturers to provide DOE with the UFHWST that is to be paired with the circulating water heater. (BWC, No. 1164 at pp. 13–14) BWC requested that DOE reconsider its proposed product-specific enforcement provisions for circulating water heaters, which include the steps DOE would take to test with an UFHWST as similar as possible to the one used by the manufacturer to rate the circulating water heater, so that the manufacturer could provide the UFHWST to DOE for testing. (BWC, No. 1164 at pp. 13–14) Rheem requested that DOE clarify whether the effective storage volume is a more appropriate metric to use than rated storage volume in the enforcement provisions proposed. Rheem supported the enforcement provisions proposed for testing these products but suggested that DOE test at the lowest storage volume available within the 80–120 gallon range for UFHWSTs. (Rheem, No. 1177 at pp. 14–15)

In response to the request from BWC, DOE does not directly source the tank from manufacturers as it would limit the ability for independent assessment testing given that manufacturers are not always notified when assessment testing occurs.

In response to Rheem's question about rewriting provisions to use the effective storage volume metric, it is unclear where a change would apply, because the provisions outline the steps with regard to the characteristics of the UFHWST, and UFHWSTs have a certified storage volume rather than an effective storage volume.

As such, DOE is finalizing the product-specific enforcement provisions for circulating water heaters as proposed in the July 2023 NOPR. DOE may re-evaluate the product-specific enforcement provisions for these products in a separate rulemaking.

3. Water Heaters Less Than 2 Gallons

The July 2023 NOPR proposed to establish new UEF-based standards for electric and gas storage-type water heaters with less than 20 gallons of effective storage volume. In its market assessment DOE has found models of consumer electric storage-type water heaters which are less than 2 gallons in nominal volume. In order for manufacturers to determine compliance for these products, the test procedure must include provisions for calculating

the rated storage volume and effective storage volume.

The current method to determine storage tank volume in the appendix E test procedure, as amended by the June 2023 TP Final Rule, states:

''For water heaters with a rated storage volume greater than or equal to 2 gallons and for separate storage tanks used for testing circulating water heaters, determine the storage capacity, of the water heater or separate storage tank under test, in gallons (liters), by subtracting the tare weight from the gross weight of the storage tank when completely filled with water at the supply water temperature specified in section 2.3.''

(See section 5.2.1 of the amended appendix E test procedure); 88 FR 40406, 40478.

However, this method does not explicitly cover storage-type water heaters less than 2 gallons which will be covered under the proposed new UEF-based standards. Therefore, in the July 2023 NOPR, DOE proposed to amend section 5.2.1 such that it is applicable to water heaters of all volumes and not restricted to only products greater than or equal to 2 gallons.

No comments were received in response to this proposal. Therefore, DOE is adopting this update to appendix E as proposed in the July 2023 NOPR.

4. Other Topics

In the June 2023 TP Final Rule, DOE adopted optional provisions at section 2.8 of appendix E to allow manufacturers to make voluntary representations of heat pump water heater performance in a variety of alternative conditions that could be useful for consumers installing these products in different locations. These alternative conditions would not be used to determine compliance with the UEF standards at 10 CFR 430.32(d) but were provided to permit representations at the NEEA Advanced Water Heating Specification version 8.0 conditions.[202] 88 FR 40406, 40476.

Rheem requested that DOE address certification and enforcement provisions for heat pump water heaters being tested to the optional test conditions in section 2.8 of appendix E. (Rheem, No. 1177 at p. 7)

DOE reiterates that optional conditions cannot be used to demonstrate compliance with standards. DOE is not adopting certification and enforcement provisions for optional test conditions in this final rule but may consider this in a future rulemaking addressing these topics.

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866, 13563, and 14094

Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011) and amended by E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in this preamble, this final regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this final regulatory action constitutes a ''significant regulatory action'' within the scope of section 3(f)(1) of E.O. 12866. Accordingly, pursuant to section 6(a)(3)(C) of E.O. 12866, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the final regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments are summarized in this preamble, and further detail can be found in the technical support document for this rulemaking.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*www.energy.gov/gc/office-general-counsel*). DOE has prepared the following FRFA for the products that are the subject of this rulemaking.

For manufacturers of consumer water heaters, the SBA has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (See 13 CFR part 121.) The size standards are listed by North American Industry Classification System (''NAICS'') code and industry description and are available at *www.sba.gov/document/support-table-size-standards.* Manufacturing of consumer water heaters is classified under NAICS 335220, ''Major Household Appliance Manufacturing.'' The SBA sets a threshold of 1,500

[202] Representations of rated values for consumer water heaters must be made in accordance with the provisions of the Federal test procedure, appendix E. (42 U.S.C. 6293(c)).

employees or fewer for an entity to be considered as a small business for this category.

1. Need for, and Objectives of, Rule

EPCA prescribed energy conservation standards for consumer water heaters (42 U.S.C. 6295(e)(1)) and directed DOE to conduct two cycles of rulemakings [203] to determine whether to amend these standards. (42 U.S.C. 6295(e)(4)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

2. Significant Issues Raised by Public Comments in Response to the IRFA

In response to the July 2023 NOPR, the Gas Association Commenters submitted comments noting that DOE identified only two small businesses, neither of which produce gas-fired water heaters. As a result, the Gas Association Commenters stated that DOE has no data on small businesses that produce gas-fired water heaters relative to redesign costs, product availability, or whether the proposed efficiency levels could cause small businesses to exit the market. (Gas Association Commenters No. 1181, pp. 38–39)

NPGA, APGA, AGA, and Rinnai stated that as the two small businesses DOE identified in the July 2023 NOPR analysis do not produce gas-fired water heaters, DOE cannot know what the effect on small businesses that manufacture gas-fired water heaters could be as DOE has no data on their redesign costs, product availability, or whether the standards proposed in the July 2023 NOPR would force these manufacturers to leave the market. Therefore, NPGA, APGA, AGA, and Rinnai asserted that the July 2023 NOPR fails to comply with Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' and must be addressed. (NPGA, APGA, AGA, and Rinnai, No. 441 at p. 5)

For the IRFA conducted in support of the July 2023 NOPR, DOE identified one small domestic original equipment manufacturer (''OEM'') of oil-fired storage water heaters and one small domestic OEM of electric storage water heaters. For this FRFA, DOE refreshed its product database to include up-to-date information on the consumer water heater models marketed for the United States. Based on its comprehensive review of the market, DOE identified an additional small, domestic OEM of electric storage water heaters. Therefore, DOE maintains its finding from the IRFA that there are no small, domestic OEMs that manufacture gas-fired water heaters. As such, DOE does not expect that the standards adopted in this final rule would directly impact small businesses that manufacture gas-fired water heaters.

BWC expressed concern about the extensive resources such an undertaking would divert from ongoing projects, as well as its potentially more severe impacts on smaller manufacturers, including component suppliers. (BWC, No. 1164 at p. 15) ASA stated that manufacturers and distributors, including small businesses, would be negatively affected by increased costs for both units and installation and that consumer choice would be restricted. ASA requested that DOE update data used to develop these standards. (ASA, No. 1160 at p. 1)

DOE agrees that the impacts small manufacturers experience may differ compared to larger, more diversified manufacturers. DOE conducts a regulatory flexibility analysis to understand and assess the potential impacts to small domestic OEMs that produce consumer water heaters for the U.S. market in accordance with the procedures and policies published on February 19, 2003. 68 FR 7990. *See* section VI.B.3 of this document for a discussion of potential impacts of amended standards on the three small businesses with U.S. manufacturing facilities identified.

3. Description and Estimated Number of Small Entities Affected

For this FRFA, DOE refreshed its product database to use up-to-date information on the models available on the U.S. market and estimate the number of companies that could be small business manufacturers of products covered by this rulemaking. DOE's research involved reviewing its CCD,[204] California Energy Commission's Modernized Appliance Efficiency Database System (''MAEDbS''),[205] EPA's Energy Star Product Finder dataset,[206] AHRI's Directory of Certified Product Performance,[207] individual company websites, and market research tools (*e.g.,* reports from D&B Hoovers) [208] to create a list of companies that manufacture, produce, import, or assemble the products covered by this rulemaking. DOE also asked stakeholders and industry representatives if they were aware of any other small manufacturers during manufacturer interviews.

DOE identified 22 OEMs of electric instantaneous, electric storage, gas-fired instantaneous, gas-fired storage, or oil-fired storage water heaters sold in the United States as part of its July 2023 NOPR analysis. In preparation for the final rule, DOE conducted additional research to ensure an up-to-date data on the consumer water heater market. After a further comprehensive review of the model listings, DOE concluded that three of the manufacturers previously identified do not manufacture consumer water heaters in-house (*i.e.,* they do not own and operate manufacturing facilities that produce consumer water heaters). However, DOE determined there are three additional manufacturers not previously identified that manufacture consumer water heaters in-house. DOE also revised its OEM count estimate to exclude manufacturers of gas-fired instantaneous water heaters since this final rule does not cover gas-fired instantaneous water heaters. Therefore, excluding manufacturers that only offer gas-fired instantaneous water heaters, DOE identified 16 OEMs of consumer water heaters covered by this final rule. Of these 16 OEMs, DOE identified three small, domestic manufacturers affected by amended standards for gas-fired storage water heater, oil-fired storage water heater, or electric storage water heater products. The first small business is an OEM of oil-fired storage water heaters. The other two small businesses are OEMs of electric storage water heaters.

[203] DOE completed the first of these rulemaking cycles on January 17, 2001, by publishing in the **Federal Register** a final rule amending the energy conservation standards for consumer water heaters. 66 FR 4474. Subsequently, DOE completed the second rulemaking cycle to amend the standards for consumer water heaters by publishing a final rule in the **Federal Register** on April 16, 2010. 75 FR 20112.

[204] U.S. Department of Energy's Compliance Certification Database is available at *regulations.doe.gov/certification-data* (last accessed May 16, 2023).

[205] California Energy Commission's Modernized Appliance Efficiency Database System is available at *cacertappliances.energy.ca.gov/Pages/Search/AdvancedSearch.aspx* (last accessed November 13, 2023).

[206] U.S. Environmental Protection Agency's ENERY STAR Product Finder dataset is available at *www.energystar.gov/productfinder/* (last accessed November 13, 2023).

[207] AHRI's Directory of Certified Product Performance is available at *www.ahridirectory.org/Search/SearchHome?ReturnUrl=%2f* (last accessed May 16, 2023).

[208] The D&B Hoovers subscription login is available at *app.dnbhoovers.com.*

4. Description of Reporting, Recordkeeping, and Other Compliance Requirements

The first small business is an OEM that certifies three models of oil-fired storage water heaters. One of the three models would meet the standard. Given the small and shrinking market for oil-fired storage water heaters, DOE does not expect the small manufacturer would redesign non-compliant models. Rather, the company would likely reduce its range of model offerings. DOE requested input on the potential impacts of standards on this manufacturer in the July 2023 NOPR, but did not receive any feedback. DOE, therefore, maintains its assumption from the IRFA that this manufacturer would not incur significant conversion costs as a result of this rulemaking.

The second small business is an OEM that certifies eleven models of electric storage water heaters. The company offers two small electric storage water heaters, six electric storage water heaters with an effective storage volume greater than or equal to 20 gallons and less than or equal to 55 gallons, and three electric storage water heaters with effective storage volumes above 55 gallons. At the adopted level (TSL 2), DOE does not expect the two small electric water heater models would require notable redesign as standard levels would remain at the baseline efficiency level (*i.e.,* EL 0) for small electric water heaters. None of the six electric storage water heaters (between 20 and 55 gallons, excluding small electric storage water heaters) would meet the amended standard. However, one of the six electric storage water heaters (between 20 and 55 gallons, excluding small electric storage water heaters) is a heat pump model that would likely not require significant redesign to meet the amended standards. DOE expects the company would expand its heat pump offering rather than redesign the electric resistance products that do not meet the amended standard. The company offers three electric storage water heaters with effective storage volumes above 55 gallons. All three of these are heat pumps that do not meet the amended standard. After reviewing the three electric storage water heaters with effective storage volumes above 55 gallons, DOE believes the three models could be updated to meet the amended standard. In total, the company would need to redesign up to nine models.

DOE assumed the company would need to invest the equivalent of one year of its R&D resources to update its product lines to meet amended standards. Therefore, to derive this company's estimated product conversion costs, DOE scaled the annual industry R&D expenditures for electric storage water heaters in the GRIM by the company's estimated market share. DOE does not anticipate significant capital conversion costs, as the company offers a broad line of heat pump electric storage water heaters today. DOE estimates total conversion costs to be $250,000 for this small manufacturer. Based on market research tools, DOE estimated the company's annual revenue to be approximately $50 million. Taking into account the 5-year conversion period, DOE expects conversion costs to be less than 1 percent of conversion period revenue.[209]

The third small business is an OEM that produces two models of circulating water heaters, which are not currently required to comply with a UEF standard. DOE expects that both of these models would qualify as small electric storage water heaters, and thus would likely be subject to new and amended UEF standards. At the adopted level (TSL 2), the standard required for small electric storage water heaters would remain at the baseline efficiency level. DOE notes that both of the models identified utilize heat pump technology. Therefore, DOE assumes these models would not need to be redesigned to comply with new and amended UEF standards. However, this small manufacturer would need to certify these models at the time of compliance with new and amended standards, incurring testing costs of $3,000 per basic model. 88 FR 40406, 40467. Based on market research tools, DOE estimated the company's annual revenue to be approximately $7.7 million. Taking into account the 5-year conversion period, DOE expects conversion costs to be less than 1 percent of conversion period revenue.[210]

5. Significant Alternatives Considered and Steps Taken To Minimize Significant Economic Impacts on Small Entities

The discussion in the previous section analyzes impacts on small businesses that would result from adopted standards, represented by TSL 2. In reviewing alternatives to the adopted standards, DOE examined energy conservation standards set at lower efficiency levels. While TSL 1 would reduce the impacts on small business manufacturers, it would come at the expense of a reduction in energy savings. TSL 1 achieves 98-percent lower energy savings compared to the energy savings at TSL 2.

Based on the presented discussion, establishing standards at TSL 2 balances the benefits of the energy savings with the potential burdens placed on consumer water heater manufacturers, including small business manufacturers. Accordingly, DOE does not adopt one of the other TSLs considered in the analysis, nor the other policy alternatives examined as part of the regulatory impact analysis and included in chapter 17 of the final rule TSD.

Additional compliance flexibilities may be available through other means. EPCA provides that a manufacturer whose annual gross revenue from all its operations does not exceed $8 million may apply for an exemption from all or part of an energy conservation standard for a period not longer than 24 months after the effective date of a final rule establishing the standard. (42 U.S.C. 6295(t)) Additionally, manufacturers subject to DOE's energy efficiency standards may apply to DOE's Office of Hearings and Appeals for exception relief under certain circumstances. Manufacturers should refer to 10 CFR part 430, subpart E, and 10 CFR part 1003 for additional details.

C. Review Under the Paperwork Reduction Act

Manufacturers of consumer water heaters must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for consumer water heaters, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including consumer water heaters. (*See* generally 10 CFR part 429). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the

[209] DOE calculated total conversion costs as a percent of revenue over the 5-year conversion period using the following calculation: ($0.25 million)/(5 years × $50 million).

[210] DOE calculated total conversion costs as a percent of revenue over the 5-year conversion period using the following calculation: ($6,000)/(5 years × $7,700,000).

data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act of 1969 (''NEPA''), DOE has analyzed this proposed action rule in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE has determined that this rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix B5.1 because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, none of the exceptions identified in B5.1(b) apply, no extraordinary circumstances exist that require further environmental analysis, and it meets the requirements for application of a categorical exclusion. *See* 10 CFR 1021.410. Therefore, DOE has determined that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA and does not require an environmental assessment or an environmental impact statement.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735.

In the July 2023 NOPR, DOE tentatively determined that the proposed rule would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. 88 FR 49058, 49170. Furthermore, DOE stated that EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of the proposed rule and that States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. *Id.* (citing 42 U.S.C. 6297). Accordingly, DOE concluded that no further action was required by E.O. 13132.

As initially discussed in section III.A.2 of this document, the Attorney General of TN commented that the proposed standards have significant federalism implications within the meaning of Executive Order 13132 because: (1) DOE's standards have a preemptive effect on States' procurement standards; and (2) States own and purchase water heaters and therefore the proposed standards' effect on water heater costs directly affect States as purchasers. (Attorney General of TN, No. 1149 at pp. 2–3)

DOE reiterates that this final rule does not have significant federalism implications. DOE has examined this rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. Additionally, Federal energy efficiency requirements for covered products established under EPCA, including consumer water heaters, generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

Even if DOE were to find otherwise, with regards to the Attorney General of TN's arguments regarding E.O. 13132, DOE notes that the Attorney General of TN does not provide any examples of a state procurement rule that conflicts with the standards adopted in this rulemaking and DOE is not aware of any such conflicts, nor has the Attorney General of TN provided any examples of States owning and purchasing a substantial number of consumer water heaters. While it is possible that a State may have to revise its procurement standards to reflect the new standards, States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. Absent such information, DOE concludes that no further action would be required by E.O. 13132 even if the Executive order were applicable here. Moreover, assuming the hypothetical preemption alleged by the Attorney General of TN were to present itself, DOE notes that, like all interested parties, states were presented with an opportunity to engage in the rulemaking process early in the development of the proposed rule. Prior to publishing the proposed rulemaking, on May 21, 2020, DOE published and sought public comment on an RFI to collect data and information to help DOE determine whether any new or amended standards for consumer water heaters would result in a significant amount of additional energy savings and whether those standards would be technologically feasible and economically justified. 85 FR 30853. DOE then published a notice of public meeting and availability of the preliminary TSD on March 1, 2022, and sought public comment again. 87 FR 11327. DOE then held a public meeting on April 12, 2022, to discuss and receive comments on the preliminary TSD, which was open to the public, including state agencies. As such, states were provided the opportunity for meaningful and substantial input as envisioned by the Executive order.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues

affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a),(b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*.

DOE has concluded that this final rule may require expenditures of $100 million or more in any one year by the private sector. Such expenditures may include (1) investment in research and development and in capital expenditures by consumer water heater manufacturers in the years between the final rule and the compliance date for the new standards, and (2) incremental additional expenditures by consumers to purchase higher-efficiency consumer water heaters, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the final rule. (2 U.S.C. 1532(c)) The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of this document and the TSD for this final rule respond to those requirements.

Under section 205 of UMRA, DOE is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. (2 U.S.C. 1535(a)) DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(m), this final rule establishes new and amended energy conservation standards for consumer water heaters that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified, as required by 6295(o)(2)(A) and 6295(o)(3)(B). A full discussion of the alternatives considered by DOE is presented in chapter 17 of the TSD for this final rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Although this final rule would not have any impact on the autonomy or integrity of the family as an institution as defined, this rule could impact a family's well-being. When developing a Family Policymaking Assessment, agencies must assess whether: (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

DOE has considered how the benefits of this rule compare to the possible financial impact on a family (the only factor listed that is relevant to this rule). As part of its rulemaking process, DOE must determine whether the energy conservation standards contained in this final rule are economically justified. As discussed in section V.C.1 of this document, DOE has determined that the standards are economically justified because the benefits to consumers far outweigh the costs to manufacturers. Families will also see LCC savings as a result of this rule. Moreover, as discussed further in section V.B.1 of this document, DOE has determined that for the for low-income households, average LCC savings and PBP at the considered efficiency levels are improved (*i.e.,* higher LCC savings and lower payback period) as compared to the average for all households. Further, the standards will also result in climate and health benefits for families.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/7=2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf*. DOE has reviewed this final rule under the OMB and DOE guidelines and has

concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action, which sets forth new and amended energy conservation standards for consumer water heaters, is not a significant energy action because the standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this final rule.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667.

In response to OMB's Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and prepared a report describing that peer review.[211] Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. Because available data, models, and technological understanding have changed since 2007, DOE has engaged with the National Academy of Sciences to review DOE's analytical methodologies to ascertain whether modifications are needed to improve DOE's analyses. DOE is in the process of evaluating the resulting report.[212]

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The Office of Information and Regulatory Affairs has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, and Small businesses.

Signing Authority

This document of the Department of Energy was signed on April 24, 2024, by Jeffrey Marootian Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 24, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE amends parts 429 and 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Amend § 429.17 by revising paragraph (a)(1)(ii)(C) and adding paragraph (a)(1)(ii)(E) to read as follows:

§ 429.17 Water heaters.

(a) * * *

(1) * * *

(ii) * * *

(C) Any represented value of the rated storage volume must be equal to the mean of the measured storage volumes of all the units within the sample. Any represented value of the effective storage volume must be equal to the mean of the effective storage volumes of all the units within the sample.

* * * * *

(E) For an electric storage water heater that has a permanent mode or setting in which it is capable of heating and storing water above 135 °F, where permanent mode or setting means a mode of operation that is continuous and does not require any external consumer intervention to maintain for longer than 120 hours, except for those that meet the definition of ''heat pump-type'' water heater at § 430.2 of this chapter, whose rated storage volumes

[211] The 2007 ''Energy Conservation Standards Rulemaking Peer Review Report'' is available at the following website: *energy.gov/eere/buildings/downloads/energy-conservation-standards-rulemaking-peer-review-report-0* (last accessed April 1, 2023).

[212] The report is available at *www.nationalacademies.org/our-work/review-of-methods-for-setting-building-and-equipment-performance-standards.*

are less than 20 gallons or greater than 55 gallons, or that are only capable of heating the stored water above 135 °F in response to instructions received from a utility or third-party demand-response program, the following applies:

(*1*) To demonstrate compliance with the energy conservation standards in § 430.32(d)(1) of this chapter, any represented value of uniform energy factor shall be determined based on testing in accordance with section 5.1.1 of appendix E to subpart B of 10 CFR part 430.

(*2*) To demonstrate compliance with the energy conservation standards in § 430.32(d)(2) of this chapter, any represented value of uniform energy factor shall be determined based on high temperature testing in accordance with section 5.1.2 of appendix E to subpart B of 10 CFR part 430.

* * * * *

■ 3. Amend § 429.134 by adding paragraph (d)(4) to read as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(d) * * *

(4) *Circulating water heaters.* A storage tank for testing will be selected as described in paragraphs (d)(4)(i) and (ii) of this section. The effective storage volume of the circulating water heater determined in testing will be measured in accordance with appendix E to subpart B of 10 CFR part 430 with the storage tank that is used for testing.

(i) *Electric heat pump circulating water heaters.* For UEF and first-hour rating testing, electric heat pump circulating water heaters will be tested with a minimally-compliant electric storage water heater (as defined at § 430.2 of this chapter) that has a rated storage volume of between 25 and 35 gallons, and is in the low draw pattern, as determined in accordance with appendix E to subpart B of 10 CFR part 430 and the standards set at § 430.32(d) of this chapter. If the manufacturer certifies the specific model of electric storage water heater used for testing to determine the certified UEF and first-hour rating of the electric heat pump circulating water heater, that model of electric storage water heater will be used for testing. If this is not possible (such as if the electric storage water heater model is no longer available or has been discontinued), testing will be performed with an electric storage water heater that has a minimally-compliant UEF rating, in the low draw pattern, and a rated storage volume that is within ± 3 gallons of the rated storage volume of the electric storage water heater used to determine the certified ratings of the electric heat pump circulating water heater (but not less than 25 gallons and not greater than 35 gallons). If no such model is available, then testing will be performed with a minimally-compliant electric storage water heater that has a rated storage volume of between 25 and 35 gallons and is in the low draw pattern.

(ii) *All other circulating water heaters.* For UEF and first-hour rating testing, circulating water heaters are paired with unfired hot water storage tanks (''UFHWSTs'') that have certified storage volumes between 80 and 120 gallons and are at exactly the minimum thermal insulation standard, in terms of R-value, for UFHWSTs, as per the standards set at § 431.110(a) of this chapter. Testing will be performed as follows:

(A) If the manufacturer certifies the specific model of UFHWST used for testing to determine the certified UEF and first-hour rating of the circulating water heater, that model of UFHWST will be used for testing.

(B) If it is not possible to perform testing with the same model of UFHWST certified by the manufacturer, testing will be carried out with a different model of UFHWST accordingly:

(1) Testing will be performed with an UFHWST from the same manufacturer as the certified UFHWST, with the same certified storage volume as the certified UFHWST, and with a certified R-value that meets but does not exceed the standard set at § 431.110(a) of this chapter. If this is not possible,

(2) Testing will be performed with an UFHWST from a different manufacturer than the certified UFHWST, with the same certified storage volume as the certified UFHWST, and with a certified R-value that meets but does not exceed the standard set at § 431.110(a) of this chapter. If this is not possible,

(3) Testing will be performed with an UFHWST from the same manufacturer as the certified UFHWST, having a certified storage volume within ±5 gallons of the certified UFHWST, and with a certified R-value that meets but does not exceed the standard set at § 431.110(a) of this chapter. If this is not possible,

(4) Testing will be performed with an UFHWST from a different manufacturer than the certified UFHWST, having a certified storage volume within ±5 gallons of the certified UFHWST, and with a certified R-value that meets but does not exceed the standard set at § 431.110(a) of this chapter. If this is not possible,

(5) Testing will be performed with an UFHWST having a certified storage volume between 80 gallons and 120 gallons and with a certified R-value that meets but does not exceed the standard set at § 431.110(a) of this chapter.

* * * * *

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 4. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 5. Amend § 430.2 by:
■ a. Revising the definition of ''Circulating water heater'';
■ b. Adding in alphabetical order the definitions of ''Electric circulating water heater'', ''Gas-fired circulating water heater'', and ''Oil-fired circulating water heater''; and
■ c. Revising the definition of ''Tabletop water heater''.

The revisions and additions read as follows:

§ 430.2 Definitions.

* * * * *

Circulating water heater means a water heater that does not have an operational scheme in which the burner, heating element, or compressor initiates and/or terminates heating based on sensing flow; has a water temperature sensor located at the inlet or the outlet of the water heater or in a separate storage tank that is the primary means of initiating and terminating heating; and must be used in combination with a recirculating pump to circulate water and either a separate storage tank or water circulation loop in order to achieve the water flow and temperature conditions recommended in the manufacturer's installation and operation instructions. A circulating water heater constitutes a storage-type water heater.

* * * * *

Electric circulating water heater means a circulating water heater with an input of 12 kW or less (including heat pump-only units with power inputs of no more than 24 A at 250 V).

* * * * *

Gas-fired circulating water heater means a circulating water heater with a nominal input of 75,000 Btu/h or less.

* * * * *

Oil-fired circulating water heater means a circulating water heater with a nominal input of 105,000 Btu/h or less.

* * * * *

Tabletop water heater means a water heater in a rectangular box enclosure

designed to slide into a kitchen countertop space with typical dimensions of 36 inches high, 25 inches deep, and 24 inches wide, and with a certified first-hour rating that results in either the very small draw pattern or the low draw pattern, as specified in Table I in section 5.4.1 of appendix E to subpart B of this part.

* * * * *

■ 6. Amend § 430.23 by revising paragraph (e) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(e) *Water heaters.* (1) The estimated annual operating cost is calculated as:

(i) For a gas-fired or oil-fired water heater, the sum of:

(A) The product of the annual gas or oil energy consumption, determined according to section 6.3.11 or 6.4.7 of appendix E to this subpart, times the representative average unit cost of gas or oil, as appropriate, in dollars per Btu as provided by the Secretary; plus

(B) The product of the annual electric energy consumption, determined according to section 6.3.10 or 6.4.6 of appendix E to this subpart, times the representative average unit cost of electricity in dollars per kilowatt-hour as provided by the Secretary. Round the resulting sum to the nearest dollar per year.

(ii) For an electric water heater, the product of the annual energy consumption, determined according to section 6.3.10 or 6.4.6 of appendix E to this subpart, times the representative average unit cost of electricity in dollars per kilowatt-hour as provided by the Secretary. Round the resulting product to the nearest dollar per year.

(2) For an individual unit, the uniform energy factor is rounded to the nearest 0.01 and determined in accordance with section 6.3.8 or section 6.4.4 of appendix E to this subpart.

* * * * *

■ 7. Appendix E to subpart B is amended by revising the Note and sections 1.19, 4.10, 5.1.2 and 5.2.1 to read as follows:

APPENDIX E TO SUBPART B OF PART 430—UNIFORM TEST METHOD FOR MEASURING THE ENERGY CONSUMPTION OF WATER HEATERS

Note: Prior to December 18, 2023, representations with respect to the energy use or efficiency of consumer water heaters covered by this test method, including compliance certifications, must be based on testing conducted in accordance with either this appendix as it now appears or appendix E as it appeared at 10 CFR part 430, subpart B revised as of January 1, 2021. Prior to June 15, 2024, representations with respect to the energy use or efficiency of residential-duty commercial water heaters covered by this test method, including compliance certifications, must be based on testing conducted in accordance with either this appendix as it now appears or appendix E as it appeared at 10 CFR part 430, subpart B revised as of January 1, 2021.

On and after December 18, 2023, representations with respect to energy use or efficiency of consumer water heaters covered by this test method, including compliance certifications, must be based on testing conducted in accordance with this appendix, except as described in the paragraphs that follow. On and after June 15, 2024, representations with respect to energy use or efficiency of residential-duty commercial water heaters covered by this test method, including compliance certifications, must be based on testing conducted in accordance with this appendix, except as follows.

Prior to May 6, 2029, consumer water heaters subject to section 4.10 of this appendix may optionally apply the requirements of section 4.10 of this appendix. For residential-duty commercial water heaters subject to section 4.10 of this appendix the requirements of section 4.10 of this appendix may optionally be applied prior to the compliance date of any final rule reviewing potential amended energy conservation standards for this equipment published after June 21, 2023.

Prior to May 6, 2029, consumer water heaters subject to section 5.1.2 of this appendix (as specified at § 429.17(a)(1)(ii)(E) of this chapter) may optionally apply the requirements of section 5.1.2 of this appendix in lieu of the requirements in section 5.1.1 of this appendix.

On or after May 6, 2029, representations with respect to energy use or efficiency of consumer water heaters subject to sections 4.10 and 5.1.2 of this appendix must be based on testing conducted in accordance with those provisions.

* * * * *

1. * * *

1.19 *Water Heater Requiring a Storage Tank* means a water heater without a storage tank supplied by the manufacturer that cannot meet the requirements of sections 2 and 5 of this appendix without the use of a storage water heater or unfired hot water storage tank.

* * * * *

4. * * *

4.10 *Storage Tank Requirement for Water Heaters Requiring a Storage Tank (i.e., Circulating Water Heaters).* On or after May 6, 2029, when testing a gas-fired, oil-fired, or electric resistance circulating water heater (*i.e.,* any circulating water heater that does not use a heat pump), the tank to be used for testing shall be an unfired hot water storage tank having volume between 80 and 120 gallons (364–546 liters) determined using the method specified in section 5.2.1 of this appendix that meets but does not exceed the minimum energy conservation standards required according to § 431.110 of this chapter. When testing a heat pump circulating water heater, the tank to be used for testing shall be an electric storage water heater that has a measured volume of 30 gallons (±5 gallons), has a First-Hour Rating less than 51 gallons resulting in classification under the low draw pattern, and has a rated UEF equal to the minimum UEF standard specified at § 430.32(d), rounded to the nearest 0.01. The operational mode of the heat pump circulating water heater and storage water heater paired system shall be set in accordance with section 5.1.1 of this appendix. If the circulating water heater is supplied with a separate non-integrated circulating pump, install this pump as per the manufacturer's installation instructions and include its power consumption in energy use measurements.

* * * * *

5. * * *

5.1.2 *High Temperature Testing.* This paragraph applies to electric storage water heaters capable of achieving a $T_{max,1}$ above 135 °F. The following exceptions apply:

(1) Electric storage water heaters that do not have a permanent mode or setting in which the water heater is capable of heating and storing water above 135 °F (as measured by $T_{max,1}$), where permanent mode or setting means a mode of operation that is continuous and does not require any external consumer intervention to maintain for longer than 120 hours;

(2) Electric storage water heaters that meet the definition of ''heat pump-type'' water heater at § 430.2;

(3) Electric storage water heaters that are only capable of heating the stored water above 135 °F in response to instructions received from a utility or third-party demand-response program.

(4) Electric storage water heaters with measured storage volumes (V_{st}) less than 20 gallons or greater than 55 gallons.

This paragraph may optionally apply to electric heat pump water heaters for voluntary representations of high-temperature operation only.

For those equipped with factory-installed or built-in mixing valves, set the unit to maintain the highest mean tank temperature possible while delivering water at 125 °F ±5 °F. For those not so equipped, install an ASSE 1017-certified mixing valve in accordance with the provisions in section 4.3 of this appendix and adjust the valve to deliver water at 125 °F ±5 °F when the water heater is operating at its highest storage tank temperature setpoint. Maintain this setting throughout the entirety of the test.

* * * * *

5.2 * * *2.1 *Determination of Storage Tank Volume.* For water heaters and separate storage tanks used for testing circulating water heaters, determine the storage capacity, $V_{st,}$ of the water heater or separate storage tank under test, in gallons (liters), by subtracting the tare weight, W_t, (measured while the tank is empty) from the gross weight of the storage tank when completely filled with water at the supply water temperature specified in section 2.3 of this appendix, W_f, (with all air eliminated and line pressure applied as described in section 2.6 of this appendix) and dividing the

resulting net weight by the density of water at the measured temperature.

* * * * *

■ 8. Amend § 430.32 by revising paragraph (d) to read as follows:

§ 430.32 Energy and water conservation standard and their compliance dates.

* * * * *

(d) *Water Heaters.* (1) The uniform energy factor of water heaters manufactured May 6, 2029 shall not be less than the following:

Product class	Rated storage volume and input rating (*if applicable*)	Draw pattern	Uniform energy factor [1]
Gas-fired Storage Water Heater	≥20 gal and ≤55 gal	Very Small	$0.3456 - (0.0020 \times V_r)$
		Low	$0.5982 - (0.0019 \times V_r)$
		Medium	$0.6483 - (0.0017 \times V_r)$
		High	$0.6920 - (0.0013 \times V_r)$
	>55 gal and ≤100 gal	Very Small	$0.6470 - (0.0006 \times V_r)$
		Low	$0.7689 - (0.0005 \times V_r)$
		Medium	$0.7897 - (0.0004 \times V_r)$
		High	$0.8072 - (0.0003 \times V_r)$
Oil-fired Storage Water Heater	≤50 gal	Very Small	$0.2509 - (0.0012 \times V_r)$
		Low	$0.5330 - (0.0016 \times V_r)$
		Medium	$0.6078 - (0.0016 \times V_r)$
		High	$0.6815 - (0.0014 \times V_r)$
Electric Storage Water Heaters	≥20 gal and ≤55 gal	Very Small	$0.8808 - (0.0008 \times V_r)$
		Low	$0.9254 - (0.0003 \times V_r)$
		Medium	$0.9307 - (0.0002 \times V_r)$
		High	$0.9349 - (0.0001 \times V_r)$
	>55 gal and ≤120 gal	Very Small	$1.9236 - (0.0011 \times V_r)$
		Low	$2.0440 - (0.0011 \times V_r)$
		Medium	$2.1171 - (0.0011 \times V_r)$
		High	$2.2418 - (0.0011 \times V_r)$
Tabletop Water Heater	≥20 gal and ≤120 gal	Very Small	$0.6323 - (0.0058 \times V_r)$
		Low	$0.9188 - (0.0031 \times V_r)$
		Medium	$0.9577 - (0.0023 \times V_r)$
		High	$0.9884 - (0.0016 \times V_r)$
Instantaneous Gas-fired Water Heater	<2 gal and >50,000 Btu/h	Very Small	0.80
		Low	0.81
		Medium	0.81
		High	0.81
Instantaneous Electric Water Heater	<2 gal	Very Small	0.91
		Low	0.91
		Medium	0.91
		High	0.92
Grid-enabled Water Heater	>75 gal	Very Small	$1.0136 - (0.0028 \times V_r)$
		Low	$0.9984 - (0.0014 \times V_r)$
		Medium	$0.9853 - (0.0010 \times V_r)$
		High	$0.9720 - (0.0007 \times V_r)$

[1] V_r is the rated storage volume (in gallons), as determined pursuant to § 429.17 of this chapter.

(2) The uniform energy factor of water heaters manufactured on or after May 6, 2029 shall not be less than the following:

Product class	Rated storage volume and input rating (*if applicable*)	Draw pattern	Uniform energy factor [1]
Gas-fired Storage Water Heater	<20 gal	Very Small	$0.2062 - (0.0020 \times V_{eff})$
		Low	$0.4893 - (0.0027 \times V_{eff})$
		Medium	$0.5758 - (0.0023 \times V_{eff})$
		High	$0.6586 - (0.0020 \times V_{eff})$
	≥20 gal and ≤55 gal	Very Small	$0.3925 - (0.0020 \times V_{eff})$
		Low	$0.6451 - (0.0019 \times V_{eff})$
		Medium	$0.7046 - (0.0017 \times V_{eff})$
		High	$0.7424 - (0.0013 \times V_{eff})$
	>55 gal and ≤100 gal	Very Small	$0.6470 - (0.0006 \times V_{eff})$
		Low	$0.7689 - (0.0005 \times V_{eff})$
		Medium	$0.7897 - (0.0004 \times V_{eff})$
		High	$0.8072 - (0.0003 \times V_{eff})$
	>100 gal	Very Small	$0.1482 - (0.0007 \times V_{eff})$
		Low	$0.4342 - (0.0017 \times V_{eff})$
		Medium	$0.5596 - (0.0020 \times V_{eff})$
		High	$0.6658 - (0.0019 \times V_{eff})$
Oil-fired Storage Water Heater	≤50 gal	Very Small	$0.2909 - (0.0012 \times V_{eff})$
		Low	$0.5730 - (0.0016 \times V_{eff})$

Product class	Rated storage volume and input rating (*if applicable*)	Draw pattern	Uniform energy factor [1]
	.....	Medium	0.6478 − (0.0016 × V_{eff})
	.....	High	0.7215 − (0.0014 × V_{eff})
	> 50 gal	Very Small	0.1580 − (0.0009 × V_{eff})
	.....	Low	0.4390 − (0.0020 × V_{eff})
	.....	Medium	0.5389 − (0.0021 × V_{eff})
	.....	High	0.6172 − (0.0018 × V_{eff})
Very Small Electric Storage Water Heater	< 20 gal	Very Small	0.5925 − (0.0059 × V_{eff})
	.....	Low	0.8642 − (0.0030 × V_{eff})
	.....	Medium	0.9096 − (0.0020 × V_{eff})
	.....	High	0.9430 − (0.0012 × V_{eff})
Small Electric Storage Water Heater	≥20 gal and ≤35 gal	Very Small	0.8808 − (0.0008 × V_{eff})
	.....	Low	0.9254 − (0.0003 × V_{eff})
Electric Storage Water Heaters	>20 and ≤55 gal (excluding small electric storage water heaters).	Very Small	2.30
	.....	Low	2.30
	.....	Medium	2.30
	.....	High	2.30
	>55 gal and ≤120 gal	Very Small	2.50
	.....	Low	2.50
	.....	Medium	2.50
	.....	High	2.50
	>120 gal	Very Small	0.3574 − (0.0012 × V_{eff})
	.....	Low	0.7897 − (0.0019 × V_{eff})
	.....	Medium	0.8884 − (0.0017 × V_{eff})
	.....	High	0.9575 − (0.0013 × V_{eff})
Tabletop Water Heater	<20 gal	Very Small	0.5925 − (0.0059 × V_{eff})
	.....	Low	0.8642 − (0.0030 × V_{eff})
	≥20 gal	Very Small	0.6323 − (0.0058 × V_{eff})
	.....	Low	0.9188 − (0.0031 × V_{eff})
Instantaneous Oil-fired Water Heater	<2 gal and ≤210,000 Btu/h	Very Small	0.61
	.....	Low	0.61
	.....	Medium	0.61
	.....	High	0.61
	≥2 gal and ≤210,000 Btu/h	Very Small	0.2780 − (0.0022 × V_{eff})
	.....	Low	0.5151 − (0.0023 × V_{eff})
	.....	Medium	0.5687 − (0.0021 × V_{eff})
	.....	High	0.6147 − (0.0017 × V_{eff})
Instantaneous Electric Water Heater	<2 gal	Very Small	0.91
	.....	Low	0.91
	.....	Medium	0.91
	.....	High	0.92
	≥2 gal	Very Small	0.8086 − (0.0050 × V_{eff})
	.....	Low	0.9123 − (0.0020 × V_{eff})
	.....	Medium	0.9252 − (0.0015 × V_{eff})
	.....	High	0.9350 − (0.0011 × V_{eff})
Grid-Enabled Water Heater	>75 gal	Very Small	1.0136 − (0.0028 × V_{eff})
	.....	Low	0.9984 − (0.0014 × V_{eff})
	.....	Medium	0.9853 − (0.0010 × V_{eff})
	.....	High	0.9720 − (0.0007 × V_{eff})

[1] V_{eff} is the Effective Storage Volume (in gallons), as determined pursuant to § 429.17 of this chapter.

(3) The provisions of paragraph (d) of this section are separate and severable from one another. Should a court of competent jurisdiction hold any provision(s) of paragraph (d) of this section to be stayed or invalid, such action shall not affect any other provision of paragraph (d) of this section.

* * * * *

Note: The following letter will not appear in the Code of Federal Regulations.

October 12, 2023

U.S. DEPARTMENT OF JUSTICE,
Antitrust Division, Ami Grace-Tardy,
Assistant General Counsel for Legislation, Regulation and Energy Efficiency, U.S. Department of Energy, Washington, DC 20585

Re: Energy Conservation Standards for Consumer Water Heaters DOE Docket No. EERE–2017–BT–STD–0019

Dear Assistant General Counsel Grace-Tardy:

I am responding to your August 23, 2023 letter seeking the views of the Attorney General about the potential impact on competition of proposed energy conservation standards for consumer water heaters.

Your request was submitted under Section 325(o)(2)(B)(i)(V) of the Energy Policy and Conservation Act, as amended (ECPA), 42 U.S.C. 6295(o)(2)(B)(i)(V), which requires the Attorney General to determine the impact of any lessening of competition that is likely to result from the imposition of proposed energy conservation standards. The Attorney General's responsibility for responding to requests from other departments about the effect of a program on competition has been delegated to the Assistant Attorney General for the Antitrust Division in 28 CFR 0.40(g). The Assistant Attorney General for the

Antitrust Division has authorized me, as the Policy Director for the Antitrust Division, to provide the Antitrust Division's views regarding the potential impact on competition of proposed energy conservation standards on his behalf.

In conducting its analysis, the Antitrust Division examines whether a proposed standard may lessen competition, for example, by substantially limiting consumer choice, by placing certain manufacturers at an unjustified competitive disadvantage, or by inducing avoidable inefficiencies in production or distribution of particular products. A lessening of competition could result in higher prices to manufacturers and consumers.

We have reviewed the proposed standards contained in the notice of proposed rulemaking (''NOPR'') (88 FR 49058, July 28, 2023) and the related Technical Support Document. We have also reviewed public comments and information provided by industry participants and have reviewed the transcript and information presented at the Webinar of the Public Meeting held on September 13, 2023. Based on this review, we do not have an evidentiary basis to conclude that the proposed energy conservation standards for consumer water heaters are likely to substantially lessen competition.

Sincerely,

David G.B. Lawrence,

Policy Director.

[FR Doc. 2024–09209 Filed 5–3–24; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL REGISTER

Vol. 89 Monday,
No. 88 May 6, 2024

Part VII

Agency for International Development

48 CFR Parts 727, 742, and 752
USAID Acquisition Regulation: Planning, Collection, and Submission of Digital Information; Submission of Activity Monitoring, Evaluation, and Learning Plan to USAID; Final Rule

AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Parts 727, 742, and 752

RIN 0412–AA90

USAID Acquisition Regulation: Planning, Collection, and Submission of Digital Information; Submission of Activity Monitoring, Evaluation, and Learning Plan to USAID

AGENCY: U.S. Agency for International Development.

ACTION: Final rule.

SUMMARY: The United States Agency for International Development (USAID) issuing a final rule amending USAID Acquisition Regulation (AIDAR) that implements USAID requirements for managing digital information as a strategic asset to inform the planning, design, implementation, monitoring, and evaluation of the Agency's foreign assistance programs. This final rule incorporates a new policy on Digital Information Planning, Collection, and Submission Requirements and the corresponding clause as well as a new clause entitled ''Activity Monitoring, Evaluation, and Learning Plan Requirements'' into the (AIDAR). This final rule is intended to reduce the burden on contractors, increase efficiency, and improve the use of data and other forms of digital information across the Agency's programs and operations.

DATES: Effective June 5, 2024.

FOR FURTHER INFORMATION CONTACT: Kelly Miskowski, USAID M/OAA/P, at 202–256–7378 or *policymailbox@usaid.gov* for clarification of content or information pertaining to status or publication schedules. All communications regarding this rule must cite AIDAR RIN No. 0412–AA90.

SUPPLEMENTARY INFORMATION:

A. Background

USAID published a proposed rule in the **Federal Register** at 86 FR 71216 on December 15, 2021, to implement USAID requirements for managing digital information as a strategic asset to inform the planning, design, implementation, monitoring, and evaluation of the Agency's foreign assistance programs as outlined in 48 CFR parts 727, 742, and 752. USAID also published a notice of availability of supplemental document containing data standards in the **Federal Register** at 88 FR 22990 on April 14, 2023, and solicited comments. A response to comments received as well as a revised copy of the supplemental document is included with this rulemaking.

On August 25, 2022, the Office of Science and Technology Policy (OSTP) published a Memorandum (viewable at this address: *https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf*). In this memorandum, OSTP provided policy guidance to ensure that publications and their supporting data resulting from federally funded research are publicly accessible without an embargo on their free and public release. This memo was released after publication of the proposed rule. USAID's language around embargoes within this rule is intentionally flexible, granting embargoes on the release of digital objects only in limited circumstances, such as in the interest of international development and foreign policy objectives, consistent with both USAID and OSTP policy and guidance, and no changes have been made to the language of the rule as a result. In implementation, any approval of embargoes will be consistent with OSTP guidance.

B. Discussion and Analysis

Response to Comments on the Proposed Rule

Seventeen respondents submitted public comments in response to the proposed rule. USAID assessed the public comments in the development of the final rule. The full text of the comments is available at the Federal Rulemaking Portal, *www.regulations.gov.* A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

1. Summary of Significant Changes

The following significant changes from the proposed rule are made in the final rule:

a. Added definitions for data inventory, digital, and digital method.

b. Revised applicability of 752.227–71 from the micro purchase threshold to the simplified acquisition threshold. Similarly, USAID has added an Alternate clause exempting certain contracts from the requirement to provide a data management plan. Specifically, contracts are exempted that: contain no data; are for emergency food assistance; are for disaster assistance, and transition-assistance activities managed by the Bureau for Humanitarian Assistance (BHA); or are for activities managed by the Bureau for Conflict Prevention and Stabilization's Office of Transition Initiatives (CPS/OTI).

c. The burden and cost estimates have been updated to reflect the changes outlined in paragraph b above, and the comments received related to this estimate are addressed in the revised Regulatory Impact Analysis. Additionally, comments regarding the number of respondents and whether the cost of design, testing, launch, and management of the Digital Front Door (DFD) website was subtracted are addressed as well.

d. Clarified the timeline for submission as outlined in AIDAR 752.227–71(f)(3)(i).

e. Various administrative amendments and clarifications have been added, such as revising references throughout the rule to indicate that the contracting officer, or contracting officer's representative if delegated, has authority to approve on behalf of USAID and renumbering of the AIDAR clause sections to conform with USAID numbering conventions.

2. Analysis of Public Comments

Below are the Agency's responses to comments on the changes proposed to United States Agency for International Development (USAID) Acquisition Regulation (AIDAR): Planning, Collection, and Submission of Digital Information as Well as Submission of Activity Monitoring, Evaluation, and Learning Plan to USAID. The Agency did not address comments unrelated to, or outside the scope of, the revisions of the proposed rule from the existing rule:

a. General Support for the Rule

1. *Comment:* Five respondents (7, 8, 9, 11, and 15) indicated general support for the rule. Some commenters noted that the rule will simplify reporting, reduce redundant data calls, and reduce the burden on contractors.

Response: USAID acknowledges the respondent's support for the rule.

b. Does Not Support the Rule

1. *Comment:* One respondent (16) did not support the rule, indicating that it will make it harder for contractors to act responsibly with data management of affected populations. Other commenters (11, 15) did not indicate a lack of support for the rule as a whole but did note that complex submission requirements may negatively impact local partners, small business, and potential market entrants due to potential cost and needed technical expertise.

Response: USAID acknowledges this feedback to the rule.

c. Data Rights and Protection

Several commenters (6, 7, 8, 11, 13, 14, 15, and 16) brought up issues around privacy, PII, publication, and informed consent, which are addressed in sub-categories as outlined below.

1. Access to Data and Data Rights—

A. *Comment:* Several commenters (6, 11, 13) inquired about whether the DFD will be public and available to other partners like the Development Experience Clearinghouse (DEC) and Development Data Library (DDL).

Response: The DFD is not its own system and is not intended to replace other systems. It is a public facing web page with centralized authentication that will direct users to the appropriate USAID systems for which they have authorized access. This includes but is not necessarily limited to the Development Information Solution (DIS), DEC, and DDL.

B. *Comment:* Commenter #8 specifically asked whether information that is exempt from the DFD (like PII) be submitted to USAID first as a restricted version before being scrubbed and sent to the DFD?

Response: The rule states that the contractor must not submit information to the DFD that contains personally identifiable information. And that to the maximum extent possible, the contractor must remove the association between the set of identifying data and the individual to which it applies unless retaining such information is essential to comply with the terms of the contract and upon written approval from the contracting officer or contracting officer's representative as delegated to submit this information. Otherwise, the ''Submission Requirements'' section states that contractors must ''submit digital information created or obtained in performance of this contract to USAID at the finest level of granularity at which it was collected.''

C. *Comment:* Commenter #16 questioned whether the contractor would be able to effectively restrict access to sensitive data without fear of losing funding.

Response: Some data might be exempted from submission under subsection (f)(4) of the clause, including as determined by the contracting officer or contracting officer's representative as delegated in (f)(4)(ii). The rule provides for categories of information not to submit to USAID. It further states that if the Contractor believes there is a compelling reason not to submit specific digital information that does not fall under an exemption in this section, including circumstances where submission may jeopardize the personal safety of any individual or group, the Contractor must obtain written approval not to submit the digital information from the contracting officer. Further specifics under an individual award may be discussed with a contracting officer.

D. *Comment:* Some commenters (11, 13) noted that they did not believe it was necessary (or questioned when circumstances would require) to provide copies of license agreements for digital information or media releases.

Response: USAID believes it is critical for USAID to have documentation regarding the licenses for the digital information submitted to the DFD so that USAID understands the license parameters for use of the data. As such, data licenses are a submission requirement in this rule.

2. Informed Consent

A. *Comment:* Commenter #16 noted that the rule appears to contemplate large collections of data for purposes that cannot be fully known, which will negate the ability for truly informed consent to be given.

Response: The contract itself will mandate the required information to be collected and requirements relating to human subjects research and USAID's data rights. The rule does not mandate new digital information collections but provides guidance on the management of the specific digital information collected under the contract. To the extent the contractually required collection triggers informed consent requirements under Human Subjects Research, this is governed by AIDAR 752.7012 (the Federal Policy for the Protection of Human Subjects (the ''Common Rule'').

B. *Comment:* Commenter #8 indicated if providing personal information is a requirement for participation in an activity (such as attending a training), then providing such information can no longer be considered ''voluntary.'' This commenter recommended that the rule explicitly address the rights of respondents/human subjects to voluntarily provide (or not provide) this data/PII or to otherwise restrict sharing of personal information.

Response: This rule does not address the provision of personal information as a precondition to receiving services. Existing informed consent requirements already address the voluntary provision of information when respondents elect to participate in human subjects research. Explicitly addressing the rights of respondents/human subjects is outside the scope of this rule. Please also refer to USAID's responses in C.4 of this section covering Protection of Information.

C. *Comment:* Two commenters (11, 13) noted that Ref (f)(1)(v) refers to AIDAR 752.7012; however, this only pertains to the protection of the individual as a research subject, which is not applicable to every contract.

Response: USAID has updated the rule to clarify that this requirement applies only when AIDAR 752.7012 is included in the contract. (See corresponding edits to 752.227–71(f)(1)(v)).

D. *Comment:* Commenter #14 requested clarity on 727.7002 Policy (b)(3) noting that it is unclear if USAID is requiring that the submission contain every signed consent form, an indication that each individual submitted consent, or just a blank copy of the form itself. They recommended adding clarifying language in 752.227–71.

Response: Paragraph (f)(1)(v) of this clause already instructs contractors to provide a ''blank copy'' so no further edits are needed.

3. Preparation of Data

A. *Comment:* Commenter #8 expressed concerns that as written proposed clause 752.227–71 requires submission of data scrubbed of PII. They indicate that scrubbing qualitative data such as speech patterns and other audio/video information is extremely costly and time consuming without sufficient guidance. As such, they recommend providing guidance on identifying high informational value qualitative data and the process for de-identifying these data. Additionally, they recommend: (1) clarifying the definition of ''machine readable'' to exclude unstructured qualitative data like audio/video recordings, interview/focus group notes and transcripts, and (2) revising submission requirement (i) to state, ''Submit machine readable digital information created or obtained in performance of this contract to USAID at the finest level of granularity at which it was collected.''

Response: Since audio or visual files may contain PII, contractors should work with their contracting officer representative to determine whether the information is necessary to submit, if an alternative such as a transcript or summary is acceptable, or an exemption from submission is appropriate. The contractor should address considerations for specific media formats and content during the development of the Data Management Plan. In addition, the draft rule allows flexibility for specific circumstances noting, ''If the Contractor believes there

is a compelling reason not to submit specific digital information that does not fall under an exemption in this section, including circumstances where submission may jeopardize the personal safety of any individual or group, the Contractor must obtain written approval not to submit the digital information from the contracting officer.'' (See 752.227–71(f)(4)(ii) of the Proposed Rule). No revisions to the rule are necessary.

To the commenter's follow-up regarding ''machine readable'', USAID has revised the final rule to indicate that the machine-readability requirement applies only to digital data and datasets, thus excluding digital objects like audio and video files (See edits to 752.227–71(f)(1)(ii)). With regard to the recommendation on submitting digital information at the ''finest level of granularity at which it was collected,'' there already exists a requirement in 752.227–71(f)(1)(i) to ''Submit digital information created or obtained in performance of this contract to USAID at the finest level of granularity at which it was collected.'' No further revisions are necessary. (See also response to c(4)(A) of this section below)

B. *Comment:* Commenter #7 questioned whether there would be analog options, noting that print outs of documents limit digital functionality (*i.e.,* a printed hyperlink cannot provide the additional information that someone may access in a digital copy).

Response: 752.227–71(f)(1)(i) states: ''Use only digital methods and USAID-approved standards to the extent practicable . . .'' This allows for analog options in the event that digital methods are not available or practicable.

4. Protection of Data

A. *Comment:* Some commenters (14, 16) expressed concerns about the broadness of ''finest level of granularity'' and requested that guidance be given as to how granular the data must be.

Response: Regarding the ''finest level of granularity'', some, but not all, USAID contracts will provide technical details regarding the level of granularity required. In the absence of such technical guidance, contractors must collect digital information at a level of granularity that allows them to comply with the terms of their award. Barring specific exceptions outlined in the rule, contractors must submit this digital information at the same level of granularity at which it was obtained, rather than aggregating or otherwise generalizing the information. USAID will not necessarily publish or otherwise share data at the same level of granularity as submitted by the contractor.

B. *Comment:* Commenter #16 noted that some international standards reference 'personal data' rather than PII, which protects broader categories of information to prevent re-identification particularly in areas with humanitarian concerns. Further, they noted that USAID requirements may be contrary to local rules and regulations regarding data protection and asked if partners will be given adequate support in these situations.

Response: USAID adheres to definitions and standards set forth by the Office of Management and Budget (OMB), including those in OMB Circular A–130, which defines personally identifiable information. USAID has processes in place to manage re-identification risks concerning personally identifiable information. In the event a USAID partner identifies a potential concern under local law that could impact their ability to plan for and adhere to the requirements of this clause, they should identify that concern during the Digital Information Planning process and contact their contracting officer representative for additional guidance.

C. *Comment:* Commenter #11 questioned whether USAID would limit methods, applications, or systems used for data collection; how USAID will define when digital data collection methods are impractical; and what process there is for Contractors to justify withholding data information.

Response: This rule does not provide specific requirements regarding applications and systems that contractors must use for data collection. Whether certain methods are impractical will be fact specific and should be addressed with the contracting officer representative. As to the process for contractors to justify withholding ''data information'' [sic], the rule states, ''(ii) If the Contractor believes there is a compelling reason not to submit specific digital information that does not fall under an exemption in this section, including circumstances where submission may jeopardize the personal safety of any individual or group, the Contractor must obtain written approval not to submit the digital information from the contracting officer.''

d. Clarity on Language and Requirements

1. Background, Authority, Timeline, and Editorial

A. *Comment:* Several commenters (8, 11, 13) requested clarity on when to submit digital information noting that the clause says 30 calendar days but also has an option to submit when the information meets the requirements of quality digital information or 30 days after closeout. Some specifically noted that allowing submission after closeout could allow the incumbent access to data which competitors for a follow-on would not. Finally, one commenter (8) asked that USAID consider providing additional time (rather than 30 days after contract end) and resources (including funding) for data submission.

Response: With regard to clarification on the submission timeline, USAID has updated the rule to emphasize that the contractor must adhere to the ''schedule of the contract.'' Should a timeline for a specific digital information not be specified in the award schedule, the language as written requires the contractor to submit the information ''once it meets the requirements of quality digital information,'' regardless of when this criterion is met during the award period. This is stated as a requirement, not as an option. This is intentional since USAID often requires access to finalized (*i.e.,* ''quality'') information well before the end of a typical five year contract. As the contract draws to a close, USAID also recognizes that valuable information funded by the Agency may remain in the contractor's possession, whether in draft or final ''quality'' form. For this reason, there is an additional, non-optional requirement to submit any ''draft'' and ''quality'' digital information not previously submitted, no later than 30-days after contract completion. The fact that the incumbent may still have access to this information during the 30-day period after contract completion does not in itself create a conflict of interest for the incumbent. The clause already allows the contractor to obtain approval from the contracting officer for variations to the 30 day submission period. Any costs associated with such submissions should be anticipated and planned for during proposal submission.

B. *Comment:* Commenter #11 recommended adding ''as approved by USAID's Chief Information Officer'' as in Section (f)(1)(vi)(D)(2) throughout the rest of the section.

Response: USAID believes the language is sufficiently clear as written.

C. *Comment:* Two commenters (11, 13) requested clarity on which parts of the mandates listed in the section 727.7000 of the proposed AIDAR text will be implemented in the Rule.

Response: By implementing this rule, USAID intends to enhance compliance with several mandates which include

but are not necessarily limited to the following: (1) Broad sections of OMB Circular A–130, with a particular focus on Section 5 e. which outlines policy on ''Information Management and Access;'' (2) Foundations for Evidence-Based Policymaking Act, with a focus on Title II, ''Open Government Data Act;'' (3) The 21st Century IDEA Act, with a focus on Section 3, ''Website Modernization;'' and Section 4, ''Digitization of Government Services and Forms;'' (4) Foreign Aid Transparency and Accountability Act, including Section 3 (c) ''Objectives of Guidelines;'' and (5) the Geospatial Data Act, with a focus on Section 2806, ''Geospatial data standards.''

D. *Comment:* Commenter #8 noted that the benefit of supporting institutional learning and public understanding of USAID program impact should be more explicit in the introduction.

Response: USAID appreciates this comment but believes that the preamble is sufficiently clear as written.

E. *Comment:* Commenter #11 asked whether digital information requested includes only information obtained for the purpose of implementing programmatic activities.

Response: USAID refers the respondent to ''727.7003 Contract clause.'' This section specifies the insertion of the clause into ''contracts fully or partially funded with program funds. . . .'' Therefore, the primary focus of this clause is on activities resourced with program funds. However, to limit burden, and per the definitions of ''data'' and ''digital information'' in the clause, there would be no requirement to submit ''information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.'' Please see also USAID's response to the comment in (4)(B) of this section.

F. *Comment:* Commenter #13 indicated that 752.227–71(f) makes a reference to (f)(4) which, the respondent suggests, does not exist.

Response: Section (f)(4) of 752.227–71 is entitled ''Exemptions.''

2. Digital Information, Methods, Objects, and Inventory

A. *Comment:* Two commenters (8, 12) requested a definition of ''digital methods'' per 752.227–71 and noted that as structured, the proposed rule requires submission of digital data that cannot comply with the machine-readable requirement (*i.e.,* audio recordings, transcripts).

Response: USAID has added a definition for ''digital methods'' to Section 727.7001 and the clause 752.227–71(a). USAID appreciates the comment highlighting the challenges with submitting audiovisual files in machine readable format. In light of this issue, USAID has revised the final rule to indicate that the machine-readability requirement applies only to digital data and datasets. (See 752.227–71(f)(1)(ii)).

B. *Comment:* Commenter #11 requested a definition of both ''data inventory'' and ''any digital object''.

Response: USAID appreciates these comments and has added definitions for ''digital'' and ''data inventory'' to Section 727.7001 and the clause 752.227–71(a). USAID notes that ''digital object'' is already defined in the clause.

3. Beneficiary Feedback

A. *Comment:* Commenter #8 requested clarity on how ''beneficiary'' is defined, and who will define the term (*i.e.,* do Contractors identify beneficiaries to elicit feedback from).

Response: This aspect of the rule is intended to implement a recurring requirement of recent appropriations acts. Most recently, in the FY 2022 Consolidated Appropriations Act Congress directed that Development Assistance (DA) funds shall be made available for the regular and systematic collection of feedback obtained directly from beneficiaries to enhance the quality and relevance of such assistance. The term ''beneficiary'' is not defined in this statute; its use herein is intended to be consistent with its use in the AIDAR, agency internal policies (Automated Directives Systems), and other agency policy and procedural documents. At times the individuals who may be considered as ''beneficiaries'' for a particular contract may depend on the specific nature of the contract and the implementation context. USAID believes it is not necessary to create a unique definition of ''beneficiary'' for the purpose of this rule, no changes to the AIDAR text are made. Specific concerns regarding identification of beneficiaries for an award may be discussed with a contracting officer.

B. *Comment:* Commenter #11 requested more clarity on what USAID means by ''feedback'' noting that there may be an appearance of coercion as beneficiaries receive benefits from the program. Given that potential conflict, will USAID use this feedback to assess contractor performance or USAID's performance? Will questions be drafted and solicited through USAID or the contractor?

Response: While USAID does not define the term ''feedback'' per se, the AIDAR clause 752.242–71 contains the definition of ''feedback from beneficiaries'', which emphasizes the voluntary nature of these communications. As with any other data collection process managed by USAID contractors, beneficiary feedback must not be collected through coercion. Contractors must not withhold benefits based on whether a beneficiary provides feedback or the nature of the feedback about the benefits received.

Contracting officers may rely on information obtained from beneficiary feedback, or any other sources, as appropriate in evaluating past performance of offerors as permitted in the FAR. (For examples see FAR 15.305(a)(2)(ii), 13.106–2(b)(3)(ii)) and FAR 12.206). Managers and decision-makers within USAID operating units will determine if beneficiary feedback will also be used to assess USAID's performance. As to whether questions for soliciting feedback from beneficiaries will be drafted by USAID or the contractor, this will depend on the specific contract and the final Activity MEL Plan which should include the contractor's plans for collecting, responding to, and reporting on feedback from beneficiaries, if required by the contract. USAID may consult with contractors as necessary in developing the Activity MEL Plan to ensure the proposed methods of collecting, responding to, and reporting beneficiary feedback is appropriate under the particular contract and activity.

C. *Comment:* Commenter #8 requested clarity on how the information will be used and recommended verification via third party or further guidance to prevent bias.

Response: USAID expects that contractors will review the feedback they receive and use it in their management decision-making as noted in the **Federal Register** notice to enhance the quality and relevance of USAID programs and to maximize the cost-effectiveness and utility of these programs for beneficiaries. We appreciate the recommendation that USAID verify beneficiary feedback information via a third party; if applicable, appropriate means of verifying contract compliance with this rule will be determined for each contract by the contract officer and contract officer's representative.

D. *Comment:* Commenter #12 requested clarity on the term ''cost-effectiveness''—specifically whether contractors will be expected to use feedback generally to over-all cost effectiveness or whether they will perform a formal cost effectiveness analysis.

Response: USAID contractors will not generally be expected to perform a formal cost effectiveness analysis solely based on beneficiary feedback. Rather, USAID expects that feedback from beneficiaries will be generally useful to the management decision-making of the contractor, particularly regarding adaptations a contractor might make to their implementation processes that could improve cost-effectiveness and utility of the assistance provided to beneficiaries.

E. *Comment:* Commenter #10 requested clarity on whether the definition of ''regularly'' collected feedback that is ''appropriate'' and ''feasible'' will be determined by the contractor and USAID during AMELP development.

Response: Rather than establishing the definition of ''regularly'', USAID expects that a determination of ''regular'' feedback collection will depend on the size and scope of the activity and will be determined by the contractor and USAID during AMELP development, unless the frequency of beneficiary feedback collection is specified in the contract.

F. *Comment:* Commenter #14 requested clarity on if beneficiary feedback data collection could be combined with other collections.

Response: Unless mandated to be collected and reported separately by the award terms, beneficiary feedback may be combined with other data collection efforts.

4. Finest Level of Granularity

A. *Comment:* Several commenters (9, 10, 11, 13, 15) requested clarity on the term ''finest level of granularity'' with several requesting that each contract should specify the level of detail (or allow for flexibility to ensure protection of data) noting concerns that a strict interpretation may result in turning over unnecessary, sensitive data. One (10) commenter inquired whether the contractor will use their own definitions of granularity or if there will be a USAID-defined standard or template (or process to determine this level of granularity) and questioned if the DFD submission would include any raw data in digital form.

Response: Some, but not all, USAID contracts will provide technical details regarding the level of granularity required. However, it is not practical to pre-specify levels of data granularity in all contracts, as the Agency may need to allow some contractor discretion in this area. Therefore, during ''Digital information planning requirements'' as specified in paragraph (b) of the clause 752.227–71, contractors should propose a level of granularity that allows them to comply with the terms of their award. Barring specific exceptions outlined in the clause 752.227–71, contractors must submit this digital information at the same level of granularity at which it was obtained, rather than aggregating or otherwise generalizing the information. Depending on the requirements of the contract, the DFD submission process may include the submission of raw data in digital form, to include entering raw data in online DFD templates or the upload of entire datasets.

B. *Comment:* Some commenters (11, 12) requested further information on how the granular data would be used and submitted—specifically asking if it will only be for the purpose of implementing programmatic activities.

Response: USAID's usage of the data will be determined by the data rights clause in the contract.

C. *Comment:* Commenter #16 recommended removing the requirement to share data at the finest level of granularity. Barring that, they requested guidance for exemptions to prevent potential re-identification of parties due to transmission of PII and potential data leaks.

Response: USAID cannot remove the ''finest level of granularity'' requirement without jeopardizing its ability to accomplish its mission. USAID is aware that re-identification risk increases with granularity and appreciates that commenters are aware of this. To this end, USAID has included exemptions from submission (See 752.227–71(f)(4)) and indicated that PII submitted should be limited to the maximum extent practicable (See 752.227–71(d)(2)). Moreover, USAID will not necessarily publish or otherwise share data at the same level of granularity as submitted by the contractor, especially if the contractor submits sensitive data. Regarding the request for additional guidance, this is outside the scope of this rule.

5. Digital Standards, Repositories, and Alternate Technologies

A. *Comment:* Some commenters (11, 13) requested a definition of alternate technology and information on how to know if the Chief Information Officer (CIO) has approved it.

Response: Technologies that are approved for USAID use fluctuate frequently, given the rapidly changing nature of technology itself. This makes it impracticable to provide a list or definition of USAID's approved technologies in a static document. Contractors must seek approval to use alternate technologies by contacting their Contracting Officer. The Contracting Officer will seek approval in consultation with USAID's Office of the Chief Information Officer and USAID policy.

B. *Comment:* Some commenters (11, 13) noted that the hyperlink provided in (h) (*data.usaid.gov/guidelines*) was inoperable and requested access to the information for review.

Response: USAID will update the hyperlink to indicate *data.usaid.gov/standards* (see revised text in 752.227–71(h)). On April 14, 2023 USAID published a Notice of availability of a supplemental document in the **Federal Register** (88 FR 22990) specifically noting that USAID received requests under the comment period for this rule to provide access to the standards. The supplemental document entitled ''USAID Digital Collection and Submission Standards'' was available for comment. USAID collected those comments and provided a response to them in this document.

C. *Comment:* Several commenters (11, 13, 14) requested information on what the USAID approved standards are and if they will be provided to contractors.

Response: USAID published the ''USAID Digital Collection and Submission Standards'' in the **Federal Register** (88 FR 22990) on April 14, 2023 and provided a comment period for the public.

D. *Comment:* Some commenters (11, 13) requested a definition of USAID-approved by digital repository.

Response: USAID is not including a definition of a ''USAID-approved digital repository'' in the rule as this determination is an internal policy decision. USAID's policies on acceptable digital repositories will be informed, in part, by the standards for digital repositories developed by the interagency Subcommittee on Open Science of the National Science and Technology Council (NSTC). This includes those found in the document Desirable Characteristics of Data Repositories for Federally Funded Research, released by OSTP in May 2022 (available at: *https://www.whitehouse.gov/wp-content/uploads/2022/05/05-2022-Desirable-Characteristics-of-Data-Repositories.pdf*).

E. *Comment:* Commenter #9 recommended using or aligning with the International Aid Transparency Initiative rather than a USAID-approved standard.

Response: Since the U.S. Government as a whole is a signatory to IATI (see: *https://iatistandard.org/en/news/united-states-marks-10-years-since-becoming-an-iati-signatory/*), USAID has included IATI as a recommended standard.

Should a data standard for a specific subject area not be available at *data.usaid.gov/standards,* the standard will be indicated in the contract itself or provided to the contractor upon consultation with the Contracting Officer.

F. *Comment:* Commenter #11 asked how USAID will define data standards—in the contract or agreed upon in the data management plan.

Response: USAID published the ''USAID Digital Collection and Submission Standards'' in the **Federal Register** (88 FR 22990) on April 14, 2023, and provided a comment period for the public.

6. Data Management Plan

A. *Comment:* Some commenters (11, 13) requested clarity on the requirements of a Data Management Plan with one noting that if DMP requirements are outlined in ADS 579, they should be directly in the rule as the ADS is USAID internal guidance.

Response: The preamble to the rule contains references to ADS 579 as background information only. However, the specific Data Management Plan (DMP) requirements are outlined in the proposed clause in 752.227–71(c)(2) *What to submit.*

B. *Comment:* Commenter #9 requested that contractors be allowed to identify which data they cannot share with USAID along with an appropriate justification.

Response: AIDAR 752.227–71(f)(4)(ii) indicates that ''[i]f the Contractor believes there is a compelling reason not to submit specific digital information that does not fall under an exemption in this section, including circumstances where submission may jeopardize the personal safety of any individual or group, the Contractor must obtain written approval not to submit the digital information from the contracting officer.''

C. *Comment:* Commenter #8 requested clarity on which types of data and/or contracts will require a DMP.

Response: The rule, as revised, states that the clause applies to ''solicitations and contracts fully or partially funded with program funds exceeding the simplified acquisition threshold.'' (See 727.7003 and 752.227–71) Paragraph (c) of this clause includes the DMP requirements. As outlined in 727.7003, this paragraph is ''[reserved]'' and DMP requirements not applicable when the anticipated contract: (1) does not collect data; (2) implements emergency food assistance under the Food for Peace Act or section 491 of the Foreign Assistance Act of 1961, including for the procurement, transportation, storage, handling and/or distribution of such assistance; (3) implements international disaster assistance under section 491 of the Foreign Assistance Act of 1961 or other authorities administered by the Bureau for Humanitarian Assistance; or (4) implements activities managed by the Bureau for Conflict Prevention and Stabilization's Office of Transition Initiatives, or fully or partially funded with the Complex Crises Fund.

D. *Comment:* Commenter #13 noted that not allowing digital information collection until the DMP is approved may delay implementation.

Response: The contractor must begin award implementation upon formal approval of the award. However, digital information collection must not begin prior to approval of the data inventory and submission of any remaining components of the DMP unless authorized in writing by the contracting officer. Based on multiple lessons learned, USAID believes the value of requiring a DMP to far outweigh potential delays in submissions.

E. *Comment:* Several commenters (8, 10, 11, 14) requested clarity on the timeline, processes, and standards for DMPs—specifically information on what the documentation will look like; how standards will be defined that the contractor may be audited against; who will review/approve DMPs and standards for such approval; how approval officials will be trained as well as the timeline for review with a recommendation that they be reviewed annually; whether USAID will provide a template.

Response: This rule does not provide specific requirements on DMP standards, review, approval, templates, or training of USAID officials. Awards will have varying requirements on these matters, and partners must consult the terms of their award for specific details. These issues will be further addressed by USAID policy which USAID staff must consult in providing direction to implementing partners. For additional information, please consult ADS 579—USAID Development Data (available at: *https://www.usaid.gov/about-us/agency-policy/series-500/579*).

F. *Comment:* Commenter #14 requested that the DMP be part of the AMELP given that many of the requirements overlap (with another (11) asking for clarity on if they are separate requirements.

Response: The requirement to submit a DMP is distinct from the requirement to submit an Activity MEL plan. Both plans serve distinct purposes, as described in the rule, and some activities that do not require an Activity MEL plan may still require a DMP. Unless otherwise precluded by the terms and conditions of their contract, contractors required to submit both a DMP and an Activity MEL plan may submit a DMP as a section of an Activity MEL plan or as a separate stand-alone plan.

7. Activity Monitoring Evaluation and Learning Plan

A. *Comment:* Commenter #13 noted that the clause cites ADS 200/201 which is internal policy and requested that the clause itself address plan requirements.

Response: The only reference to ADS 201 in the proposed AIDAR text is included in section 742.1170–5, as a source of additional information on USAID program cycle activity monitoring, evaluation and learning. The clause at 752.242–71 fully addresses the requirements for the Activity Monitoring, Evaluation, and Learning Plan.

B. *Comment:* Commenter #11 requested adoption of a longer timeline to develop the Activity MEL Plan (currently 90 days) citing UK agencies which use a six- to 12-month timeframe.

Response: Regarding the recommendation to adopt a longer timeline to develop the Activity MEL Plan, USAID, after consideration of the public comment, has determined to maintain the 90-day timeline, unless otherwise specified in the contract schedule. OMB guidance M–18–04 regarding Monitoring and Evaluation Guidelines for Federal Departments and Agencies that Administer United States Foreign Assistance recommends that monitoring and evaluation be planned early. USAID's experience has shown that adherence to a 90-day timeline has provided sufficient time to generate an actionable AMELP without resulting in significant programmatic delays. Without obtaining an AMELP from the contractor in the early stages of activity implementation, USAID faces decreased ability to determine that U.S. Foreign Assistance goals are being met. Notably, AMELPs may be revised and updated, in coordination with USAID, as additional information becomes available.

8. Risk

A. *Comment:* Commenter #16 requested that a limited purpose for the collection be set out as well as time limits of data retention and clear requirements for data security and literacy.

Response: The scope of the contract itself will provide clarity on the purpose of the collection. USAID adheres to the requirements of the Federal Records Act for the retention of records and any

retention requirements on contractors will be outlined in the award. USAID requirements on data literacy and security are determined by the Agency's internal policies. USAID requirements for the contractor on data literacy and security would be outlined in the award.

B. *Comment:* Commenter #13 requested that paragraph (g)(2) be amended to indicate that the government *may* direct an embargo for one year when the contractor submits digital objects as mandating it may result in ineligibility to bid for follow-on contracts.

Response: The rule as currently written indicates that the ''Contractor *may* request . . an embargo. . . .'' and that the ''contracting officer or delegated contracting officer's representative *may* approve an embargo. . . .'' (See 752.227–71(g)(2), emphasis added) This is intentionally permissive language. Per the August 25, 2022, memo from the White House Office of Science and Technology Policy entitled, ''Ensuring Free, Immediate, and Equitable Access to Federally Funded Research,'' USAID may approve embargoes, including those that support foreign policy and international development objectives but currently has no reason to mandate embargoes.

C. *Comment:* Commenter #13 requested that the rule allow for the implementer to add a disclaimer of liability of information per section (f)(vi)(B).

Response: Please note that contractors are already allowed under 752.227–71(f)(1)(vi) of the rule to ''provide additional details or metadata'' regarding the ''quality of submissions of draft digital information.'' This additional information would alert USAID, as well as other potential users of the data, to any potential drawbacks of using the submitted information to draw definitive conclusions.

D. *Comment:* Some commenters (11, 13) requested information on who will perform the ''rigorous risk assessment of digital information submitted to USAID'' and whether there will be guidance or a timeline provided; they additionally asked about permissions and restrictions to digital information to the DFD and whether the public will have access.

Response: USAID's risk assessment process will begin after submission of information via the DFD and will involve multiple experts spanning several parts of the Agency. For additional information, ADS 579 outlines the existing implementation of this process. USAID will apply permissions and restrictions to digital information submitted via the DFD as consistent with its existing information technology policies as outlined in the ADS 500 series. Information submitted via the DFD may be entirely restricted from public view, made available to bona fide research institutions, made partially available to the public, or made entirely available to the public, in accordance with existing U.S. government mandates, depending on the sensitivity of the information or other legal considerations.

e. USAID Systems and Processes

1. Digital Portals

A. *Comment:* Several commenters (6, 11, 12, 13, 17) asked whether this rule will retire existing digital portals such as the DEC, DDL, DIS, FTFMS, and other Mission level systems and if so, that a list of portals, processes, and protocols eliminated be provided with a timeline to ease transition.

Response: The DFD is not its own system and is not intended to replace other systems. It is a public facing web page with centralized authentication that will direct users to the appropriate USAID systems for which they have authorized access. This includes but is not necessarily limited to the Development Information Solution (DIS), Development Experience Clearinghouse (DEC), and Development Data Library (DDL). Upon publication of this rule, contractor requirements in AIDAR Clause (DEC) 752.7005 will be eliminated.

B. *Comment:* Some commenters (6, 8, 13) wondered if legacy documents from existing portals (DEC/DDL) will be available or if these portals can be maintained during the transitional period (and if maintained, how would they change)?

Response: Digital objects that are publicly available via the DEC, DDL, and other public-facing data portals will continue to be available as the DFD requirement is implemented.

C. *Comment:* Some commenters (11, 13, 17) asked that in the event that other portals are not retired, under what circumstances would contractors be required to submit to these other portals (*i.e.* the DIS; or whether draft digital information goes to the DFD or another digital repository).

Response: While the DEC and other submission clauses will be retired upon implementation of this rule, the systems will continue to exist in their current form. However, submission workflows into those systems will take place via the DFD, reducing the total number of URLs required to meet contractual requirements.

D. *Comment:* Some commenters (11, 13) noted that the link to *dfd.usaid.gov* is not live and requested access to review.

Response: The link to the DFD will be active upon publication of the final rule.

E. *Comment:* Commenter #11 asked whether contractors will maintain unique registrations on the DFD for each contract.

Response: The contractor can choose whether to assign a single individual to submit information on behalf of multiple contracts or to assign a single individual to submit information for each individual contract. However, contractors must ensure compliance with the requirements in the clause for each individual award.

F. *Comment:* Commenter #17 requested standard reporting templates for submissions to the DFD and asked about integration of existing monitoring tools. They (17) further asked about USAID's plan to address technical challenges and limitations for global systems implementation and learning curves/technical deficiencies internationally.

Response: Rather than providing standard USAID templates, the user interface for each system will guide partners in entering the information required. To address the learning curve associated with these changes, USAID will continue to provide training, communications, and instructional guides to facilitate the transition.

G. *Comment:* Commenter #8 noted that the current DDL platform has a 500-variable maximum for .csv submission resulting in large datasets needing to be broken up into parts.

Response: The Agency is aware of technical limitations in submitting datasets to the DDL and continues to work to make ongoing enhancements to these technologies.

2. Revisions to Existing Policy

Comment: Two commenters (11, 13) asked whether ADS 302.3.5.21 (Submissions of Datasets to the Development Data Library (DDL) (October 2014)) will be removed or revised as the proposed rule removes AIDAR 752.7005 and the anticipated timeline for removal.

Response: Yes. USAID's internal policy guidance will be amended to reflect the change to the AIDAR. The rule currently removes and reserves AIDAR 752.7005.

3. Contracting Officer's Representative Approvals

A.*Comment:* Some commenters (11, 13) noted that language giving Contracting Officer's Representative

discretion to change submission requirements may lead to confusion, and commenter #11 recommended that COR discretion to tell a contractor where to submit information should be on a mission basis instead. Commenter #11 noted that requiring COR approval each time an exception is necessary is prohibitively costly in politically insecure or otherwise challenging environments.

Response: USAID believes that allowing COR discretion on submission requirements is essential given that submission questions are often fact specific. In addition, USAID is developing guidance for CORs and USAID staff on how to handle such requests in order to ensure a consistent approach to the greatest extent possible. This guidance will also outline alternate technologies and USAID-approved repositories for the submission of digital information. USAID does not agree that COR involvement in granting exemptions is unreasonable in challenging operational environments. To the maximum extent practicable, the contractor should address these challenges during the digital information planning process in order to mitigate unforeseen costs and to obtain necessary approvals should such circumstances arise.

B. *Comment:* Some commenters (11, 13) requested more information on processes for the approval of digital information, to include whether approvals of digital information are granted within or outside the DFD. These commenters also requested information on the submission exemption process.

Response: The means of granting approval will vary based on the type of digital information submitted. USAID has updated the AIDAR requirements in 752.227–71(f)(3)(i) to clarify that with the exception of datasets, the Contractor must submit all other digital objects within 30 days of obtaining the contracting officer or delegated contracting officer representative's approval. This pre-submission approval process will generally take place via email. The direct submission of digital data (*e.g.* indicator data) and datasets via the DFD will trigger a semi-automated approval process that will take place directly within USAID information systems. This process will take place via a combination of system-generated messages and email exchanges with USAID personnel. Exemptions are already addressed in AIDAR 752.227–71(f)(4) and will be granted on a case-by-case basis.

4. Exceptions and Oversight

A. *Comment:* Commenter #11 requested information on the process to exempt data submission when the personal safety of an individual or group is jeopardized.

Response: Circumstances that jeopardize the safety of an individual or group can vary widely, and USAID will address these on a case-by-case basis. To enable USAID to make an informed decision tailored to the specific circumstance, AIDAR 752.227–71(f)(1)(vi)(A) requires that the contractor furnish details and/or metadata regarding known sensitivities within digital information that may jeopardize the personal safety of any individual or group. In addition, contractors should use the digital information planning process to identify any potential security or safety concerns early in the activity to the greatest extent possible.

B. *Comment:* Commenter #7 asked whether there would be USAID/Washington oversight of the recommended contractual requirements.

Response: Contract Officers will monitor individual contracts for compliance with submission requirements. In addition, USAID/Washington will periodically monitor information systems to help ensure that submissions received are consistent with planned submissions identified by the contractor during the digital information planning process. Members of the public who observe that documents or other digital artifacts are missing from USAID's public websites are encouraged to contact USAID directly. In some cases, these documents may be awaiting further curation by staff or exempted from public disclosure due to sensitivities or other legal considerations.

f. Applicability

1. Acquisition vs. Assistance

Comment: Several commenters (5, 6, 8) inquired about whether these provisions would be for contracts only—specifically asking about the use of the word 'contractor' rather than 'implementing partner'.

Response: This rulemaking action is to amend the AIDAR which is USAID's supplement to the FAR. As such, this only pertains to contracts.

2. Existing Contracts

Comment: Some commenters (8, 12) asked whether existing contracts would be amended resulting in revisions to already approved AMELPs or the need to develop DMPs and whether additional funding would be provided for these actions.

Response: The requirements established by this rule will apply to all new contracts that meet the applicability criteria defined in this rule. However, USAID may modify, in accordance with FAR 1.108(d): 1) existing indefinite delivery contracts to include the new AIDAR clauses for future orders, and 2) existing contract or task or delivery order when exercising an option or modifying a contract or order to extend the period of performance.

3. Burden on Small Entities

A. *Comment:* Some commenters (11, 13) inquired as to the need to apply these clauses to any contract above the micro-purchase threshold noting the increased burden on small entities. They requested it to be changed to the Simplified Acquisition Threshold.

Response: USAID accepts the recommendation to revise applicability to contracts above the Simplified Acquisition Threshold. The corresponding changes are made to sections 727.7003 and 752.227–71.

B. *Comment:* Commenter #11 noted that the requirement to submit media release templates is particularly onerous to small business and requested that images be allowed to be credited/captioned by source.

Response: In order to use photos submitted by contractors which contain images of individuals, USAID must establish that the individuals provided consent to appear in the photos. USAID therefore requires media releases for these photos, which cannot be accomplished via photo captioning.

C. *Comment:* Two commenters (10, 15) noted that requiring only digital methods will carry substantial burden and cost which may disadvantage local and new contractors. They recommend allowing a broader range of approaches, from digital to manual (with digital being preferred and used as appropriate and practical) and asked whether USAID approval would be necessary.

Response: Should the contractor encounter obstacles adhering to digital collection methods, the contractor must first identify these in the Data Management Plan. USAID may allow for an alternative collection method on a case-by-case basis per the exception in Section 752.227–71(d)(1)(i). This exception may apply, for instance, to situations where availability of or access to digital technologies is limited; where the knowledge and capacity to use them may be limited; or circumstances where their use may prove overly burdensome.

4. Other Applicability Questions

A. *Comment:* Commenter #6 asked whether this rule covers GIS data projects that are submitted to Missions.

Response: The draft rule applies to ''digital information produced, furnished, acquired, or collected in performance of a USAID contract,'' and therefore also applies to GIS data projects that may be submitted to missions.

B. *Comment:* Commenter #15 asked if the rule is applicable only for US Government standard indicators or custom indicators as well.

Response: The rule applies to both standard and custom indicator data under the broader definition of ''digital information.''

g. Out of Scope

A. *Comment:* Several commenters (1, 2, 3, and 4) included comments which were not within the scope of the rule including topics such as Presidential visits, criticism of the agency broadly, questions about registration, and concerns related to COVID vaccination.

Response: USAID acknowledges receipt of these out-of-scope comments.

B. *Comment:* Commenter #13 inquired about USAID's response to the Paperwork Reduction Act request for comments on the DIS Pilot.

Response: The DIS Pilot comments are addressed separately alongside this rule.

C. *Comment: Commenter* #13 questioned the cost analysis—specifically about the determination of respondents; whether the DIS costs were included in the Rule; whether decommissioning of certain portals was included; and whether the cost of design, testing, launch, and management of the DFD system was considered.

Response: Please see the Regulatory Impact Analysis (RIA) for more detail regarding respondents. Because DIS is intended to be an Agency-wide portfolio management system covering the entire program cycle, internal costs unrelated to this rulemaking effort were not included in the RIA. Costs related to partner submission of information via the Digital Front Door have been added to the revised RIA. USAID's long-term vision is to combine the Development Experience Clearinghouse (DEC) and Development Data Library (DDL) into a single digital repository. As this repository is still in planning stages and is outside the scope of this rulemaking, costs are not available, and USAID did not take them into account in the RIA for this rulemaking. Please see the revised RIA for detail on the estimated cost of establishing the Digital Front Door.

D. *Comment: Commenter* #15 requested suggested language for informed consent forms noting that in order to obtain informed consent, the contractor will need to clearly describe how the data submitted to the DFD will be accessed and used.

Response: Suggested language for informed consent is outside the scope of this rule.

E. *Comment: C*ommenter #8 noted that local partners under assistance may lack the data management capacity to implement this rule.

Response: USAID's assistance awards are outside the scope of this rule.

F. *Comment: C*ommenter #11 requested a definition of forms of informed consent, guidance on collection, and what forms of collection are appropriate to document informed consent.

Response: USAID requirements relative to informed consent for human subjects research are found in *22 CFR part 225* and are thus not covered under the scope of this rule.

*G. Comment: C*ommenter #15 requested that the rule include language regarding coordination of contractors with in-country review boards and other governing bodies.

Response: This is outside the scope of this rule which deals with digital information planning, collection, and submission.

H. *Comment:* Two commenters (11, 13) questioned how USAID will protect proprietary data if contractors submit such data in accordance with (f)(1)(ii) from competitors; how USAID will share data security issues with partners; and how USAID and the contractor will share data security responsibility.

Response: These comments regarding USAID's security responsibilities are beyond the scope of this rule. USAID is subject to legal and policy requirements on implementing adequate safeguards for handling business confidential and proprietary information. Contractors must follow the terms of their award regarding security and privacy requirements.

I. *Comment: C*ommenter #16 indicated concern about the length of time of data retention by USAID, data security for certain local organizations who may lack expertise

Response: USAID retains and disposes of electronic records in accordance with National Archives and Records Administration rules and policies. Regarding concerns that local partners may lack data security expertise and the need for support, this is outside the scope of the rule.

J. *Comment: C*ommenter #7 asked if the DMP requirements will relate in any way to the USAID Digital Strategy requirements of a Digital Learning Plan and the regular requirement of a Learning Agenda; and if so, whether USAID will manage and communicate evolving guidance to contractors on these various mandates.

Response: Specifics on how DMPs relate to internal USAID guidance are outside the scope of this rule.

Summary of Changes and Response to Comments on the Notice of Availability of Supplemental Document, Published in the ***Federal Register*** *at 88 FR 22990 on April 14, 2023*

Three respondents submitted public comments in response to the Notice. USAID reviewed the public comments in the development of the final rule. Based on the comments, the supplemental document has been revised as outlined in (i) below. Additionally, changes to the ''geospatial'' language have been made to align with USAID policy. Note that the text is provided without hyperlinks in this document, but they are available at *data.usaid.gov/standards.* Below are the Agency's responses to comments and the changes made to the rule as a result of those comments are provided as follows:

h. *Comment* #1: requested information on how to access an account.

Response: This is outside the scope of this rulemaking.

i. *Comment* #2: noted that the inclusion of ''Metadata Creation Tools'' may be inappropriate. They indicated that including specific tools may give an appearance of preference or endorsement of such tools as they may not be the best for the job and that updating the AIDAR will take a long time potentially locking in the use of outdated tools.

Response: USAID has updated the standards to cite a non-exhaustive list of potential metadata tools, rather than to explicitly list them under ''Recommended Digital Information Technical Standards.''

j. *Comment* #3: indicated general support for rule and moving to digital information. The respondent requested that there be policies to standardize information collection in the Data Management Plan and noted that USAID may be able to provide standardized templates for data collection.

Response: This comment is outside the scope of the rulemaking. USAID solicited comments as to the standards, including the text of AIDAR 752.227–71(h) that refers to the standards. USAID

received comments on the Data Management Plan during the comment period for the proposed rulemaking, and responses to those comments are available in Section d.6 above.

Response to Comments on DIS Pilot

Seventeen respondents submitted public comments in response to the DIS Pilot. USAID reviewed the public comments in the development of the final rule. Below are the Agency's responses to comments on the DIS Pilot. Some of the comments received will not be addressed as RIN 0412–AA90 makes a response unnecessary. Those comments are summarized in the section below. Additionally, some comments have already been addressed in responses to comments received under the proposed rule which are also summarized below. The Agency did not address comments unrelated to, or outside the scope of, the 30-day Information Collection Notice:

k. General Support for the Collection

1. *Comment:* Commenter #17 indicated general support for the collection. They noted that the rule will simplify reporting, reduce redundant data calls, and reduce the burden on contractors.

Response: USAID acknowledges the support for the collection.

1. Comments That Are Superseded by the Rule

Comment: Two commenters (14, 17) requested information on the burden estimate. Commenter #14 questioned the benefit of the system. Commenter #10 questioned which countries had to implement the pilot. Two commenters (3, 17) questioned the length of the pilot, if the pilot results would be made public, how data migration will occur after the pilot, what language should be included in contracts, and whether RIN 0412–AA90 would be published for comment. Several commenters (3, 12, 13, 14, 16, 17) asked about API and connections to other data systems, standardizing requirements and guidance, concern regarding reidentification and other security risks, what data would need to be submitted, cost allowability, information about approvals and how data will be used, reporting frequency, data aggregation, what indicator information would be used as well as if they can be customized, and other process questions about the pilot. Commenter #3 asked about an OIG Audit and its impact on the pilot. Commenter #8 indicated that on Item 20, Sec 2 (''login.gov username''), the instructions on the access form do not clarify what the username is or if IPs already have one. Commenter #8 also requested clarity on what IPs are expected to do in DIS.

Response: The pilot, applicable to several missions, ended with publication of RIN 0412–AA90. Questions around benefits, API connections, adding contract language, standardization, security, submission requirements, reporting, access forms and other items related to the pilot are superseded by the text of the Rule. The rule also clarifies what contractors must do when submitting digital information to USAID.

m. Comments That Have Been Answered Through Comment Responses to the Rule

Comment: Commenter #13 asked about whether staff will be able to access more than one project or see across a variety of projects. Commenter #2 requested that the system be aligned to build upon the Common Data Model for Nonprofits. Commenter #13 asked about what the Development Experience Clearinghouse is. Commenter #14 asked about integration of various USAID platforms (the Development Data Library, for example).

Response: USAID has provided robust responses to these questions in response to comments received under the rulemaking. Specifically, see sections B.2)(e)(1)(E); B.2)(d)(5); and B.2)(e)(1)(A)–(C) of the **Federal Register** Notice for RIN 0412–AA90 which includes the text of relevant comments and responses.

n. Access to Data

1. *Comment:* Commenter #4 questioned whether a prime contractor will have to enter data for subcontractors or whether the subs will have separate access to enter their data directly.

Response: The clause requires the contractor to submit all digital information produced, furnished, acquired or collected in performance of this contract by its subcontractors at any tier. While some USAID systems may allow delegation of the submission role, it remains the responsibility of the prime contractor to ensure the submission of the digital information per the requirements of the rule.

2. *Comment:* Several commenters (8, 13, 15) asked about system access. Specifically, whether the system will have a place to specify roles in the ''implementing partner user information'' section; how IPs can manage employees offboarding from the system when they leave the IP or award; and whether the system will be open to allow all users to see information or be limited by award.

Response: The system will have a place to specify user roles. The COR will assign the contractor a user role within the system. Once assigned a user role, the contractor will manage further access to the award, including during offboarding. Submitters will only be able to see data for awards with which they are associated in the system; data access is not open to all users.

3. *Comment:* Commenter 16 asked whether the public will be able to access the data in the DIS system.

Response: USAID will release data to the public from its internal systems in keeping with its internal policies as informed by US Government and international transparency commitments. USAID will not provide direct public access to the DIS system.

o. System Design Information

1.*Comment:* Commenter #3) asked if USAID had a help center for DIS and requested a FAQ page.

Response: Contractors can email *AskDIS@usaid.gov* for help center assistance. The DIS Frequently Asked Questions (FAQ) document for contractors is found on the USAID public website (available at: *https://www.usaid.gov/partner-with-us/resources-for-partners/development-information-solution/faqs*).

2.*Comment:* Commenter #13 asked if the DIS will be the place where they enter information about indicators or just view them once reports are submitted.

Response: Per the Rule, USAID contractors will submit all digital information to one centralized portal, the USAID Digital Front Door (DFD). The DFD is intended as a submission mechanism, whereas viewing will take place via established USAID systems and websites.

3. *Comment:* Commenter #13 asked who is responsible for setting up the website for each respective project in DIS (if there are specific indicators being reported for each of the projects).

Response: USAID operating units are responsible for establishing activities in DIS within a contract. The person with the COR role in DIS is responsible for establishing the indicators associated with the activity.

4. *Comment:* Commenter #13 asked if the system will allow for central level viewing of an IP portfolio.

Response: The system currently does not allow for linkages among multiple activities to provide a central portfolio view for an implementing partner.

p. USAID Approval and Oversight

Comment: Commenter #16 requested comment on when comprehensive information about the structure and operation of the DIS system will be available.

Response: USAID will continue to provide information on the Agency's public DIS website (available at: *https://www.usaid.gov/partner-with-us/resources-for-partners/development-information-solution*) as it becomes available.

q. Outside the Scope

Comment: Many commenters (1, 5, 6, 7, 9, and 11) submitted comments that were outside the scope of the DIS Pilot.

Response: USAID acknowledges receipt of these out-of-scope comments.

USAID Digital Collection and Submission Standards

We are publishing the revised Collection & Submission Standards in this final rule. As noted in the regulatory text, the standards can also be found at *data.usaid.gov/standards* with hyperlinks:

USAID's Digital Collection and Submission Standards are a compendium of standards for USAID staff and contractors to use in support of USAID programs and operations. The standards in Section A are required. Section B contains recommended standards that represent industry best practices.

Section A: Required Digital Information Technical Standards

I. File Format Standards

A. Acceptable Non-Proprietary Formats

1. Text and Documents
   (a) Portable Document Format (PDF/A is preferred, however .pdf is acceptable)
   (b) Plain text (.txt)
   (c) LaTeX documents (.tex)
   (d) Hypertext Markup Language (.html)
   (e) Open Document Format (.odt)
   (f) Extensible Markup Language (.xml)
   (g) JavaScript Object Notation (.json)
2. Tables, Spreadsheets, and Databases
   (a) Comma-Separated Values (.csv)
   (b) Tab-separated tables (.txt—sometimes .tsv)
   (c) Comma-separated tables (.csv or .txt)
   (d) Other standard delimiter (*e.g.* colon, pipe)
   (e) Fixed-width
   (f) OpenDocument Spreadsheet (.ods)
3. Audio Files
   (a) WAVE (.wav)
   (b) FLAC (.flac)
   (c) MPEG–3
   (d) MP3
4. Image Files
   (a) JPEG (.jpg or .jp2)
   (b) Portable Network Graphics (.png)
   (c) TIFF (.tiff or .tif)
   (d) Portable Document Format (.pdf)
5. Video Files
   (a) Video File (.mov)
   (b) MPEG–4 (mp4)
   (c) JPEG2 2000 (mj2)
6. Geospatial Files
   (a) QGIS Project (.qgs)
   (b) ESRI Shapefile (.shp, .shx, .dbf)
   (c) Annotated TIFF Raster Files (.tif)
   (d) Keyhole Mark Language (.kml)
   (e) Geographic Data Format based on JSON (.geojson)
   (f) Google Earth GIS Format (.kml, .kmz)
   (g) Well Known Text for Spatial Objects (.wkt)
   (h) Raster GIS File Format
   (i) Unidata Scientific Data Format

II. Subject Area Standards

A. Narrative Text

1. Digital narrative text that is written in the English language, including narrative about USAID programs and operations, must comply with the *Plain Writing Act of 2010* and associated guidelines and resources found on the *federal plain language website.* Because USAID may publish a narrative in keeping with the U.S. Government legislative requirements (*e.g.* the *Foreign Aid Transparency and Accountability Act of 2016*) and other transparency commitments (*e.g. International Aid Transparency Initiative; Open Government Partnership*) or Freedom of Information Act requests, the narrative must be clear, thorough, and descriptive to facilitate public understanding.

B. Geospatial

1. The location(s) where an activity is implemented must be collected at the Exact Site Location. Exact Site Location is defined as a populated place, an actual exact site location, or an exact area or line feature. The location(s) of the activity's intended beneficiaries must be collected at least at the first level administrative boundary. When the location of the activity's intended beneficiaries is considered nationwide, it must be collected at the country/territory level. USAID follows the *Geopolitical Entities, Names, and Codes (GENC) Standard* and additional geospatial data standards as outlined in *ADS 579saa* ''Geographic Data Collection and Submission Standards'' and ADS 579mab ''Activity Location Data.''

C. Date

1. YYYY–MM–DD.

Section B: Recommended Digital Information Technical Standards

USAID recommends the following standards that have not been formally adopted as a requirement by the Agency, but encouraged and recommended for use to improve the management, quality and usefulness of the data. USAID recommends the use of the following standards when appropriate and practicable:

I. Code, Algorithm, and Analytical Files.
A. Javascript (.js)
B. Java
C. .NET
D. Python (.py)
E. Ruby (.rb)
F. R (.r)
G. SQL

II. GS1 Standards—USAID-funded programs beyond Global Health are strongly recommended to adopt GS1 Standards for the supply chain to facilitate product identification, location identification, and product master data of Agency-funded commodities. Additional guidance for implementation of GS1 Standards can be found here.

III. Statistical Data and Metadata eXchange (SDMX) for statistical data.

IV. CGIAR Ontologies for crop and agronomy ontology.

V. FHIR for healthcare data exchange.

VI. ISO 8601 for Date, Time, and Time Zone.

VII. Open Geospatial Consortium (OGC) Standards for geospatial data. The Open Geospatial Consortium (OGC) is an international consortium of more than 500 businesses, government agencies, research organizations, and universities driven to make geospatial (location) information and services FAIR—Findable, Accessible, Interoperable, and Reusable..

VIII. International Aid Transparency Initiative (IATI).

IX. FAIR Data Principles—To the extent possible, USAID-funded data and metadata must align with data principles which are Findable, Accessible, Interoperable, and Reusable.

Resources for creating metadata to meet these standards include, but are not limited to, the following:

I. Content Standard for Digital Geospatial Metadata (CSDGM) Tools.

II. USGS TKME—A Windows platform tool for creating FGDC–CSDGM which can be configured for Biological Data Profile and other extensions. The software program is closely aligned with the Metadata Parser, and can be configured for French and Spanish.

III. mdEditor—Create ISO and FGDC–CSDGM metadata with this web-based tool.

IV. Data dictionary conversion service—Convert a data dictionary table to/from metadata format (instructions).

V. USDA Metavist—A desktop metadata editor for creating FGDC–CSDGM for geospatial metadata. Includes the Biological Data Profile (version 1.6). Produced and maintained by the USDA Forest Service. Download the USGS Alaska Science Center (ASC) Metavist User Guide [PDF] to learn more about the tool and ASC best practices for authors.

VI. Microsoft XML Notepad—A simple intuitive user interface for browsing and editing XML files. Does not automatically produce FGDC–CSDGM records but allows easy editing and validation of existing metadata records. See Advanced Users to learn how to configure this tool.

C. Regulatory Considerations and Determinations

(1) Executive Orders 12866 and 13563

This final rule was drafted in accordance with Executive Order (E.O.) 12866, as amended by E.O. 14094, and E.O. 13563. OMB has determined that this rule is a ''significant regulatory action,'' as defined in section 3(f) of E.O. 12866, as amended, and is therefore subject to review by OMB. This rule is not a major rule under 5 U.S.C. 804.

(2) Expected Cost Impact on the Public

USAID remains committed to reducing the burden on its contractors while maximizing taxpayer value. By launching the USAID Digital Front Door (DFD) as outlined in this clause, USAID intends to reduce the total number of portals through which its contractors must submit information to USAID, thereby reducing time and effort and improving operational efficiency.

The following is a summary of the impact on contractors awarded contracts that include the new AIDAR clause. The cost estimates were developed by subject matter experts based on USAID's experience collecting reports and information products through the Development Experience Clearinghouse (DEC) (see AIDAR 752.7005) and piloting digital data collection through the Development Data Library (DDL) and the Development Information Solution (DIS).

This rule results in a total annualized (7% discount) public net cost of $2.5 million. This annual burden takes into account the current baseline that contractors already prepare, maintain, and submit AMELPs, already remove PII from data prior to submission, already collect standard indicator data, and already request embargoes and data submission exemptions from Contracting officer's Representative on a case-by-case basis. Further, since contractors already submit documents and data to the DEC and DDL, these costs were removed from the overall estimated cost. The following is a summary of the annual public costs over a 20-year time horizon.

Year	Public	Total
1	$1,867,000	$1,867,000
2	2,650,000	2,650,000
3	2,703,000	2,703,000
. . .	2,756,000	2,756,000
20	2,756,000	2,756,000
Total undiscounted costs		65,988,000
Present Value (PV) of Costs Discounted at 7%		54,072,000
Annualized Costs Discounted at 7%		2,514,000

This rule has extensive benefits for the public, contractors, the research community, the private sector, and the USG, though many of these benefits are challenging to quantify. Overarchingly, this rule will increase efficiency for contractors, minimize data errors, and improve the privacy and security of data. Further, this rule will help contractors to produce data assets that are trustworthy, high-quality, and usable by the general public and the research community for accountability, research, communication, and learning. For the public, there is an immense richness in the data collected by USAID and its partners around the world, and this data holds the potential to improve the lives of some of the world's most vulnerable people. When a development project ends, the data can yield new insights for years or decades into the future. It is the responsibility of the Agency and those representing the government to ensure that data is accessible, standardized, and secure. Finally, these estimates have been downwardly adjusted since the publication of the proposed rule to reflect USAID's responses to comments from the public.

In addition, under current protocols, USAID contractors are required to submit digital information to USAID under multiple award requirements using several different information management portals. The maintenance of these separate portals has made it challenging for USAID to integrate this information strategically to render a more holistic and detailed view of its global portfolio. By implementing these changes, USAID intends to reduce administrative burden on contractors and USG staff.

(3) Regulatory Flexibility Act

USAID does not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* USAID has therefore not performed an Initial Regulatory Flexibility Analysis (IRFA).

(4) Paperwork Reduction Act

This rule contains information collection requirements that have been submitted to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). This information collection requirement has been assigned OMB Control Number 0412–0620, entitled ''AIDAR: Planning, Collection and Submission of Digital Information and Activity Monitoring, Evaluation, and Learning Plans to USAID''. Following receipt of comments, USAID has made several revisions to this collection to downwardly adjust the burden. Specifically, USAID revised the applicability of 752.227–71 from the micro purchase threshold to the simplified acquisition threshold. Similarly, USAID has added an Alternate clause exempting certain contracts from the requirement to provide a data management plan. Specifically, contracts are exempted that: contain no data; are for emergency food assistance; are for disaster assistance, and transition-assistance

activities managed by the Bureau for Humanitarian Assistance (BHA); or are for activities managed by the Bureau for Conflict Prevention and Stabilization's Office of Transition Initiatives (CPS/OTI). For additional detail, please see the Regulatory Impact Assessment as well as responses to comments in sections B. 2)(g)(C) and B. 2)(f)(3)(A) above.

Additionally, USAID posted a 60-Day Notice of Information Collection: Proposals, Submissions, and Approvals (the ''DIS Pilot'') in the **Federal Register** at 85 FR 83027 on December 21, 2020. USAID published a 30-Day Notice including a response to comments received on May 25, 2021 and solicited additional comments (See 86 FR 28053). Following receipt of additional comments, USAID, with approval from OMB, is providing a response to comments received to the 30-day Collection Notice with this Rulemaking. As the ''DIS Pilot'' collection has been discontinued due to this rulemaking action, this separate information collection approval request has been canceled.

List of Subjects in 48 CFR Parts 727, 742, and 752

Government procurement.

For the reasons discussed in the preamble, USAID amends 48 CFR chapter 7 as set forth below:

■ 1. The authority citation for 48 CFR parts 727, 742, and 752 continues to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445, (22 U.S.C. 2381) as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; and 3 CFR 1979 Comp., p. 435.

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART 727—PATENTS, DATA, AND COPYRIGHTS

■ 2. Add subpart 727.70 to read as follows:

Subpart 727.70—Digital Information Planning, Collection, and Submission Requirements

Sec.

Subpart 727.70—Digital Information Planning, Collection, and Submission Requirements

727.7000 Scope of subpart.

(a) This part prescribes the policies, procedures, and a contract clause pertaining to data and digital information management. It implements the following requirements:

(1) Digital Accountability and Transparency (DATA) Act of 2014;

(2) Foundations for Evidence-Based Policymaking Act (''Evidence Act'') of 2018;

(3) 21st Century Integrated Digital Experience Act (21st Century IDEA Act);

(4) Foreign Aid Transparency and Accountability (FATAA) Act of 2016;

(5) Geospatial Data Act of 2018;

(6) OMB Circular A–130.

(b) [Reserved]

727.7001 Definitions.

As used in this subpart—

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Data asset is a collection of data elements or data sets that may be grouped together.

Data inventory is the first component of a Data Management Plan (DMP). The data inventory is a list of high-value data assets that the contractor anticipates producing during the period of award performance.

Data management plan (DMP) is a tool that guides the identification of anticipated data assets and outlines tasks needed to manage these assets across a full data lifecycle.

Data set is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a data set may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. A data set does not include unstructured data, such as email or instant messages, PDF files, PowerPoint presentations, word processing documents, images, audio files, or collaboration software.

Digital means the coding scheme generally used in computer technology to represent data.

Digital data means quantitative and qualitative programmatic measurements that are entered directly into a computer. Examples include numeric targets established during activity design or implementation; baseline, mid-line, or final measurements created or obtained via field assessments; surveys or interviews; performance monitoring indicators as specified in the Contractor's approved Activity Monitoring, Evaluation, and Learning (AMELP) (see 752.242–71); evaluation results; or perception metrics collected from beneficiaries on the quality and relevance of International Disaster Assistance and Development Assistance.

Digital information is a subset of data and means:

(1) Digital text;

(2) Digital data;

(3) Digital objects; and

(4) Metadata created or obtained with USAID funding supported by this award that are represented, stored, or transmitted in such a way that they are available to a computer program.

Digital method is a means of using computer technology to gather, process, analyze, transmit, store, or otherwise use data and other forms of information.

Digital object includes digital or computer files that are available to a computer program. Examples include digital word processing or PDF documents or forms related to activity design, assessment reports, periodic progress and performance reports, academic research documents, publication manuscripts, evaluations, technical documentation and reports, and other reports, articles and papers prepared by the contractor, whether published or not. Other examples include data sets, spreadsheets, presentations, publication-quality images, audio and video files, communication materials, information products, extensible mark-up language (XML) files, and software, scripts, source code, and algorithms that can be processed by a computer program.

Digital text includes text-based descriptions of programmatic efforts that are entered directly into a computer, rather than submitted as a digital object.

727.7002 Policy.

(a) It is the policy of USAID to manage data as a strategic asset to inform the planning, design, implementation, monitoring, and evaluation of the Agency's foreign assistance programs. To achieve this, it is also USAID's policy to manage data and digital information across a full life cycle. This life cycle includes the following stages: Govern, Plan, Acquire, Process, Analyze, Curate, and Publish/Share. For more information about the USAID Development Data policy, see ADS Chapter 579 at *https://www.usaid.gov/about-us/agency-policy/series-500/579.* For more information about USAID's Program Cycle policy, see ADS Chapter 201 at *https://www.usaid.gov/about-us/agency-policy/series-200/201.*

(b) In furtherance of this policy, USAID requires that contractors:

(1) Engage in digital information planning, including creating a Data Management Plan (DMP) to identify and plan for the management of data assets that will be produced, furnished, acquired, or collected in a USAID-funded activity.

(2) Use only digital methods and USAID-approved standards, to the extent practicable, to produce, furnish, acquire, or collect information necessary to implement the contract requirements.

(3) Provide documentation of informed consent the contractor receives when obtaining information on individuals.

(4) Submit to USAID digital information produced, furnished, acquired, or collected in performance of a USAID contract at the finest level of granularity employed during contract implementation.

(c) As specified in ADS Chapter 579, USAID implements appropriate controls to restrict data access in a way that balances the potential benefits with any underlying risks to its beneficiaries and contractors.

727.7003 Contract clause.

(a) Insert the clause 752.227–71 to USAID in Section H of solicitations and contracts fully or partially funded with program funds exceeding the simplified acquisition threshold. The contracting officer may insert this clause in other USAID contracts if the contracting officer, in consultation with the requiring office, determines that doing so is in the best interest of the Agency.

(b) Insert the clause at 752.227–71, with its Alternate I when the anticipated contract:

(1) Does not collect data;

(2) Implements emergency food assistance under the Food for Peace Act or section 491 of the Foreign Assistance Act of 1961, including for the procurement, transportation, storage, handling and/or distribution of such assistance;

(3) Implements international disaster assistance under section 491 of the Foreign Assistance Act of 1961 or other authorities administered by the Bureau for Humanitarian Assistance; or

(4) Implements activities managed by the Bureau for Conflict Prevention and Stabilization's Office of Transition Initiatives, or is fully or partially funded with the Complex Crises Fund.

SUBCHAPTER G—CONTRACT MANAGEMENT

PART 742—CONTRACT ADMINISTRATION

Subpart 742.11—Production, Surveillance, and Reporting

■ 3. Amend 742.1170–3, by redesignating paragraphs (b)(2) through (7) as paragraphs (b)(3) through (8) and adding a new paragraph (b)(2).

The addition reads as follows:

742.1170–3 Policy.

* * * * *

(b) * * *

(2) The contract requirements for an activity monitoring, evaluation, and learning plan, as applicable;

* * * * *

■ 4. Add 742.1170–5 to read as follows:

742.1170–5 Activity Monitoring, Evaluation, and Learning Plan requirement and contract clause.

(a) When the requiring office needs information on how the contractor expects to monitor implementation performance and context, conduct or collaborate on an evaluation, and generate evidence to inform learning and adaptive management, the contracting officer may require the contractor to submit an Activity Monitoring, Evaluation, and Learning Plan (AMELP) tailored to specific contract requirements. For more information on monitoring, evaluation, and learning during the design and implementation of activities, see ADS Chapter 201 at *https://www.usaid.gov/about-us/agency-policy/series-200/201.*

(b) Unless instructed otherwise in writing by the requiring office, the contracting officer must insert the clause at 752.242–71 in section F of solicitations and contracts exceeding the simplified acquisition threshold, except as specified in paragraph (c) of this section. The contracting officer may insert this clause in other USAID contracts if the contracting officer, in consultation with the requiring office, determines that an Activity Monitoring, Evaluation, and Learning Plan is necessary, as provided in paragraph (a) of this section.

(c) The clause is not required to be included in contracts for:

(1) Supplies and services that USAID acquires for its own direct use or benefit;

(2) Emergency food assistance under the Food for Peace Act or section 491 of the Foreign Assistance Act of 1961, including for the procurement, transportation, storage, handling and/or distribution of such assistance;

(3) International disaster assistance under section 491 of the Foreign Assistance Act of 1961 or other authorities administered by the Bureau for Humanitarian Assistance; or

(4) Activities managed by the Bureau for Conflict Prevention and Stabilization's Office of Transition Initiatives, or fully or partially funded with the Complex Crises Fund.

SUBCHAPTER H—CLAUSES AND FORMS

PART 752—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Add 752.227–71 to read as follows:

752.227–71. Planning, Collection, and Submission of Digital Information to USAID.

As prescribed in AIDAR 727.7003, insert the following clause in Section H of solicitations and contracts:

Planning, Collection, and Submission of Digital Information to USAID (JUN 2024)

(a) *Definitions.* As used in this clause—

Computer is a fixed or mobile device that accepts digital data and manipulates the information based on a program or sequence of instructions for how data is to be processed.

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Data asset is a collection of data elements or data sets that may be grouped together.

Data inventory is the first component of a Data Management Plan (DMP). The data inventory is a list of high-value data assets that the contractor anticipates producing during the period of award performance.

Data management plan (DMP) is a tool that guides the identification of anticipated data assets and outlines tasks needed to manage these assets across a full data lifecycle.

Data set is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a data set may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. A data set does not include unstructured data, such as email or instant messages, PDF files, PowerPoint presentations, word processing documents, images, audio files, or collaboration software.

Digital means the coding scheme generally used in computer technology to represent data.

Digital data means quantitative and qualitative programmatic measurements that are entered directly into a computer. Examples include numeric targets established during activity design or implementation; baseline, mid-line, or final measurements created or obtained via field assessments; surveys or interviews;

performance monitoring indicators as specified in the Contractor's approved AMELP; evaluation results; or perception metrics collected from beneficiaries on the quality and relevance of International Disaster Assistance and Development Assistance.

Digital information is a subset of data and means:

(i) Digital text;

(ii) Digital data;

(iii) Digital objects; and

(iv) Metadata created or obtained with USAID funding regarding international development or humanitarian assistance activities supported by this award that are represented, stored, or transmitted in such a way that they are available to a computer program.

Digital method is a means of using computer technology to gather, process, analyze, transmit, store, or otherwise use data and other forms of information.

Digital object includes digital or computer files that are available to a computer program. Examples include digital word processing or PDF documents or forms related to activity design, assessment reports, periodic progress and performance reports, academic research documents, publication manuscripts, evaluations, technical documentation and reports, and other reports, articles and papers prepared by the Contractor under this contract, whether published or not. Other examples include data sets, spreadsheets, presentations, publication-quality images, audio and video files, communication materials, information products, extensible mark-up language (XML) files, and software, scripts, source code, and algorithms that can be processed by a computer program.

Digital repository refers to information systems that ingest, store, manage, preserve, and provide access to digital content.

Digital text includes text-based descriptions of programmatic efforts that are entered directly into a computer, rather than submitted as a digital object.

Draft digital information refers to digital information that, in the professional opinion of the Contractor, does not adhere to the information quality standards such that it presents preliminary, unverified, incomplete, or deliberative findings, claims, analysis, or results that may lead the consumer of such material to draw erroneous conclusions.

Granularity refers to the extent to which digital content or objects provide access to detailed, distinct data points. Coarse granularity generally means that distinct data points reflect larger, representational units or have been joined together or aggregated, thus providing less detail. A fine level of granularity generally means that distinct data points reflect smaller, individualized units that have not been aggregated, thus providing a higher level of detail. For example, a data set containing a list of every activity conducted by week would generally exhibit a finer level of granularity than a data set listing the various categories of activities conducted by month. The degree of granularity can be relative to the contents of a specific data set and can be geographic, temporal, or across other dimensions.

Information quality standards means the elements of utility, objectivity, and integrity collectively.

Integrity is an element of the information quality standards that means information has been protected from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

Machine readable means data in a format that can be easily processed by a computer without human intervention while ensuring that no semantic meaning is lost.

Metadata includes structural or descriptive information about digital data or digital objects such as content, format, source, rights, accuracy, provenance, frequency, periodicity, granularity, publisher or responsible party, contact information, method of collection, and other descriptions.

Objectivity is an element of the information quality standards that means whether information is accurate, reliable, and unbiased as a matter of presentation and substance.

Personally identifiable information (PII) means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. [See Office of Management and Budget (OMB) Circular No. A–130, Managing Federal Information as a Strategic Resource.] PII can include both direct identifiers (such as name, health identification numbers, etc.), and indirect identifiers (geographic location, age) that when linked with other information can result in the identification of an individual.

Publication object is a digital object that has been accepted for publication prior to the end date of this contract and whose content is based on or includes any other digital information created or obtained in performance of this contract. In the research community, a publication object is often synonymous with a quality research manuscript that has been accepted by an academic journal for publication. However, publication objects can also consist of other digital objects (*e.g.,* photos, videos, etc.) published via news media, the internet, or other venues.

Quality digital information means digital information that, in the professional opinion of the Contractor, adheres to the information quality standards and presents reasonably sound and substantiated findings, claims, analysis, or results regarding activities.

Registered with the USAID Digital Front Door (DFD) means: that—

(i) The Contractor entered all mandatory information required to obtain access to the DFD.

(ii) The Contractor agrees to abide by the DFD terms and conditions of use.

(iii) The Government has validated the Contractor's registration by providing access to the DFD.

USAID Digital Front Door (DFD), located at *dfd.usaid.gov* is a website where the Contractor transacts business with USAID, such as submitting digital information.

Utility is an element of the information quality standards that means whether information is useful to its intended users, including the general public, and for its intended purpose.

(b) *Digital information planning requirements.* The Contractor must engage in digital information planning to ensure compliance with the collection and submission of all digital information, as required under this award.

(c) *Data Management Plan (DMP)*—(1) *What is required.* The Contractor must prepare and maintain a Data Management Plan (DMP) that reflects the digital information planning requirements outlined in paragraph (b) of this clause.

(2) *What to submit.* The DMP must be appropriate to the programmatic scope and context of the contract, and to the nature and complexity of the data to be collected or acquired in the course of the contract. The DMP must address, at a minimum, the following:

(i) Data inventory; and

(ii) If requested in writing by the Contracting Officer,

(A) Protocols for data collection, management and storage;

(B) Protocols for maintaining adequate safeguards that include the privacy and security of digital information collected under the award;

(C) Documentation that ensures other users can understand and use the data;

(D) Protocols for preserving digital information and facilitating access by other stakeholders; and

(E) Terms of use on data usage, publication, curation, or other dissemination plans.

(3) *When to submit.* The Contractor must develop and submit, at a minimum, the data inventory component of the DMP to the contracting officer for approval within ninety (90) days after contract award, unless the contracting officer establishes a different time period. The Contractor must submit the remaining components of the DMP to the contracting officer for approval, as soon as they become available. The contractor must not begin digital information collection prior to approval of the data inventory and submission of any remaining components of the DMP unless authorized in writing by the contracting officer.

(4) *When to revise.* The Contractor must revise the DMP as necessary throughout the period of performance of this contract. Any revisions to the plan must be approved by the contracting officer or contracting officer's representative as delegated.

(d) *Digital information production and collection requirements.* (1) The Contractor must:

(i) Use only digital methods to the extent practicable to produce, furnish, acquire, or collect information in performance of this contract. If the Contractor is unable to consistently collect data using digital methods, the Contractor must obtain the contracting officer or delegated contracting officer's representative's approval for any alternative collection method.

(ii) Collect digital information at the finest level of granularity that enables the Contractor to comply with the terms of this contract.

(2) To the extent practicable, the Contractor must limit the collection of PII to only that

which is necessary to comply with the requirements of the contract.

(e) *Registration requirements.* The Contractor must:

(1) Be registered with the USAID Digital Front Door (DFD) within ninety (90) days after award of this contract; and

(2) Maintain access to the DFD during the period of performance of this contract.

(f) *Submission requirements*—(1) *What to submit.* Unless an exemption in paragraph (f)(4) of this section applies, the Contractor must:

(i) Submit digital information created or obtained in performance of this contract to USAID at the finest level of granularity at which it was collected.

(ii) Submit digital information in nonproprietary formats and digital data and data sets in machine readable formats. The Contractor may also submit proprietary formats in addition to a nonproprietary format.

(iii) Submit a copy of any usage license agreement that the Contractor obtained from any third party who granted usage rights for the digital information.

(iv) Submit a copy of any photo or media release template that the Contractor used to obtain permission from any third party for the use of the photo or media.

(v) When the contract includes AIDAR clause 752.7012, Protection of the Individual as a Research Subject, provide a blank copy of the form, document, instructions, or other instruments used to obtain informed consent from persons whose individual information is contained in the original version of the digital object.

(vi) If applicable, provide additional details or metadata regarding:

(A) Where and how to access digital information that the Contractor submits to a USAID-approved digital repository or via alternate technology as approved by USAID's Chief Information Officer;

(B) The quality of submissions of draft digital information;

(C) Known sensitivities within digital information that may jeopardize the personal safety of any individual or group, whether the Contractor has submitted the information or has received a submission exemption;

(D) Digital information for which the Contractor was unable to obtain third party usage rights, a media release, or informed consent or which has other proprietary restrictions.

(2) *Where to submit.* The Contractor must submit digital information through the DFD, unless specifically authorized by the contracting officer in writing to submit to a USAID-approved digital repository instead or via alternate technology as approved by USAID's Chief Information Officer.

(3) *When to submit.* (i) With the exception of data sets, the Contractor must submit all other Digital Objects within 30 days of obtaining the contracting officer or delegated contracting officer representative's approval. Unless otherwise specified in the schedule of the contract or otherwise instructed by the contracting officer or delegated contracting officer's representative, the Contractor must submit data sets and all other digital information created or obtained in performance of this contract to USAID once it meets the requirements of quality digital information. Unless otherwise approved by the contracting officer in writing, within thirty (30) days after the contract completion date, the Contractor must submit all digital information not previously submitted, including both draft digital information and quality digital information required under this contract.

(ii) Upon written approval of the contracting officer or delegated contracting officer's representative, the Contractor must submit draft digital information to USAID when the ''best available'' information is required in order to meet time constraints or other programmatic or operational exigencies.

(4) *Exemptions.* (i) The Contractor must not submit digital information through the DFD that contains:

(A) Classified information.

(B) Personally identifiable information. The Contractor must, to the maximum extent possible, remove the association between the set of identifying data and the individual to which it applies unless retaining such information is essential to comply with the terms of this contract and upon written approval from the contracting officer or delegated contracting officer's representative to submit this information.

(ii) If the Contractor believes there is a compelling reason not to submit specific digital information that does not fall under an exemption in this section, including circumstances where submission may jeopardize the personal safety of any individual or group, the Contractor must obtain written approval not to submit the digital information from the contracting officer.

(5) *Approval requirements.* Upon receipt of digital information submitted by the Contractor, the contracting officer or delegated contracting officer's representative will either approve or reject the submission. When a submission is rejected, the Contractor must make corrections and resubmit the required information. USAID does not consider the submission accepted until the contracting officer or delegated contracting officer's representative provides written approval to the Contractor.

(g) *Publication considerations.* (1) If the Contractor produces a publication object, the Contractor must submit via the DFD a copy of the publication object, the publication acceptance notification, along with a link at which the final published object may be accessed.

(2) For any digital object the Contractor submits in compliance with the terms of this contract, the Contractor may request from the contracting officer or delegated contracting officer's representative an embargo on the public release of the digital object. The contracting officer or delegated contracting officer's representative may approve an embargo request that is for no more than 12 months at a time, with additional scrutiny for digital objects relied upon for journal publication. A determination on this request will be provided to the Contractor in writing.

(3) If the Contractor used a digital object previously submitted via the DFD to generate the publication object, and that digital object is governed by a pre-existing embargo, that embargo will expire on the day the publication object is scheduled for publication. USAID may elect to publish digital information on which the publication object is based as early as the date the publication object is scheduled for publication.

(h) *USAID digital collection and submission standards.* The Contractor must comply with the version of USAID's Digital Collection and Submission Standards in effect on the date of award as outlined at *data.usaid.gov/standards.* If the Contractor is unable to adhere to USAID's Digital Collection and Submission Standards, the Contractor must obtain USAID's written approval for an alternative approach.

(i) *Access to the digital information.* USAID will conduct a rigorous risk assessment of digital information that the Contractor submits to USAID to determine the appropriate permissions and restrictions on access to the digital information. USAID may release the data publicly in full, redact or otherwise protect aspects of the information prior to public release, or hold the information in a non-public status.

(j) *Obligations regarding subcontractors.* (1) The Contractor must furnish, acquire, or collect information and submit to USAID, in accordance with paragraph (f) of this clause, all digital information produced, furnished, acquired, or collected in performance of this contract by its subcontractors at any tier.

(2) The Contractor must insert the terms of this clause, except paragraph (e) of this clause, in all subcontracts.

(End of clause)

Alternate I (JUN 2024). As prescribed in AIDAR 727.7003, substitute the following paragraph (c) for paragraph (c) of the basic clause:

(c) [Reserved]

■ 6. Add 752.242–71 to read as follows:

752.242–71 Activity Monitoring, Evaluation, and Learning Plan

As prescribed in AIDAR 742.1170–5, insert the following clause in section F of solicitations and contracts.

Activity Monitoring, Evaluation, and Learning Plan (JUN 2024)

(a) *Definitions.* As used in this clause—

Activity Monitoring, Evaluation, and Learning Plan (AMELP) means a plan for monitoring, evaluating, and collaborating, learning, and adapting during implementation of a USAID contract. Some USAID documentation may refer to ''MEL Plan'' or ''Activity MEL Plan''. These terms are synonymous.

Contract will be interpreted as ''task order'' or ''delivery order'' when this clause is used in an indefinite-delivery contract.

Evaluation means the systematic collection and analysis of data and information about the characteristics and outcomes of the programming carried out through a contract, conducted as a basis for judgments, to understand and improve effectiveness and efficiency, and timed to inform decisions about current and future programming.

Feedback from beneficiaries means perceptions or reactions voluntarily communicated by a beneficiary of USAID assistance about the USAID assistance received.

Indicator means a quantifiable measure of a characteristic or condition of people, institutions, systems, or processes that might change over time.

Learning activity means efforts for the purpose of generating, synthesizing, sharing, and applying evidence and knowledge.

Monitoring context means the systematic collection of information about conditions and external factors relevant to implementation and performance of the contract.

Output means the tangible, immediate, and intended products or consequences of contract implementation within the Contractor's control or influence.

Outcome means the conditions of people, systems, or institutions that indicate progress or lack of progress toward the achievement of the goals and objectives of the contract.

Performance indicator means an indicator that measures expected outputs and/or outcomes of the contract implementation.

Target means a specific, planned level of results to achieve within a specific timeframe with a given level of resources.

(b) *Requirements.* (1) Unless otherwise specified in the schedule of the contract, the Contractor must develop and submit a proposed AMELP to the contracting officer or delegated contracting officer's representative within ninety (90) days of contract award. The contracting officer or delegated contracting officer's representative will review and provide comments within thirty (30) days after receiving the proposed AMELP. The Contractor must submit a final AMELP for contracting officer or delegated contracting officer's representative approval no later than 15 days after receiving comments.

(2) The Contractor must revise the AMELP as necessary during the period of performance of this contract. Any revisions to the plan must be approved by the contracting officer or delegated contracting officer's representative.

(c) *Content.* (1) The Contractor's proposed AMELP must include, at a minimum, the following:

(i) The Contractor's plan for monitoring, including any existing systems or processes for monitoring progress, any Standard Foreign Assistance Indicators as agreed upon by the contracting officer or delegated contracting officer's representative, any other USAID required indicators, and other relevant performance indicators of the contract's outputs and outcomes, their baseline (or plan for collecting baseline), and targets; and

(ii) The Contractor's plan for regular and systematic collection of feedback from beneficiaries, responding to feedback received, and reporting to USAID a summary of feedback and actions taken in response to the feedback received, or a rationale for why collecting feedback from beneficiaries is not applicable for this contract.

(2) The Contractor's proposed AMELP must be appropriate to the size and complexity of the contract and address the following, as applicable:

(i) Plans for monitoring context and emerging risks that could affect the achievement of the contract's results;

(ii) Plans for any evaluations to be conducted by the contractor, sub-contractor or third-party, including collaboration with an external evaluator;

(iii) Learning activities, including plans for capturing knowledge at the close-out of the contract;

(iv) Estimated resources for the AMELP tasks that are a part of the contract's budget; and

(v) Roles and responsibilities for all proposed AMELP tasks.

[End of clause]

752.7005 [Removed and Reserved]

■ 7. Remove and Reserve 752.7005.

Jami J. Rodgers,

Chief Acquisition Officer.

[FR Doc. 2024–09373 Filed 5–3–24; 8:45 am]

BILLING CODE 6116–01–P

Reader Aids

Federal Register

Vol. 89, No. 88

Monday, May 6, 2024

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, MAY

CFR PARTS AFFECTED DURING MAY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

39 CFR

111.....35716

40 CFR

52.....36679, 37137
131.....35717
228.....36681
268.....35008
372.....35748
702.....37028
1500.....35442
1501.....35442
1502.....35442
1503.....35442
1504.....35442
1505.....35442
1506.....35442
1507.....35442
1508.....35442

Proposed Rules:

51.....36870
52.....36729, 36870
180.....36737

42 CFR

438.....37522
440.....37522
457.....37522
460.....37522

Proposed Rules:

412.....35934
413.....35934
431.....35934
482.....35934
485.....35934
495.....35934
512.....35934

43 CFR

2800.....35634

45 CFR

75.....36684
80.....37522
84.....37522
92.....37522
147.....37522
155.....37522
156.....37522

47 CFR

73.....36705, 36718

48 CFR

727.....37948
742.....37948
752.....37948
1602.....37061
1609.....37061

Proposed Rules:

40.....36738

49 CFR

24.....36908
1500.....35580
1503.....35580
1515.....35580
1540.....35580
1542.....35580
1544.....35580
1546.....35580
1548.....35580
1549.....35580
1550.....35580
1552.....35580
1554.....35580
1570.....35580
1572.....35580

Proposed Rules:

385.....36742

50 CFR

17.....36982
92.....35010
622.....35011
635.....37139
648.....35755
660.....35012
679.....35013

Proposed Rules:

216.....35769

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List April 26, 2024

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://portalguard.gsa.gov/__*layouts/PG/register.aspx.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.